

Study Number: I10482B
Test Type: TOX
Route: Dosing in Feed
Species/Strain: Rat/Harlan Sprague Dawley

I05P: Pup Clinical Observations Summary
Test Compound: N-Butylbenzenesulfonamide
CAS Number: 3622-84-2

Date Report Requested: 11/20/2020
Time Report Requested: 12:56:21
Lab: Burleson Research Technologies

Study Number: I10482B
Study Gender: Both
PWG Approval Date: See web page for date of PWG Approval
Version: v1.1.1

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	F1 Pups			
	Treatment Groups (ppm)			
	0	250	500	1000
Total Pups (PND 0)	410	376	385	368
No. pups post cull (PND 4)	240	232	240	229
Total Litters (PND 0)	30	29	30	29
No. litters post cull (PND 4)	30	29	30	29
Pup Clinical Observations PND 0-4				
Anal Atresia	0	0	1 (0.3)	0
	0	0	1 (3.3) PND 1	0
Bruising	1 (0.2)	3 (0.8)	1 (0.3)	6 (1.6)
Abdomen	1 (3.3) PND 0-2	3 (10.3) PND 0-1	1 (3.3) PND 0-1	5 (17.2) PND 0-2
Bruising	6 (1.5)	3 (0.8)	11 (2.9)	8 (2.2)
Dorsum	4 (13.3) PND 0-1	3 (10.3) PND 0-2	6 (20.0) PND 0-1	6 (20.7) PND 0-3
Bruising	0	1 (0.3)	0	0
Fore Limb	0	1 (3.4) PND 2	0	0
Bruising	14 (3.4)	22 (5.9)	34 (8.8)	36 (9.8)
Fore Paw	10 (33.3) PND 2-4	15 (51.7) PND 2-4	17 (56.7) PND 2-4	19 (65.5) PND 2-4

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F1 Pups

Treatment Groups (ppm)

	0	250	500	1000
Bruising	30 (7.3)	15 (4.0)	14 (3.6)	14 (3.8)
Head	18 (60.0) PND 0-2	9 (31.0) PND 0-2	11 (36.7) PND 0-2	10 (34.5) PND 0-1
Bruising	3 (0.7)	0	1 (0.3)	1 (0.3)
Hind Limb	2 (6.7) PND 0-2	0	1 (3.3) PND 0-1	1 (3.4) PND 0-2
Bruising	25 (6.1)	12 (3.2)	28 (7.3)	10 (2.7)
Hind Paw	13 (43.3) PND 0-3	6 (20.7) PND 0-3	12 (40.0) PND 0-3	7 (24.1) PND 0-4
Cold To Touch	2 (0.5)	4 (1.1)	3 (0.8)	1 (0.3)
	2 (6.7) PND 0-1	4 (13.8) PND 0-2	3 (10.0) PND 0-2	1 (3.4) PND 0
Damaged	1 (0.2)	0	0	0
Tail	1 (3.3) PND 1-4	0	0	0
Discolored	0	0	1 (0.3)	0
Tip of Tail; Black	0	0	1 (3.3) PND 4	0
Discolored	0	1 (0.3)	0	0
Tip of Tail; White	0	1 (3.4) PND 1-3	0	0

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	F1 Pups			
	Treatment Groups (ppm)			
	0	250	500	1000
Kinked Tail	0	0	1 (0.3)	0
	0	0	1 (3.3) PND 1	0
Milk Band Absent Abdomen	1 (0.2)	1 (0.3)	2 (0.5)	2 (0.5)
	1 (3.3) PND 0	1 (3.4) PND 0	2 (6.7) PND 0-2	2 (6.9) PND 0-4
Missing Fore Limb; Right	1 (0.2)	0	0	0
	1 (3.3) PND 0	0	0	0
Missing Hind Limb; Right	0	0	1 (0.3)	0
	0	0	1 (3.3) PND 0	0
Missing Tail	0	0	1 (0.3)	0
	0	0	1 (3.3) PND 0-1	0
Missing Tip of Tail; Bilateral	0	1 (0.3)	0	0
	0	1 (3.4) PND 0	0	0
Missing Tip of Tail	0	0	3 (0.8)	1 (0.3)
	0	0	3 (10.0) PND 0-4	1 (3.4) PND 0-4

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	F1 Pups			
	Treatment Groups (ppm)			
	0	250	500	1000
Pale	2 (0.5) 2 (6.7) PND 0-1	3 (0.8) 3 (10.3) PND 0-3	5 (1.3) 4 (13.3) PND 0-2	2 (0.5) 2 (6.9) PND 1-2
Scab Abdomen	1 (0.2) 1 (3.3) PND 1-4	0 0	1 (0.3) 1 (3.3) PND 4	0 0
Scab Head; Bilateral	0 0	0 0	0 0	2 (0.5) 2 (6.9) PND 0-1
Scab Hind Limb; Right	0 0	1 (0.3) 1 (3.4) PND 3-4	0 0	0 0
Scab Neck; Bilateral	0 0	0 0	1 (0.3) 1 (3.3) PND 1	1 (0.3) 1 (3.4) PND 0
Scab Tail; Bilateral	1 (0.2) 1 (3.3) PND 3-4	0 0	1 (0.3) 1 (3.3) PND 1-4	0 0
Scab Tail; Left	0 0	0 0	0 0	2 (0.5) 2 (6.9) PND 0-4

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F1 Pups

Treatment Groups (ppm)

