

Study Number: MOG006

Test Type: MOG - Range Finding

Route: Oral Gavage - Constant Volume

Species/Strain: Rat/Sprague-Dawley

C Number:

Study Gender:

PWG Approval Date

I05P: Pup Clinical Observations Summary

Test Compound: Hydroxyurea

CAS Number: 127-07-1

MOG006

Female

See web page for date of PWG Approval

Date Report Requested: 02/03/2020

Time Report Requested: 13:26:49

Lab: RTI

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F1 Pups

Treatment Groups (mg/kg/day)

	0	37.5	75	100	150
Total Pups (PND 0)	104	78	105	89	89
No. pups post cull (PND 4)	99	63	83	86	70
Total Litters (PND 0)	8	6	8	7	7
No. litters post cull (PND 4)	8	5	7	7	6

Pup Clinical Observations PND 0-4

Bruising	0	0	0	0	1 (1.1)
Abdomen	0	0	0	0	1 (14.3) PND 1-2
Bruising	0	0	0	0	1 (1.1)
Back	0	0	0	0	1 (14.3) PND 1
Bruising	1 (1.0)	0	0	1 (1.1)	1 (1.1)
Head	1 (12.5) PND 0	0	0	1 (14.3) PND 0-2	1 (14.3) PND 0
Bruising	0	0	0	0	1 (1.1)
Multiple Sites (>2)	0	0	0	0	1 (14.3) PND 1
Bruising	0	0	0	1 (1.1)	0
Tail	0	0	0	1 (14.3) PND 1-4	0

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F1 Pups

Treatment Groups (mg/kg/day)

	0	37.5	75	100	150
Cold To Touch	7 (6.7)	4 (5.1)	3 (2.9)	0	13 (14.6)
	1 (12.5)	1 (16.7)	1 (12.5)	0	1 (14.3)
	PND 2-4	PND 3	PND 3		PND 3
No Milk in Stomach	10 (9.6)	4 (5.1)	3 (2.9)	0	13 (14.6)
	2 (25.0)	1 (16.7)	1 (12.5)	0	1 (14.3)
	PND 2-4	PND 3	PND 3		PND 3
Pale	2 (1.9)	0	0	0	1 (1.1)
	2 (25.0)	0	0	0	1 (14.3)
	PND 0-2				PND 1-2
Pup - Found Dead	0	4 (5.1)	11 (10.5)	3 (3.4)	5 (5.6)
	0	2 (33.3)	2 (25.0)	3 (42.9)	3 (42.9)
		PND 0-1	PND 1	PND 0-1	PND 0-3
Pup Cannibalised	0	2 (2.6)	0	0	0
	0	2 (33.3)	0	0	0
		PND 0			
Pup Missing - Presumed Dead	0	5 (6.4)	8 (7.6)	0	0
	0	2 (33.3)	2 (25.0)	0	0
		PND 1-2	PND 1-3		

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F1 Pups

Treatment Groups (mg/kg/day)

	0	37.5	75	100	150
Pup Clinical Observations PND 5-28					
Alopecia	0	0	14 (16.9)	2 (2.3)	0
Head	0	0	4 (57.1)	1 (14.3)	0
			PND 17-28	PND 19-28	
Alopecia	0	0	8 (9.6)	37 (43.0)	62 (88.6)
Multiple Sites (>2)	0	0	2 (28.6)	4 (57.1)	6 (100.0)
			PND 18-28	PND 16-28	PND 16-18
Ataxia	0	0	0	1 (1.2)	0
Mild	0	0	0	1 (14.3)	0
				PND 22	
Bruising	0	0	0	0	1 (1.4)
Head	0	0	0	0	1 (16.7)
					PND 18
Bruising	0	0	0	0	3 (4.3)
Multiple Sites (>2)	0	0	0	0	2 (33.3)
					PND 17-18
Cold To Touch	1 (1.0)	0	0	3 (3.5)	5 (7.1)
	1 (12.5)	0	0	1 (14.3)	2 (33.3)
	PND 13			PND 8-24	PND 13-17

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F1 Pups

Treatment Groups (mg/kg/day)

