

Experiment Number: R92025B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

R20: Pup Necropsy (Gross Observations for Unweaned Pups) Summary

Test Compound: 4-Methylimidazole
CAS Number: 822-36-6

Date Report Requested: 08/25/2017
Time Report Requested: 11:19:11
Lab: RTI

C Number: R92025B
Cage Range: All
Date Range: All
Reasons For Removal: All
Removal Date Range: All
Treatment Groups: All
Study Gender: Both

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F1 Pups (Litter A)

Treatment Groups (ppm)

0 750 2500 5000

Disposition Summary

Pups	322	292	168	34
Litters	22	22	17	6
Scheduled Sacrifice				
Scheduled Removal (Terminal)	296 (22)	275 (22)	119 (15)	2 (1)
Early Deaths				
Cannibalized	1 (1)	1 (1)	6 (2)	6 (2)
Euthanized Moribund			1 (1)	
Found Dead	24 (14)	15 (9)	38 (12)	19 (4)
Pup Missing - Presumed Dead	1 (1)	1 (1)	4 (2)	7 (3)

No. pups examined	25	16	45	25
No. Litters	14	10	12	5
Normal	9 (7)	10 (8)	11 (6)	4 (1)

ALIMENTARY SYSTEM

No findings

CARDIOVASCULAR SYSTEM

No findings

ENDOCRINE SYSTEM

No findings

GENERAL BODY SYSTEM

General

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F1 Pups (Litter A)

Treatment Groups (ppm)

	0	750	2500	5000
Abdomen, Autolyzed, unable to evaluate	8 (32.0)	1 (6.3)	12 (26.7)	9 (36.0)
	6 (42.9)	1 (10.0)	7 (58.3)	2 (40.0)
General, Autolyzed, unable to evaluate	5 (20.0)	0 (0.0)	10 (22.2)	6 (24.0)
	3 (21.4)	0 (0.0)	4 (33.3)	2 (40.0)
General, Cannibalized, unable to evaluate	1 (4.0)	1 (6.3)	9 (20.0)	6 (24.0)
	1 (7.1)	1 (10.0)	4 (33.3)	2 (40.0)
GENITAL SYSTEM				
No findings				
HEMATOPOIETIC SYSTEM				
No findings				
INTEGUMENTARY SYSTEM				
No findings				
MUSCULOSKELETAL SYSTEM				
No findings				
NERVOUS SYSTEM				
No findings				
RESPIRATORY SYSTEM				
No findings				
SPECIAL SENSES SYSTEM				
No findings				
URINARY SYSTEM				
Abdomen				
Kidney, bilateral, Hydronephrosis	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)
	0 (0.0)	0 (0.0)	1 (8.3)	0 (0.0)
Pelvis				

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F1 Pups (Litter A)

Treatment Groups (ppm)

	0	750	2500	5000
Ureter, bilateral, Distended	0 (0.0) 0 (0.0)	2 (12.5) 1 (10.0)	1 (2.2) 1 (8.3)	0 (0.0) 0 (0.0)
Ureter, bilateral, Hydroureter	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (2.2) 1 (8.3)	0 (0.0) 0 (0.0)
Ureter, left, Distended	0 (0.0) 0 (0.0)	1 (6.3) 1 (10.0)	1 (2.2) 1 (8.3)	0 (0.0) 0 (0.0)
Ureter, left, Enlarged	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (2.2) 1 (8.3)	0 (0.0) 0 (0.0)
Ureter, right, Distended	2 (8.0) 2 (14.3)	1 (6.3) 1 (10.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)
Urinary bladder, Agenesis	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (2.2) 1 (8.3)	0 (0.0) 0 (0.0)

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F1 Pups (Litter B)

Treatment Groups (ppm)

	0	750	2500	5000
Disposition Summary				
Pups	270	311	157	28
Litters	19	23	17	6
Scheduled Sacrifice				
Scheduled Removal (Terminal)	253 (19)	288 (23)	133 (17)	2 (1)
Early Deaths				
Cannibalized	2 (1)	2 (2)	2 (2)	10 (3)
Found Dead	12 (6)	18 (10)	17 (10)	13 (5)
Pup Missing - Presumed Dead	3 (2)	3 (3)	5 (2)	3 (2)
No. pups examined				
	14	20	19	18
No. Litters				
	6	11	11	5
Normal				
	9 (6)	6 (6)	7 (6)	1 (1)
ALIMENTARY SYSTEM				
Abdomen				
Intestine, Enlarged	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
CARDIOVASCULAR SYSTEM				
Heart				
Auricular flap, bilateral, Enlarged	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)
	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
Thorax (excluding heart)				

