

ADME NTP Study S0618 Benzene

The contract laboratory abbreviation for the test article is BNZ.

Sex/Species: adult male F344 rats, B6C3F₁ mice, and LVG Golden Syrian Hamsters.

Vehicle: oral, corn oil; intraperitoneal, corn oil.

CASRN 71-43-2

Radiolabeled with carbon-14 randomly in the phenyl ring; Benzene, [Ring-U-¹⁴C]-

Benzene Studies Performed:

1. Single 0.02 mg/kg oral gavage dose in rats with sacrifice at 48 hours postdose.
2. Single 0.1 mg/kg oral gavage dose in rats with sacrifice at 48 hours postdose.
3. Single 0.5 mg/kg oral gavage dose in rats with sacrifice a 48 hours postdose.
4. Single 0.5 mg/kg intraperitoneal dose in rats with sacrifice at 48 hours postdose.
5. Single 10 mg/kg oral gavage dose in rats with sacrifice at 48 hours postdose.
6. Single 100 mg/kg oral gavage dose in rats with sacrifice at 48 hours postdose.
7. 10 mg/kg/day 8-day repeat, oral gavage administration in rats with radiolabel dosed on day 7 and excreta collections made to 48 hours post day-7 dose.
8. Single 0.1 mg/kg oral gavage dose in mice with sacrifice at 48 hours postdose.
9. Single 100 mg/kg oral gavage dose in mice with sacrifice at 48 hours postdose.
10. Single 0.02 mg/kg oral gavage dose in hamsters with sacrifice at 48 hours postdose.
11. Single 0.1 mg/kg oral gavage dose in hamsters with sacrifice at 48 hours postdose.
12. Single 100 mg/kg oral gavage dose in hamsters with sacrifice at 48 hours postdose.

All studies are single dose studies except for Study 7 and had N = 4. In Study 7, male rats received 8 daily doses of 10 mg benzene per kg body weight. Non-radiolabeled benzene was administered on days 1-6 and on day 8. On day 7, radiolabeled benzene was added to the non-radiolabeled benzene dose solution and excretion was determined for the 48 hours following this radiolabel dose.

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Table 1

Disposition of Radioactivity 48 h After Administration of
[¹⁴C]BNZ to Male F-344 Rats

Cumulative Excretion of Radioactivity

0.1 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
3		0.3 ± 0.0	0.1 ± 0.1		0.4 ± 0.1
4	14.6 ± 25.3				15.0 ± 25.0
6		0.4 ± 0.1	0.1 ± 0.1		15.1 ± 25.3
8	63.1 ± 13.5			1.5 ± 0.1	65.1 ± 13.6
24	95.4 ± 1.9	0.5 ± 0.1	0.1 ± 0.1	2.0 ± 0.2	97.5 ± 2.0
48	98.7 ± 0.8			2.0 ± 0.2	101.5 ± 0.9
Cage Rinse	99.3 ± 1.0				101.9 ± 0.9

0.5 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	22.8 ± 17.2	1.9 ± 1.1	0.0 ± 0.0	0.0 ± 0.0	24.8 ± 17.3
8	42.1 ± 13.3	2.3 ± 1.3	0.1 ± 0.0	0.0 ± 0.0	44.5 ± 12.7
24	87.8 ± 3.0	2.6 ± 1.3	0.1 ± 0.1	1.5 ± 0.2	91.9 ± 3.3
48	94.1 ± 2.0			1.8 ± 0.2	98.6 ± 2.1
Cage Rinse	95.4 ± 2.2				99.9 ± 2.3

0.5 mg/kg IP Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	39.8 ± 3.8	5.9 ± 1.3	0.1 ± 0.0	0.0 ± 0.0	45.8 ± 4.0
8	53.0 ± 5.8	6.4 ± 1.2	0.1 ± 0.0	0.1 ± 0.1	59.6 ± 6.7
24	68.4 ± 3.3	6.6 ± 1.1	0.1 ± 0.0	1.1 ± 0.3	76.3 ± 4.3
48	70.7 ± 2.6			1.3 ± 0.3	78.9 ± 3.6
Cage Rinse	71.4 ± 2.5				79.6 ± 3.6