	0	37.5	75	100	150
Convulsion	1 (1.0) 1 (12.5) PND 17	0	0	0	0
Dehydrated	0	0	0	2 (2.3) 1 (14.3) PND 21-22	0
Emaciated	0	0	0	1 (1.2) 1 (14.3) PND 8	0
Gasping	1 (1.0) 1 (12.5) PND 17	0	0	0	0
Hypoactive	0	0	0	6 (7.0) 2 (28.6) PND 21-28	2 (2.9) 2 (33.3) PND 17
Lethargic	1 (1.0) 1 (12.5) PND 13	0	0	0	8 (11.4) 3 (50.0) PND 13-17
Limb held up Left Hindlimb	0	0	0	1 (1.2) 1 (14.3) PND 21	0

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	F1 Pups				
	Treatment Groups (mg/kg/day)				
	0	37.5	75	100	150
Loss of Limb Function	1 (1.0)	0	0	0	3 (4.3)
Left Hindlimb	1 (12.5) PND 13	0	0	0	2 (33.3) PND 13
Loss of Limb Function	1 (1.0)	0	0	0	3 (4.3)
Right Hindlimb	1 (12.5) PND 13	0	0	0	2 (33.3) PND 13
Loss of Righting Reflex	0	0	0	0	2 (2.9)
	0	0	0	0	1 (16.7) PND 13
Mass	0	0	0	0	1 (1.4)
Neck	0	0	0	0	1 (16.7) PND 18
No Milk in Stomach	1 (1.0)	0	0	0	2 (2.9)
	1 (12.5) PND 9	0	0	0	2 (33.3) PND 11-16
Pale	2 (2.0)	0	0	5 (5.8)	9 (12.9)
	2 (25.0) PND 13-17	0	0	2 (28.6) PND 21-28	4 (66.7) PND 13-17
Pup - Found Dead	4 (4.0)	1 (1.6)	0	8 (9.3)	10 (14.3)
	4 (50.0) PND 5-21	1 (20.0) PND 6	0	2 (28.6) PND 7-28	3 (50.0) PND 5-18

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	F1 Pups				
	Treatment Groups (mg/kg/day)				
	0	37.5	75	100	150
Pup Cannibalised	0	0	0	0	1 (1.4)
	0	0	0	0	1 (16.7)
					PND 18
Respiration	0	0	0	2 (2.3)	3 (4.3)
Labored	0	0	0	2 (28.6)	2 (33.3)
				PND 21-24	PND 17
Scab(s)	0	0	0	1 (1.2)	1 (1.4)
Nose/Snout	0	0	0	1 (14.3)	1 (16.7)
				PND 21-22	PND 17
Scab(s)	0	0	0	1 (1.2)	0
Right Ear	0	0	0	1 (14.3)	0
				PND 22	
Skin Discolored	0	0	23 (27.7)	72 (83.7)	55 (78.6)
Yellow	0	0	2 (28.6)	6 (85.7)	6 (100.0)
			PND 20-28	PND 18-28	PND 16-18
Sore(s) On Body	0	0	0	1 (1.2)	0
Right Flank	0	0	0	1 (14.3)	0
				PND 28	
Swelling	0	0	0	0	17 (24.3)
Abdomen	0	0	0	0	2 (33.3)
					PND 18

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F1 Pups

Treatment Groups (mg/kg/day)

	0	37.5	75	100	150
Swelling	0	0	0	1 (1.2)	0
Left Hind Paw	0	0	0	1 (14.3) PND 21	0
Tail Damaged	0	0	0	1 (1.2)	0
	0	0	0	1 (14.3) PND 7-28	0

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LEGEND

Animals exhibiting clinical observations "within normal limits" were recorded as scheduled but are omitted from the table for clarity.

Upper row denotes the pup incidence N (%)

Middle row denotes the litter incidence N (%)

Lower row denotes the range of postnatal days the finding was seen for the group

F1 litter incidence based on the number of F0 dams.

No. live litters includes litters with ≥ 1 live pup

Percent incidence calculated using number of live pups or litters on PND 0 (pre cull) or PND 4 (post cull)

PND - Postnatal Day, pups pre-weaning

**** END OF REPORT ****