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F1 Pups (Litter B)

Treatment Groups (ppm)

	0	750	2500	5000
Aorta, Enlarged	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)
	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
ENDOCRINE SYSTEM				
No findings				
GENERAL BODY SYSTEM				
General				
Abdomen, Autolyzed, unable to evaluate	3 (21.4)	5 (25.0)	5 (26.3)	2 (11.1)
	2 (33.3)	2 (18.2)	3 (27.3)	2 (40.0)
General, Autolyzed, unable to evaluate	0 (0.0)	2 (10.0)	4 (21.1)	3 (16.7)
	0 (0.0)	2 (18.2)	3 (27.3)	2 (40.0)
General, Cannibalized, unable to evaluate	2 (14.3)	2 (10.0)	2 (10.5)	9 (50.0)
	1 (16.7)	2 (18.2)	2 (18.2)	2 (40.0)
GENITAL SYSTEM				
No findings				
HEMATOPOIETIC SYSTEM				
No findings				
INTEGUMENTARY SYSTEM				
No findings				
MUSCULOSKELETAL SYSTEM				
No findings				
NERVOUS SYSTEM				
No findings				
RESPIRATORY SYSTEM				
No findings				
SPECIAL SENSES SYSTEM				
No findings				

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F1 Pups (Litter C)

Treatment Groups (ppm)

	0	750	2500	5000
Intestine, Enlarged	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)
	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)
Stomach, Distended with gas	1 (2.9)	1 (5.3)	1 (4.2)	0 (0.0)
	1 (7.7)	1 (8.3)	1 (11.1)	0 (0.0)
Stomach, Milk/food absent	3 (8.8)	1 (5.3)	7 (29.2)	0 (0.0)
	3 (23.1)	1 (8.3)	6 (66.7)	0 (0.0)
CARDIOVASCULAR SYSTEM				
Heart				
Auricular flap, right, Enlarged	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)
Heart, Dextrocardia	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)
ENDOCRINE SYSTEM				
No findings				
GENERAL BODY SYSTEM				
General				
Abdomen, Autolyzed, unable to evaluate	14 (41.2)	3 (15.8)	10 (41.7)	0 (0.0)
	5 (38.5)	3 (25.0)	5 (55.6)	0 (0.0)
Abdomen, entire, Autolyzed, unable to evaluate	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)
	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)
General, Autolyzed, unable to evaluate	2 (5.9)	1 (5.3)	0 (0.0)	0 (0.0)
	2 (15.4)	1 (8.3)	0 (0.0)	0 (0.0)
General, Cannibalized, unable to evaluate	2 (5.9)	2 (10.5)	2 (8.3)	0 (0.0)
	2 (15.4)	2 (16.7)	2 (22.2)	0 (0.0)

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F2 Pups (Litter A) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Disposition Summary			
Pups	434	375	284
Litters	33	34	31
Scheduled Sacrifice			
Scheduled Removal (Terminal)	344 (32)	301 (32)	181 (26)
Early Deaths			
Cannibalized	1 (1)	1 (1)	8 (4)
Found Dead	83 (24)	64 (23)	59 (24)
Pup Missing - Presumed Dead	6 (5)	9 (5)	36 (16)
No. pups examined			
	84	65	67
No. Litters			
	24	23	26
Normal			
	36 (18)	26 (14)	32 (17)
ALIMENTARY SYSTEM			
Abdomen			
Liver, all lobes, Mottled	0 (0.0)	0 (0.0)	1 (1.5)
	0 (0.0)	0 (0.0)	1 (3.8)
Stomach, Milk/food absent	2 (2.4)	4 (6.2)	2 (3.0)
	1 (4.2)	2 (8.7)	2 (7.7)
CARDIOVASCULAR SYSTEM			
Heart			
Auricular flap, right, Enlarged	0 (0.0)	0 (0.0)	1 (1.5)
	0 (0.0)	0 (0.0)	1 (3.8)

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F2 Pups (Litter A) F1 Parental Females

Treatment Groups (ppm)

0

750

2500

ENDOCRINE SYSTEM

No findings

GENERAL BODY SYSTEM

General

Abdomen, Autolyzed, unable to evaluate

4 (4.8)

4 (6.2)

1 (1.5)

2 (8.3)

2 (8.7)

1 (3.8)

Abdomen, entire, Autolyzed, unable to evaluate

26 (31.0)

22 (33.8)

10 (14.9)

