

**Study Number:** R10997

**Test Type:** RACB

**Route:** Dosing in Feed

**Species/Strain:** Rat/Sprague-Dawley

**C Number:**

**Study Gender:**

**PWG Approval Date**

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

**Test Compound:** Diisobutyl Phthalate

**CAS Number:** 84-69-5

R10997

Both

See web page for date of PWG Approval

**Date Report Requested:** 07/30/2019

**Time Report Requested:** 13:36:49

**Lab:** RTI

Study Number: R10997

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: Diisobutyl Phthalate

CAS Number: 84-69-5

Date Report Requested: 07/30/2019

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Lab: RTI

	F0 Male			
	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	23	23	23	23
Scheduled Sacrifice				
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (SD 139 - 141)	23	23	23	23
Animals Examined Microscopically	23	10	6	23
ALIMENTARY SYSTEM				
LIVER	(23)	(0)	(0)	(23)
CARDIOVASCULAR SYSTEM				
BLOOD VESSEL	(0)	(0)	(0)	(1)
ENDOCRINE SYSTEM				
ADRENAL GLAND	(23)	(0)	(0)	(23)
PITUITARY GLAND	(22)	(0)	(0)	(22)
THYROID GLAND	(23)	(0)	(0)	(23)
GENERAL BODY SYSTEM				
FAT	(0)	(0)	(0)	(1)
GENITAL SYSTEM				
COAGULATING GLAND	(23)	(0)	(0)	(23)
DORSAL PROSTATE	(23)	(0)	(0)	(23)
EPIDIDYMIS	(23)	(0)	(0)	(23)
PREPUTIAL GLAND	(10)	(10)	(4)	(9)
SEMINAL VESICLE	(23)	(0)	(0)	(23)
TESTIS	(23)	(0)	(0)	(23)
VENTRAL PROSTATE	(23)	(0)	(0)	(23)
HEMATOLYMPHOID SYSTEM				
THYMUS	(23)	(0)	(0)	(23)

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	<b>F0 Male</b>			
	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>1000</b>	<b>5000</b>	<b>10000</b>
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(1)	(1)
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
EYE	(0)	(0)	(1)	(0)
URINARY SYSTEM				
KIDNEY	(23)	(0)	(0)	(23)
No Systemic Lesions				

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Tumor Summary Data for F0 Male	Treatment Groups (ppm)			
	0	1000	5000	10000
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

Study Number: R10997

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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	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	23	23	23	23
Scheduled Sacrifice				
Early Deaths				
Euthanized, moribund	2	2	2	1
Unscheduled Sacrifice			1	
Scheduled Deaths				
Scheduled sacrifice, terminal (SD 176 - 177)	21	21	20	22
Animals Examined Microscopically	23	3	4	23
<b>ALIMENTARY SYSTEM</b>				
LIVER	(23)	(0)	(1)	(23)
BILE DUCT; CHOLANGIOMA				1 (4%)
SALIVARY GLAND	(0)	(1)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(23)	(0)	(0)	(23)
PITUITARY GLAND	(23)	(0)	(0)	(23)
THYROID GLAND	(23)	(0)	(0)	(23)
<b>GENERAL BODY SYSTEM</b>				
FAT	(1)	(0)	(0)	(0)
<b>GENITAL SYSTEM</b>				
CERVIX	(21)	(0)	(0)	(23)
CLITORAL GLAND	(1)	(0)	(0)	(1)
OVARY	(23)	(0)	(0)	(23)
UTERUS	(21)	(0)	(0)	(23)
VAGINA	(21)	(0)	(0)	(23)

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	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, MESENTERIC	(0)	(0)	(1)	(0)
SPLEEN	(0)	(0)	(2)	(1)
THYMUS	(23)	(0)	(0)	(23)
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(2)	(3)	(2)	(0)
ADENOCARCINOMA	1 (50%)		1 (50%)	
FIBROADENOMA	1 (50%)	1 (33%)	1 (50%)	
SKIN	(1)	(0)	(0)	(0)
SKIN, ABDOMINAL	(0)	(0)	(0)	(1)
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				
URINARY SYSTEM				
KIDNEY	(23)	(0)	(1)	(23)
No Systemic Lesions				

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Tumor Summary Data for F0 Female	Treatment Groups (ppm)			
	0	1000	5000	10000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	1	1	1	1
Total Benign Neoplasms	1	1	1	1
Total Animals with Malignant Neoplasms	1	0	1	0
Total Malignant Neoplasms	1	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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**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**  
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**F1 Male: F1c NonParent Males**

