

**Study Number:** R16011

**Test Type:** Teratology

**Route:** Oral Gavage

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

**C Number:**

**Study Gender:**

**PWG Approval Date**

**R10: Fetal Defects**

**Test Compound:** 2-((1-(4-Phenoxyphenoxy)propan-2-yl)oxy)pyridine

**CAS Number:** 95737-68-1

R16011

Female

See web page for date of PWG Approval

**Date Report Requested:** 10/30/2019

**Time Report Requested:** 11:46:54

**Lab:** Southern Research

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F0 Female

Treatment Groups (mg/kg/day)

Classification	Treatment Groups (mg/kg/day)					
	0	62.5	125	250	500	
Total number of fetuses examined	314	286	290	265	318	
	<b>External</b>					
No. Fetuses examined	314	286	290	265	318	
No. Litters examined	23	20	21	20	22	
<b>Body - General</b>						
Body, Subcutaneous hemorrhage	Gross Finding	0 (0.00)	1 (0.35)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	1 (5.00)	0 (0.00)	1 (5.00)	0 (0.00)
<b>Extremities</b>						
Tail, Thread-like	Malformation	0 (0.00)	0 (0.00)	1 (0.34)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	1 (4.76)	1 (5.00)	0 (0.00)

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F0 Female

Treatment Groups (mg/kg/day)

Classification	Treatment Groups (mg/kg/day)					
	0	62.5	125	250	500	
<b>Visceral</b>						
No. Fetuses examined	314	286	290	265	318	
No. Litters examined	23	20	21	20	22	
<b>Abdominal Viscera</b>						
Liver lobe, Additional fissure	Variation	4 (1.27)	7 (2.45)	5 (1.72)	2 (0.75)	8 (2.52)
		4 (17.39)	5 (25.00)	4 (19.05)	2 (10.00)	3 (13.64)
Liver lobe, Misshapen	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	2 (0.63)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	2 (9.09)
Liver lobe, Discolored	Variation	0 (0.00)	0 (0.00)	1 (0.34)	4 (1.51)	3 (0.94)
		0 (0.00)	0 (0.00)	1 (4.76)	3 (15.00)	2 (9.09)
Liver lobe, Supernumerary	Variation	4 (1.27)	5 (1.75)	4 (1.38)	1 (0.38)	2 (0.63)
		4 (17.39)	5 (25.00)	4 (19.05)	1 (5.00)	2 (9.09)
Liver lobe, left lateral, Additional fissure	Variation	0 (0.00)	6 (2.10)	4 (1.38)	2 (0.75)	7 (2.20)
		0 (0.00)	5 (25.00)	3 (14.29)	2 (10.00)	2 (9.09)
Liver lobe, left lateral, Discolored	Variation	0 (0.00)	0 (0.00)	0 (0.00)	4 (1.51)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	3 (15.00)	0 (0.00)
Liver lobe, left lateral, Misshapen	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.31)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Liver lobe, left lateral, Supernumerary	Variation	0 (0.00)	1 (0.35)	2 (0.69)	0 (0.00)	0 (0.00)
		0 (0.00)	1 (5.00)	2 (9.52)	0 (0.00)	0 (0.00)
Liver lobe, left medial, Additional fissure	Variation	4 (1.27)	1 (0.35)	1 (0.34)	0 (0.00)	1 (0.31)
		4 (17.39)	1 (5.00)	1 (4.76)	0 (0.00)	1 (4.55)
Liver lobe, left medial, Discolored	Variation	0 (0.00)	0 (0.00)	1 (0.34)	1 (0.38)	3 (0.94)
		0 (0.00)	0 (0.00)	1 (4.76)	1 (5.00)	2 (9.09)
Liver lobe, left medial, Misshapen	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.31)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Liver lobe, left medial, Supernumerary	Variation	1 (0.32)	4 (1.40)	1 (0.34)	0 (0.00)	0 (0.00)
		1 (4.35)	4 (20.00)	1 (4.76)	0 (0.00)	0 (0.00)

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R10: Fetal Defects

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Lab: Southern Research

F0 Female

Treatment Groups (mg/kg/day)