	0	250	500	1000
Scab	1 (0.2)	0	0	0
Tail	1 (3.3)	0	0	0
	PND 1			
Scab	0	1 (0.3)	0	0
Tip of Tail	0	1 (3.4)	0	0
		PND 4		
Swelling	3 (0.7)	3 (0.8)	11 (2.9)	8 (2.2)
Fore Paw; Left	3 (10.0)	3 (10.3)	5 (16.7)	5 (17.2)
	PND 2-4	PND 2-3	PND 2-4	PND 2-4
Swelling	1 (0.2)	6 (1.6)	8 (2.1)	11 (3.0)
Fore Paw; Right	1 (3.3)	5 (17.2)	4 (13.3)	6 (20.7)
	PND 2	PND 2-4	PND 2-4	PND 2-4
Swelling	1 (0.2)	7 (1.9)	11 (2.9)	14 (3.8)
Fore Paw	1 (3.3)	4 (13.8)	7 (23.3)	8 (27.6)
	PND 2	PND 2-4	PND 2-4	PND 2-4
Swelling	1 (0.2)	0	0	0
Hind Paw; Right	1 (3.3)	0	0	0
	PND 2			
Wound	0	1 (0.3)	0	0
Abdomen; Left	0	1 (3.4)	0	0
		PND 0		

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	F1 Pups			
	Treatment Groups (ppm)			
	0	250	500	1000
Wound	0	0	1 (0.3)	0
Nose/Snout; Right	0	0	1 (3.3) PND 0	0
Pup Clinical Observations PND 5-28				
Alopecia	0	1 (0.4)	0	0
Dorsum	0	1 (3.4) PND 9-10	0	0
Alopecia	0	0	1 (0.4)	0
Head	0	0	1 (3.3) PND 13-14	0
Bruising	3 (1.2)	5 (2.2)	10 (4.2)	15 (6.6)
Fore Paw	3 (10.0) PND 5-6	4 (13.8) PND 5-11	5 (16.7) PND 5-8	12 (41.4) PND 5-8
Damaged	1 (0.4)	0	0	0
Tail	1 (3.3) PND 12-28	0	0	0
Discharge	0	0	2 (0.8)	0
Eye; Left, Red	0	0	1 (3.3) PND 18-27	0

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	F1 Pups			
	Treatment Groups (ppm)			
	0	250	500	1000
Discharge	1 (0.4)	0	0	0
Eye; Red, Bilateral	1 (3.3)	0	0	0
	PND 26			
Discharge	0	0	2 (0.8)	0
Eye; Red, Left	0	0	1 (3.3)	0
			PND 19-28	
Discharge	1 (0.4)	0	0	0
Eye; Red, Right	1 (3.3)	0	0	0
	PND 27-28			
Discolored	0	1 (0.4)	0	0
Tip of Tail; Black	0	1 (3.4)	0	0
		PND 7-11		
Discolored	0	1 (0.4)	0	0
Tip of Tail; Red	0	1 (3.4)	0	0
		PND 6-12		
Distended	1 (0.4)	0	0	0
Abdomen	1 (3.3)	0	0	0
	PND 17-18			
Eye Abnormality	0	1 (0.4)	0	0
Right	0	1 (3.4)	0	0
		PND 19		

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F1 Pups

Treatment Groups (ppm)

	0	250	500	1000
Kinked	0	5 (2.2)	1 (0.4)	1 (0.4)
Tail	0	5 (17.2) PND 5-28	1 (3.3) PND 28	1 (3.4) PND 7-28
Missing	0	2 (0.9)	0	1 (0.4)
Tip of Tail	0	2 (6.9) PND 12-28	0	1 (3.4) PND 5-28
Nails Broken	1 (0.4)	0	0	0
Hind Paw; Right	1 (3.3) PND 21-28	0	0	0
Scab	1 (0.4)	0	1 (0.4)	0
Abdomen	1 (3.3) PND 9-12	0	1 (3.3) PND 5-6	0
Scab	1 (0.4)	0	0	0
Dorsum; Left	1 (3.3) PND 9	0	0	0
Scab	0	1 (0.4)	0	0
Dorsum	0	1 (3.4) PND 7-8	0	0
Scab	0	0	0	2 (0.9)
Fore Limb; Left	0	0	0	2 (6.9) PND 6-7

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F1 Pups

Treatment Groups (ppm)

	0	250	500	1000
Scab	0	1 (0.4)	1 (0.4)	4 (1.7)
Fore Limb; Right	0	1 (3.4) PND 5-6	1 (3.3) PND 5-8	3 (10.3) PND 5-8
Scab	0	0	0	1 (0.4)
Fore Limb	0	0	0	1 (3.4) PND 9-12
Scab	0	0	0	1 (0.4)
Head	0	0	0	1 (3.4) PND 9-10
Scab	1 (0.4)	0	0	0
Tail; Bilateral	1 (3.3) PND 5-11	0	0	0
Scab	0	0	0	1 (0.4)
Tail; Left	0	0	0	1 (3.4) PND 5-6
Scab	0	1 (0.4)	0	0
Tip of Tail	0	1 (3.4) PND 5-13	0	0
Swelling	0	0	1 (0.4)	1 (0.4)
Fore Paw; Right	0	0	1 (3.3) PND 5	1 (3.4) PND 5-7

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F1 Pups

Treatment Groups (ppm)

	0	250	500	1000
Swelling	0	0	0	2 (0.9)
Fore Paw	0	0	0	2 (6.9) PND 5
Swelling	1 (0.4)	0	0	0
Hind Limb; Left	1 (3.3) PND 7-8	0	0	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; F2 litter incidence based on number of F1 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 ****