ADME NTP Study S0162 1,4-Butanediol

The contract laboratory abbreviation for the test article is BDL.
Sex/Species: adult male F344 rats.
Vehicles: oral, distilled water.

CASRN 110-63-4

Radiolabeled with carbon-14 in the 1- and 4-carbon position; 1,4-[1,4-^{14}C]Butanediol

Studies Performed:

- Single oral gavage dose of 4, 40, 120, or 400 mg/kg BDL administered to rats with sacrifice 72 hours postdose.

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Table 1

Cumulative Excretion of Radioactivity for 72 h after Oral Administration of [^{14}C]BDL to Male F-344 Rats (N=4)

End of Interval (h)	Cumulative % of Dose[a]				
	Volatiles	CO_2	Urine	Feces	Total Excreta
		4 mg/kg			
2	0.32 ± 0.14	50.3 ± 12.1			50.7 ± 12.0
4	0.47 ± 0.20	65.5 ± 9.6			66.0 ± 9.5
8	0.50 ± 0.22	78.9 ± 3.9	2.83 ± 0.23	0.16 ± 0.04	82.4 ± 3.7
12	0.52 ± 0.23	82.1 ± 1.9			85.6 ± 1.6
24	0.52 ± 0.23	83.9 ± 1.8	3.67 ± 0.28	0.46 ± 0.06	88.5 ± 1.4
32		84.4 ± 1.8			89.0 ± 1.4
48	0.53 ± 0.23	85.0 ± 1.8	3.82 ± 0.26	0.60 ± 0.04	89.9 ± 1.4
56		85.2 ± 1.8			90.2 ± 1.4
72	0.53 ± 0.23	85.6 ± 1.8	3.89 ± 0.25	0.64 ± 0.04	90.6 ± 1.4
		40 mg/kg			
2		54.4 ± 8.0			54.4 ± 8.0
4		70.1 ± 6.1			70.1 ± 6.1
8		79.3 ± 2.1	2.99 ± 0.29	0.12 ± 0.10	82.4 ± 1.8
12		81.7 ± 1.0			84.8 ± 0.8
24		83.6 ± 0.6	4.19 ± 0.15	0.47 ± 0.12	88.2 ± 0.6
32		84.0 ± 0.5			88.7 ± 0.6
48		84.7 ± 0.4	4.37 ± 0.15	0.60 ± 0.09	89.7 ± 0.4
56		85.0 ± 0.4			89.9 ± 0.4
72		85.3 ± 0.3	4.43 ± 0.15	0.63 ± 0.09	90.4 ± 0.3
		120 mg/kg			
2		51.5 ± 3.7			51.5 ± 3.7
4		69.0 ± 3.3			69.0 ± 3.3
8		80.9 ± 1.2	2.99 ± 0.12	0.09 ± 0.09	84.0 ± 1.1
12		83.1 ± 1.1			86.6 ± 1.0
24		84.7 ± 1.0	4.35 ± 0.26	0.42 ± 0.18	89.4 ± 1.2
32		85.1 ± 1.0			89.9 ± 1.2
48		85.7 ± 1.0	4.51 ± 0.27	0.60 ± 0.09	90.8 ± 1.2
56		85.9 ± 1.0			91.0 ± 1.2
72		86.2 ± 1.0	4.57 ± 0.26	0.64 ± 0.09	91.4 ± 1.1
		400 mg/kg			
2	0.60 ± 0.48	23.9 ± 2.6			24.5 ± 2.2
4	0.92 ± 0.55	51.0 ± 2.5			52.0 ± 2.1
8	0.99 ± 0.59	71.6 ± 3.0	4.84 ± 0.51	0.07 ± 0.03	77.5 ± 2.3
12	1.00 ± 0.59	75.2 ± 2.7			81.1 ± 2.1
24	1.01 ± 0.60	77.1 ± 2.7	6.19 ± 0.65	0.40 ± 0.04	84.8 ± 2.3
32		77.5 ± 2.7			85.1 ± 2.2
48	1.01 ± 0.59	78.2 ± 2.7	6.36 ± 0.68	0.56 ± 0.04	86.2 ± 2.2
56		78.5 ± 2.6			86.4 ± 2.2
72	1.01 ± 0.59	78.8 ± 2.6	6.45 ± 0.69	0.61 ± 0.06	86.9 ± 2.1

[a] Values are means ± standard deviations.

Table 2

Cumulative Excretion of $^{14}CO_2$ after Oral Administration of [^{14}C]BDL to Rats (% Dose)[a]

Time at End of Interval (h)	4 mg/kg (N=4)	40 mg/kg (N=4)	120 mg/kg (N=4)	400 mg/kg (N=4)
2	50.3 ± 12.1	54.4 ± 8.0	51.5 ± 3.7	23.9 ± 2.6
4	65.5 ± 9.6	70.1 ± 6.1	69.0 ± 3.3	51.0 ± 2.5
8	78.9 ± 3.9	79.3 ± 2.1	80.9 ± 1.2	71.6 ± 3.0
12	82.1 ± 1.9	81.7 ± 1.0	83.1 ± 1.1	75.2 ± 2.7
24	83.9 ± 1.8	83.6 ± 0.6	84.7 ± 1.0	77.1 ± 2.7
32	84.4 ± 1.8	84.0 ± 0.5	85.1 ± 1.0	77.5 ± 2.7
48	85.0 ± 1.8	84.7 ± 0.4	85.7 ± 1.0	78.2 ± 2.7
56	85.2 ± 1.8	85.0 ± 0.4	85.9 ± 1.0	78.5 ± 2.6
72	85.6 ± 1.8	85.3 ± 0.3	86.2 ± 1.0	78.8 ± 2.6

[a] Values are means ± standard deviations.

Table 3

Tissue Distribution of Radioactivity 72 h after Oral Administration of [^{14}C]BDL (40 mg/kg) to Male F-344 Rats (N=4)[a]

Tissue	ng-eq BDL per g Tissue	Tissue-Blood Ratio	% Dose in Total Tissue
Adipose	891 ± 129	0.95 ± 0.14	0.15 ± 0.02
Blood	941 ± 41	Unity	0.12 ± 0.01
Brain	805 ± 147	0.85 ± 0.12	0.01 ± 0.00
Liver	4930 ± 1230	5.24 ± 1.32	0.52 ± 0.18
Muscle	803 ± 164	0.85 ± 0.16	0.93 ± 0.21
Skin	1350 ± 251	1.44 ± 0.25	0.55 ± 0.12
Total			2.28 ± 0.44%

[a] Values are means ± standard deviations.

Table 4

^{14}C-Levels Present in Blood 72 h after an Oral Dose of BDL to Male F-344 Rats (N=4)

Dose Level (mg/kg)	% of Dose in Blood	ng-eq BDL per g blood
4	0.09 ± 0.02	72 ± 11
40	0.12 ± 0.01	941 ± 41
120	0.12 ± 0.00	2780 ± 151
400	0.11 ± 0.00	8580 ± 295