10 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	40.5 ± 9.8	8.6 ± 2.4	0.1 ± 0.0	0.0 ± 0.0	49.1 ± 11.7
8	68.2 ± 7.2	9.2 ± 2.6	0.1 ± 0.0	0.3 ± 0.5	77.8 ± 7.7
24	90.0 ± 3.2	9.4 ± 2.7	0.1 ± 0.0	1.4 ± 0.4	100.9 ± 2.5
48	92.6 ± 3.7			1.6 ± 0.4	103.7 ± 3.2
Cage Rinse	93.2 ± 3.8				104.3 ± 3.3

100 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	2.2 ± 2.3	37.8 ± 4.7	0.0 ± 0.0	0.0 ± 0.0	40.1 ± 4.0
8	18.1 ± 4.4	48.6 ± 4.4	0.0 ± 0.0	0.0 ± 0.0	66.8 ± 5.9
24	45.5 ± 2.3	50.5 ± 4.6	0.0 ± 0.0	0.3 ± 0.1	96.4 ± 2.8
48	47.2 ± 2.7			0.4 ± 0.1	98.2 ± 3.1
Cage Rinse	47.5 ± 2.9				98.5 ± 3.2

Table 1 (con't)

Disposition of Radioactivity 48 h After Administration of
[¹⁴C]BNZ to Male F-344 Rats

Cumulative Excretion of Radioactivity

0.02 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:			Total
	Urine	Breath	Feces	
4	37.3 ± 12.9	1.8 ± 0.6	0.1 ± 0.2	38.3 ± 13.0
8	60.2 ± 18.1	2.2 ± 0.8	0.2 ± 0.2	62.6 ± 17.6
24	96.1 ± 2.3	2.3 ± 0.7	1.9 ± 0.5	100.3 ± 2.1
48	98.1 ± 1.6		2.4 ± 0.5	102.8 ± 1.2
Cage Rinse	99.3 ± 0.7			103.9 ± 0.5

10 mg/kg Repeat Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:			Total
	Urine	Breath	Feces	
2		2.5 ± 1.1		2.5 ± 1.1
4	23.4 ± 17.4	4.2 ± 1.2	0.0 ± 0.0	27.6 ± 17.7
8	52.4 ± 14.9	5.1 ± 1.2	0.2 ± 0.0	57.6 ± 15.0
24	95.8 ± 2.3	5.3 ± 1.2	0.8 ± 0.6	101.9 ± 1.9
48	98.6 ± 1.8		1.6 ± 0.3	103.9 ± 0.7
Cage Rinse	99.6 ± 1.7			106.4 ± 1.2

Table 2

Disposition of Radioactivity 48 h after Oral Administration (10 mg/kg) of
BNZ to Male F-344 Rats

Cumulative Excretion of Radioactivity

10 mg/kg Single Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	40.5 ± 9.8	8.6 ± 2.4	0.1 ± 0.0	0.0 ± 0.0	49.1 ± 11.7
8	68.2 ± 7.2	9.2 ± 2.6	0.1 ± 0.0	0.3 ± 0.5	77.8 ± 7.7
24	90.0 ± 3.2	9.4 ± 2.7	0.1 ± 0.0	1.4 ± 0.4	100.9 ± 2.5
48	92.6 ± 3.7			1.6 ± 0.4	103.7 ± 3.2
Cage Rinse	93.2 ± 3.8				104.3 ± 3.3