7 (29.2)

8 (34.8)

7 (26.9)

General, Autolyzed, unable to evaluate

9 (10.7)

3 (4.6)

6 (9.0)

2 (8.3)

2 (8.7)

2 (7.7)

General, Cannibalized, unable to evaluate

1 (1.2)

1 (1.5)

8 (11.9)

1 (4.2)

1 (4.3)

4 (15.4)

GENITAL SYSTEM

No findings

HEMATOPOIETIC SYSTEM

No findings

INTEGUMENTARY SYSTEM

No findings

MUSCULOSKELETAL SYSTEM

No findings

NERVOUS SYSTEM

No findings

RESPIRATORY SYSTEM

No findings

SPECIAL SENSES SYSTEM

No findings

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F2 Pups (Litter A) F1 Parental Females

Treatment Groups (ppm)

0

750

2500

URINARY SYSTEM

Pelvis

Ureter, bilateral, Distended

2 (2.4)

1 (1.5)

1 (1.5)

2 (8.3)

1 (4.3)

1 (3.8)

Ureter, left, Distended

4 (4.8)

2 (3.1)

3 (4.5)

4 (16.7)

2 (8.7)

3 (11.5)

Ureter, right, Distended

0 (0.0)

2 (3.1)

4 (6.0)

0 (0.0)

2 (8.7)

3 (11.5)

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F2 Pups (Litter B) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Disposition Summary			
Pups	518	455	303
Litters	34	37	29
Scheduled Sacrifice			
Scheduled Removal (Terminal)	444 (34)	420 (36)	255 (29)
Early Deaths			
Cannibalized	2 (2)		3 (3)
Found Dead	67 (25)	28 (18)	30 (17)
Pup Missing - Presumed Dead	5 (3)	7 (4)	15 (11)
No. pups examined			
	68	28	33
No. Litters			
	25	18	17
Normal			
	45 (20)	21 (15)	21 (15)
ALIMENTARY SYSTEM			
Abdomen			
Intestine, Short	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
Stomach, Milk/food absent	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
Body			
Anus, Atresia	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)

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F2 Pups (Litter B) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
CARDIOVASCULAR SYSTEM			
No findings			
ENDOCRINE SYSTEM			
No findings			
GENERAL BODY SYSTEM			
General			
Abdomen, Autolyzed, unable to evaluate	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
Abdomen, entire, Autolyzed, unable to evaluate	9 (13.2)	4 (14.3)	3 (9.1)
	6 (24.0)	4 (22.2)	3 (17.6)
General, Autolyzed, unable to evaluate	2 (2.9)	1 (3.6)	3 (9.1)
	2 (8.0)	1 (5.6)	3 (17.6)
General, Cannibalized, unable to evaluate	2 (2.9)	0 (0.0)	3 (9.1)
	2 (8.0)	0 (0.0)	3 (17.6)
GENITAL SYSTEM			
Body			
Genital papilla, Atresia	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
HEMATOPOIETIC SYSTEM			
No findings			
INTEGUMENTARY SYSTEM			
Limbs			
Digit, left forepaw, Micromelia	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)

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F2 Pups (Litter B) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Digit, right forepaw, Micromelia	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
Tail			
Tail, Kinked	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
MUSCULOSKELETAL SYSTEM			
No findings			
NERVOUS SYSTEM			
No findings			
RESPIRATORY SYSTEM			
No findings			
SPECIAL SENSES SYSTEM			
No findings			
URINARY SYSTEM			
Pelvis			
Ureter, bilateral, Distended	1 (1.5)	0 (0.0)	0 (0.0)
	1 (4.0)	0 (0.0)	0 (0.0)
Ureter, left, Distended	5 (7.4)	1 (3.6)	2 (6.1)
	5 (20.0)	1 (5.6)	2 (11.8)
Ureter, right, Distended	1 (1.5)	1 (3.6)	1 (3.0)
	1 (4.0)	1 (5.6)	1 (5.9)

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F2 Pups (Litter C) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Disposition Summary			
Pups	311	339	204
Litters	28	35	23
Scheduled Sacrifice			
Pup Culled	16 (7)	10 (4)	1 (1)
Scheduled Removal (Terminal)	205 (27)	264 (33)	145 (22)
Early Deaths			
Cannibalized	4 (2)	1 (1)	
Euthanized Humane	2 (2)	3 (2)	1 (1)
Euthanized Moribund		3 (3)	1 (1)
Found Dead	63 (20)	52 (20)	27 (13)
Pup Missing - Presumed Dead	21 (10)	6 (6)	29 (15)
No. pups examined			
	66	59	29
No. Litters			
	20	23	14
Normal			
	26 (13)	23 (12)	12 (9)
ALIMENTARY SYSTEM			
Abdomen			
Colon, Distended with gas	0 (0.0)	1 (1.7)	0 (0.0)
	0 (0.0)	1 (4.3)	0 (0.0)
Intestine, Distended with gas	0 (0.0)	1 (1.7)	1 (3.4)
	0 (0.0)	1 (4.3)	1 (7.1)