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	45	31	39	40
Scheduled Sacrifice				
Early Deaths				
Euthanized, moribund				1
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	45	31	39	39
Animals Examined Microscopically	45	31	39	40
Total number litters	17	13	17	16
<b>ALIMENTARY SYSTEM</b>				
LIVER	(45)	(1)	(2)	(40)
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(45)	(0)	(1)	(40)
PITUITARY GLAND	(45)	(31)	(39)	(40)
THYROID GLAND	(45)	(0)	(0)	(40)
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				



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**F1 Male: F1c NonParent Males**

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>GENITAL SYSTEM</b>				
COAGULATING GLAND	(45)	(0)	(3)	(40)
COWPERS GLAND	(44)	(31)	(39)	(39)
DORSAL PROSTATE	(45)	(31)	(39)	(38)
EPIDIDYMIS	(45)	(31)	(39)	(40)
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(45)	(0)	(2)	(39)
PENIS	(2)	(0)	(0)	(1)
PREPUTIAL GLAND	(2)	(0)	(1)	(1)
SEMINAL VESICLE	(45)	(0)	(4)	(40)
TESTIS	(45)	(31)	(39)	(40)
VENTRAL PROSTATE	(45)	(31)	(39)	(40)
<b>HEMATOLYMPHOID SYSTEM</b>				
SPLEEN	(45)	(0)	(1)	(40)
THYMUS	(45)	(0)	(0)	(40)
<b>INTEGUMENTARY SYSTEM</b>				
DIGIT	(0)	(0)	(0)	(1)
<b>MUSCULOSKELETAL SYSTEM</b>				
PAW	(0)	(0)	(0)	(1)
<b>NERVOUS SYSTEM</b>				
No Tissues/Organs Examined				
<b>RESPIRATORY SYSTEM</b>				
No Tissues/Organs Examined				
<b>SPECIAL SENSES SYSTEM</b>				
No Tissues/Organs Examined				

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**F1 Male: F1c NonParent Males**

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	Treatment Groups (ppm)			
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(45)	(3)	(3)	(40)
RENAL TUBULE; ADENOMA				1 (3%) [1]
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>1000</b>	<b>5000</b>	<b>10000</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>1</b>
<b>Total Benign Neoplasms</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</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	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	28	32	40	32
Scheduled Sacrifice				
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	28	32	40	32
Animals Examined Microscopically	28	5	3	32
Total number litters	15	4	3	13
<b>ALIMENTARY SYSTEM</b>				
LIVER	(28)	(0)	(1)	(32)
MESENTERY	(2)	(1)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(28)	(0)	(1)	(32)
PITUITARY GLAND	(28)	(0)	(0)	(32)
THYROID GLAND	(28)	(0)	(0)	(32)
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				
<b>GENITAL SYSTEM</b>				
CERVIX	(28)	(0)	(0)	(32)
OVARY	(28)	(0)	(0)	(32)
UTERUS	(28)	(1)	(0)	(32)
VAGINA	(28)	(0)	(0)	(32)

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**F1 Female: F1c NonParent Female**

	Treatment Groups (ppm)			
	0	1000	5000	10000
HEMATOLYMPHOID SYSTEM				
SPLEEN	(28)	(0)	(1)	(32)
THYMUS	(28)	(0)	(0)	(32)
INTEGUMENTARY SYSTEM				
DIGIT	(0)	(1)	(0)	(1)
MAMMARY GLAND	(28)	(0)	(0)	(32)
MUSCULOSKELETAL SYSTEM				
PAW	(0)	(2)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				
URINARY SYSTEM				
KIDNEY	(28)	(1)	(1)	(32)
NEPHROBLASTOMA				1 (3%) [1]
No Systemic Lesions				

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Tumor Summary Data for F1 Female F1c NonParent Female	Treatment Groups (ppm)			
	0	1000	5000	10000
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	1
Total Malignant Neoplasms	0	0	0	1
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	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	40	40	40	40
Scheduled Sacrifice				
Early Deaths				
Unscheduled Sacrifice			3	
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 213 - 223)	40	40	37	40
Animals Examined Microscopically	40	40	40	40
Total number litters	21	20	19	18
<b>ALIMENTARY SYSTEM</b>				
LIVER	(40)	(0)	(3)	(40)
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(40)	(0)	(3)	(40)
PITUITARY GLAND	(40)	(40)	(40)	(40)
THYROID GLAND	(40)	(0)	(3)	(40)
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				