	Classification	Treatment Groups (mg/kg/day)				
		0	62.5	125	250	500
Liver lobe, right lateral, Supernumerary	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.31)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Liver lobe, right medial, Additional fissure	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.31)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Liver lobe, right medial, Supernumerary	Variation	3 (0.96)	0 (0.00)	1 (0.34)	1 (0.38)	1 (0.31)
		3 (13.04)	0 (0.00)	1 (4.76)	1 (5.00)	1 (4.55)
Stomach, Hemorrhagic	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	2 (0.75)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	2 (10.00)	0 (0.00)
<b>Heart</b>						
Aortic valve, Misshapen	Malformation	10 (3.18)	9 (3.15)	5 (1.72)	10 (3.77)	5 (1.57)
		9 (39.13)	7 (35.00)	5 (23.81)	7 (35.00)	4 (18.18)
<b>Major Vessels</b>						
Aortic arch, Retroesophageal	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Innominate artery, Absent	Variation	13 (4.14)	9 (3.15)	11 (3.79)	9 (3.40)	7 (2.20)
		9 (39.13)	7 (35.00)	9 (42.86)	5 (25.00)	6 (27.27)
Innominate artery, Short	Variation	5 (1.59)	3 (1.05)	2 (0.69)	4 (1.51)	4 (1.26)
		5 (21.74)	2 (10.00)	2 (9.52)	3 (15.00)	4 (18.18)
Innominate artery, Short or Absent	Variation	18 (5.73)	12 (4.20)	13 (4.48)	13 (4.91)	11 (3.46)
		13 (56.52)	8 (40.00)	10 (47.62)	7 (35.00)	8 (36.36)
Innominate artery, Supernumerary	Variation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Subclavian artery, left, Absent	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Subclavian artery, right, Absent	Malformation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
<b>Reproductive Tract</b>						
Testis, left, Hemorrhagic	Malformation	1 (0.32)	2 (0.70)	0 (0.00)	3 (1.13)	0 (0.00)
		1 (4.35)	2 (10.00)	0 (0.00)	3 (15.00)	0 (0.00)

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Lab: Southern Research

F0 Female

Treatment Groups (mg/kg/day)

	Classification	0	62.5	125	250	500
Testis, left, Malpositioned	Malformation	0 (0.00)	1 (0.35)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)	0 (0.00)
Testis, right, Hemorrhagic	Malformation	0 (0.00)	1 (0.35)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)	0 (0.00)
<b>Urinary Tract</b>						
Kidney, bilateral, Hydronephrosis	Malformation	0 (0.00)	1 (0.35)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)	0 (0.00)
Kidney, renal capsule, Misshapen	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.31)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Ureter, left, Dilated	Variation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

Head

No. Fetuses examined	163	147	148	138	163
No. Litters examined	23	20	21	20	22

NO VISIBLE LESIONS PRESENT

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F0 Female

Treatment Groups (mg/kg/day)

Classification	Treatment Groups (mg/kg/day)					
	0	62.5	125	250	500	
<b>Skeletal - Body</b>						
No. Fetuses examined	314	286	290	264	317	
No. Litters examined	23	20	21	20	22	
<b>Forelimb</b>						
Metacarpal, Unossified	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.32)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
<b>Hindlimb</b>						
Metatarsal, Unossified	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.32)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
<b>Ribs</b>						
Costal cartilage, 7th left, Not fused to sternum	Malformation	0 (0.00)	1 (0.35)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)	0 (0.00)
Costal cartilage, 7th right, Not fused to sternum	Malformation	0 (0.00)	0 (0.00)	1 (0.34)	0 (0.00)	0 (0.00)
		0 (0.00)	0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
<b>Sternebrae</b>						
Sternebra, between sternebra, Supernumerary site	Variation	0 (0.00)	1 (0.35)	1 (0.34)	0 (0.00)	3 (0.95)
		0 (0.00)	1 (5.00)	1 (4.76)	0 (0.00)	2 (9.09)
<b>Supernumerary Rib</b>						
Thoracolumbar, bilateral, Full	Malformation	2 (0.64)	1 (0.35)	0 (0.00)	0 (0.00)	1 (0.32)
		2 (8.70)	1 (5.00)	0 (0.00)	0 (0.00)	1 (4.55)
Thoracolumbar, bilateral, Short	Variation	1 (0.32)	3 (1.05)	0 (0.00)	1 (0.38)	0 (0.00)
		1 (4.35)	3 (15.00)	0 (0.00)	1 (5.00)	0 (0.00)
Thoracolumbar, left, Full	Malformation	4 (1.27)	2 (0.70)	0 (0.00)	0 (0.00)	0 (0.00)
		3 (13.04)	2 (10.00)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracolumbar, left, Short	Variation	4 (1.27)	4 (1.40)	3 (1.03)	5 (1.89)	3 (0.95)
		4 (17.39)	4 (20.00)	3 (14.29)	3 (15.00)	2 (9.09)
Thoracolumbar, right, Full	Malformation	1 (0.32)	0 (0.00)	1 (0.34)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)