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F2 Pups (Litter C) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Stomach, Distended with gas	0 (0.0)	1 (1.7)	1 (3.4)
	0 (0.0)	1 (4.3)	1 (7.1)
Stomach, Milk/food absent	5 (7.6)	8 (13.6)	2 (6.9)
	2 (10.0)	6 (26.1)	2 (14.3)
CARDIOVASCULAR SYSTEM			
No findings			
ENDOCRINE SYSTEM			
No findings			
GENERAL BODY SYSTEM			
General			
Abdomen, Autolyzed, unable to evaluate	2 (3.0)	4 (6.8)	1 (3.4)
	1 (5.0)	3 (13.0)	1 (7.1)
Abdomen, entire, Autolyzed, unable to evaluate	14 (21.2)	12 (20.3)	6 (20.7)
	5 (25.0)	7 (30.4)	2 (14.3)
General, Autolyzed, unable to evaluate	18 (27.3)	6 (10.2)	6 (20.7)
	8 (40.0)	5 (21.7)	5 (35.7)
General, Cannibalized, unable to evaluate	1 (1.5)	1 (1.7)	0 (0.0)
	1 (5.0)	1 (4.3)	0 (0.0)
GENITAL SYSTEM			
No findings			
HEMATOPOIETIC SYSTEM			
Abdomen			
Spleen, Enlarged	1 (1.5)	0 (0.0)	0 (0.0)
	1 (5.0)	0 (0.0)	0 (0.0)

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F2 Pups (Litter C) F1 Parental Females

Treatment Groups (ppm)

0

750

2500

INTEGUMENTARY SYSTEM

No findings

MUSCULOSKELETAL SYSTEM

Limbs

Limb, left hind, Malpositioned

0 (0.0)

0 (0.0)

1 (3.4)

0 (0.0)

0 (0.0)

1 (7.1)

Limb, right hind, Fracture

1 (1.5)

0 (0.0)

0 (0.0)

1 (5.0)

0 (0.0)

0 (0.0)

Paw, bilateral fore, Enlarged

0 (0.0)

1 (1.7)

0 (0.0)

0 (0.0)

1 (4.3)

0 (0.0)

Paw, left fore, Enlarged

1 (1.5)

0 (0.0)

0 (0.0)

1 (5.0)

0 (0.0)

0 (0.0)

Paw, left hind, Enlarged

0 (0.0)

1 (1.7)

0 (0.0)

0 (0.0)

1 (4.3)

0 (0.0)

Paw, right fore, Enlarged

0 (0.0)

1 (1.7)

0 (0.0)

0 (0.0)

1 (4.3)

0 (0.0)

NERVOUS SYSTEM

No findings

RESPIRATORY SYSTEM

No findings

SPECIAL SENSES SYSTEM

No findings

URINARY SYSTEM

Abdomen

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R20: Pup Necropsy (Gross Observations for Unweaned Pups) Summary
Test Compound: 4-Methylimidazole
CAS Number: 822-36-6

Date Report Requested: 08/25/2017
Time Report Requested: 11:19:11
Lab: RTI

F2 Pups (Litter C) F1 Parental Females

	Treatment Groups (ppm)		
	0	750	2500
Kidney, bilateral, Pale	0 (0.0)	1 (1.7)	0 (0.0)
	0 (0.0)	1 (4.3)	0 (0.0)
Kidney, right, Enlarged	0 (0.0)	1 (1.7)	0 (0.0)
	0 (0.0)	1 (4.3)	0 (0.0)
Pelvis			
Ureter, right, Distended	0 (0.0)	0 (0.0)	1 (3.4)
	0 (0.0)	0 (0.0)	1 (7.1)

Experiment Number: R92025B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

R20: Pup Necropsy (Gross Observations for Unweaned Pups) Summary
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LEGEND

Disposition Summary is Number of pups (litters represented)
Upper row denotes number of affected pups (%) and lower row the number of affected litters (%)
MGWM - Mammary Gland Whole Mount

**** END OF REPORT ****