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Species/Strain: Rat/Sprague-Dawley

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F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>GENITAL SYSTEM</b>				
COAGULATING GLAND	(40)	(0)	(3)	(40)
COWPERS GLAND	(40)	(40)	(40)	(40)
DORSAL PROSTATE	(40)	(0)	(3)	(40)
EPIDIDYMIS	(40)	(40)	(40)	(40)
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(40)	(0)	(3)	(40)
PREPUTIAL GLAND	(2)	(1)	(2)	(8)
SEMINAL VESICLE	(40)	(0)	(3)	(40)
TESTIS	(40)	(40)	(40)	(40)
VENTRAL PROSTATE	(40)	(40)	(40)	(40)
<b>HEMATOLYMPHOID SYSTEM</b>				
LYMPH NODE	(0)	(0)	(0)	(1)
LYMPH NODE, MANDIBULAR	(2)	(0)	(0)	(0)
SPLEEN	(0)	(0)	(3)	(0)
THYMUS	(40)	(0)	(3)	(39)
<b>INTEGUMENTARY SYSTEM</b>				
SKIN	(0)	(0)	(0)	(1)
<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>				
No Tissues/Organs Examined				



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**F1 Male: F1c Parental Males**

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	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>1000</b>	<b>5000</b>	<b>10000</b>
URINARY SYSTEM				
KIDNEY	(40)	(1)	(3)	(40)
No Systemic Lesions				

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

	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>1000</b>	<b>5000</b>	<b>10000</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>

Study Number: R10997  
 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: Diisobutyl Phthalate  
 CAS Number: 84-69-5

Date Report Requested: 07/30/2019  
 Time Report Requested: 13:36:49  
 Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	40	40	40	40
Scheduled Sacrifice				
Early Deaths				
Euthanized, moribund	1		4	
Found Dead	1		1	
Scheduled Deaths				
Scheduled sacrifice, terminal (LD 21, PND 232 - 237)	38	40	35	40
Animals Examined Microscopically	40	7	9	40
Total number litters	20	7	9	18
ALIMENTARY SYSTEM				
LIVER	(40)	(2)	(6)	(40)
MESENTERY	(0)	(1)	(1)	(0)
CARDIOVASCULAR SYSTEM				
HEART	(0)	(0)	(1)	(0)
ENDOCRINE SYSTEM				
ADRENAL GLAND	(40)	(0)	(5)	(40)
PHEOCHROMOCYTOMA; BENIGN	1 (3%) [1]			
PITUITARY GLAND	(40)	(0)	(5)	(40)
THYROID GLAND	(40)	(0)	(5)	(40)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

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	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
CERVIX	(40)	(0)	(5)	(40)
CLITORAL GLAND	(3)	(1)	(1)	(0)
OVARY	(40)	(0)	(5)	(40)
UTERUS	(39)	(1)	(5)	(40)
VAGINA	(40)	(0)	(5)	(40)
HEMATOLYMPHOID SYSTEM				
LYMPH NODE	(0)	(0)	(1)	(0)
LYMPH NODE, AXILLARY	(1)	(0)	(1)	(0)
LYMPH NODE, MANDIBULAR	(0)	(0)	(1)	(0)
SPLEEN	(40)	(0)	(5)	(40)
THYMUS	(39)	(0)	(4)	(40)
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(38)	(2)	(6)	(40)
ADENOCARCINOMA	1 (3%) [1]		1 (17%) [1]	
FIBROADENOMA		1 (50%) [1]	1 (17%) [1]	1 (3%) [1]
SKIN	(1)	(0)	(0)	(0)
SKIN, SUBCUTANEOUS TISSUE	(0)	(0)	(1)	(0)
MUSCULOSKELETAL SYSTEM				
PAW	(2)	(0)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				

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**F1 Female: F1c Parental Females**

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	Treatment Groups (ppm)			
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(40)	(0)	(6)	(40)
NEPHROBLASTOMA				1 (3%) [1]
No Systemic Lesions				

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**Tumor Summary Data for F1 Female F1c Parental Females**

	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>1000</b>	<b>5000</b>	<b>10000</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>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Total Benign Neoplasms</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Total Animals with Malignant Neoplasms</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>
<b>Total Malignant Neoplasms</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</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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## 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 \*\***