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## F0 Female

## Treatment Groups (mg/kg/day)

	Classification	Treatment Groups (mg/kg/day)				
		0	62.5	125	250	500
Thoracolumbar, right, Short	Variation	6 (1.91)	9 (3.15)	3 (1.03)	1 (0.38)	3 (0.95)
		4 (17.39)	6 (30.00)	3 (14.29)	1 (5.00)	3 (13.64)
Thoracolumbar, unilateral or bilateral, Full	Malformation	7 (2.23)	3 (1.05)	1 (0.34)	0 (0.00)	1 (0.32)
		5 (21.74)	3 (15.00)	1 (4.76)	0 (0.00)	1 (4.55)
Thoracolumbar, unilateral or bilateral, Short	Variation	11 (3.50)	16 (5.59)	6 (2.07)	7 (2.65)	6 (1.89)
		6 (26.09)	9 (45.00)	5 (23.81)	3 (15.00)	5 (22.73)
<b>Vertebrae</b>						
Cervical vertebra, 4th, Misshapen	Malformation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Cervical vertebra, 5th, Misshapen	Malformation	7 (2.23) ##	4 (1.40)	2 (0.69)	0 (0.00) #	0 (0.00) #
		6 (26.09)	4 (20.00)	2 (9.52)	0 (0.00)	0 (0.00)
Cervical vertebra, 6th, Misshapen	Malformation	7 (2.23) #	4 (1.40)	1 (0.34)	0 (0.00)	0 (0.00) #
		6 (26.09)	4 (20.00)	1 (4.76)	0 (0.00)	0 (0.00)
Cervical vertebra, 4th, 5th, or 6th, Misshapen	Malformation	8 (2.55) ##	4 (1.40)	2 (0.69)	0 (0.00) #	0 (0.00) #
		7 (30.43)	4 (20.00)	2 (9.52)	0 (0.00)	0 (0.00)
Presacral vertebrae, Greater than 26	Variation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, 10th, Incomplete ossification	Variation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, 12th, Hemicentric	Variation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Thoracic centrum, 13th, Hemicentric	Variation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Thoracic centrum, 1st, Incomplete ossification	Variation	1 (0.32)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, multiple sites, Absent	Malformation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)

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F0 Female

Treatment Groups (mg/kg/day)

Classification	Treatment Groups (mg/kg/day)				
	0	62.5	125	250	500
<b>Skeletal - Skull</b>					
No. Fetuses examined	151	138	142	126	154
No. Litters examined	23	20	20	20	22
<b>Skull</b>					
General, Enlarged fontanel	Variation	1 (0.66)	0 (0.00)	0 (0.00)	0 (0.00)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)
General, Isolated ossification site	Variation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.79)
		0 (0.00)	0 (0.00)	0 (0.00)	2 (9.09)
General, Supernumerary site	Variation	1 (0.66)	0 (0.00)	0 (0.00)	1 (0.79)
		1 (4.35)	0 (0.00)	0 (0.00)	0 (0.00)
Interparietal, Incomplete ossification	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Interparietal, Isolated ossification site	Variation	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.79)
		0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Supraoccipital, Incomplete ossification	Variation	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)



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LEGEND

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Upper row denotes number of affected fetuses (%) and lower row the number of affected litters (%)

Trend and pairwise significance levels are determined using one-sided tests.

Statistical analysis for fetal data including litter effects were performed by using a Rao-Scott modification to the Cochran-Armitage test where the Dam ID was the random effect for both trend and pairwise analysis.

# Statistically significant at  $P \leq 0.05$  (litter based analysis)

## Statistically significant at  $P \leq 0.01$  (litter based analysis)

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

**\*\* END OF REPORT \*\***