10 mg/kg/day Repeat Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:			Total
	Urine	Breath	Feces	
2		2.5 ± 1.1		2.5 ± 1.1
4	23.4 ± 17.4	4.2 ± 1.2	0.0 ± 0.0	27.6 ± 17.7
8	52.4 ± 14.9	5.1 ± 1.2	0.0 ± 0.0	57.6 ± 15.0
24	95.8 ± 2.3	5.3 ± 1.2	0.8 ± 0.6	101.9 ± 1.9
48	98.6 ± 1.8		1.6 ± 0.3	103.9 ± 0.7
Cage Rinse	99.6 ± 1.7			106.4 ± 1.2

Table 3

**Cumulative Excretion of Radioactivity 48 h after Administration of
[¹⁴C]BNZ to Male B6C3F1 Mice**

0.1 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	0.02 ± 0.0	1.3 ± 0.9	0.4 ± 0.1	0.01 ± 0.0	1.7 ± 1.0
8	0.02 ± 0.0	1.4 ± 1.0	0.5 ± 0.1	1.0 ± 0.5	3.0 ± 0.6
24	55.8 ± 10.3	1.6 ± 1.0	0.5 ± 0.2	5.5 ± 1.8	63.4 ± 9.7
48	66.2 ± 13.5			18.8 ± 7.4	87.1 ± 6.7
Cage Rinse	76.1 ± 8.7				97.0 ± 3.3

100 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	0.0 ± 0.0	20.1 ± 3.7	0.1 ± 0.0	0.0 ± 0.0	20.3 ± 3.7
8	1.9 ± 3.3	21.6 ± 4.4	0.2 ± 0.0	0.3 ± 0.4	24.0 ± 2.7
24	16.3 ± 14.5	22.6 ± 4.6	0.6 ± 0.0	13.19 ± 18.2	52.7 ± 3.6
48	23.9 ± 18.3			31.1 ± 23.5	79.1 ± 5.7
Cage Rinse	43.1 ± 21.9				97.5 ± 1.5

Table 4

Cumulative Excretion of Radioactivity 48 h After Administration of
[¹⁴C]BNZ to Male LVG Hamsters

0.02 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	0.0 ± 0.0	1.4 ± 0.6	0.4 ± 0.1	0.0 ± 0.0	1.7 ± 0.7
8	33.4 ± 24.7	1.7 ± 0.5	0.7 ± 0.1	0.4 ± 0.5	36.9 ± 25.9
24	68.5 ± 7.7	2.0 ± 0.5	1.2 ± 0.4	5.4 ± 4.8	78.3 ± 3.5
48	76.5 ± 7.4			6.8 ± 5.2	87.7 ± 2.2
Cage Rinse	81.7 ± 7.8				93.0 ± 2.3

0.1 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	20.5 ± 24.4	1.6 ± 0.2	0.3 ± 0.1	0.0 ± 0.0	22.4 ± 24.3
8	51.3 ± 9.9	1.8 ± 0.2	0.6 ± 0.1	0.2 ± 0.2	54.0 ± 9.8
24	80.8 ± 7.1	2.0 ± 0.3	1.0 ± 0.1	1.7 ± 0.8	85.5 ± 7.4
48	86.1 ± 6.0			3.4 ± 0.7	89.2 ± 5.9
Cage Rinse	89.3 ± 4.4				95.7 ± 4.5

100 mg/kg Oral Dose

End of Collection Period (h)	Percent of Dose Recovered in:				Total
	Urine	Breath	CO ₂	Feces	
4	3.0 ± 6.1	24.5 ± 1.7	0.1 ± 0.0	0.0 ± 0.0	27.7 ± 5.5
8	25.1 ± 9.1	27.7 ± 2.1	0.2 ± 0.0	0.0 ± 0.0	53.0 ± 10.1
24	51.2 ± 3.8	29.0 ± 2.1	0.5 ± 0.0	1.5 ± 0.2	82.1 ± 3.8
48	56.6 ± 3.2			2.7 ± 1.1	88.7 ± 3.3
Cage Rinse	60.2 ± 3.0				92.3 ± 3.2