

ADME NTP Study S0638 Diazoaminobenzene

The contract laboratory abbreviation for the test article is DAAB.

Sex/Species male and female F344 rats and male B6C3F1 mice.

Vehicles: intravenous, Emulphor EL-620:water (1:9); oral, Emulphor EL-620:water (2:8); dermal, acetone.

CASRN 693-13-0

Radiolabeled with carbon-14 randomly in the phenyl rings; Diazoaminobenzene, [UL-14C]-

Studies Performed:

- Single 20 mg/kg oral gavage dose in male rats with sacrifice 72 hours postdose.
- Single 20 mg/kg oral dose in male rats with pretreatment of 100 mg/kg intraperitoneal dose of 1-aminobenzotriazole (an inhibitor of cytochrome P450). Rats were sacrificed at 72 hours after radiolabeled dose.
- Single 2 mg/kg intravenous dose in male rats with sacrifice 72 hours postdose.
- Single 4 mg/kg dermal administration to male rats with covered dose sites and sacrifice 72 hours postdose.
- Single 40 mg/kg dermal administration to male rats with covered dose sites and sacrifice 72 hours postdose.
- Single 20 mg/kg oral dose in male mice with sacrifice 72 hours postdose.
- Single 2 mg/kg intravenous dose in male mice with sacrifice 72 hours postdose.
- Single 2 mg/kg dermal administration to male mice with covered dose sites and sacrifice 72 hours postdose.
- Single 20 mg/kg dermal administration to male mice with covered dose sites and sacrifice 72 hours postdose.
- Single 20 mg/kg oral dose in male and female rats with serial blood sampling and sacrifice at 24 hours (toxicokinetics).

For dermal studies, all dose sites were covered in all doses. No toxicokinetic analysis information or parameters were given in the report.

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Table 1

Cumulative Excretion of Radioactivity after Oral Administration of [¹⁴C]DAAB (20 mg/kg) to Male F-344 Rats^a

No Pretreatment					
End of Collection Period (h)	Percent of Dose Recovered in:				
	Urine	Feces	Volatile Breath	CO ₂	Total
8 h	48.9 ± 1.9	c	1.15 ± 0.21	0.03 ± 0.00	50.1 ± 1.9
24 h	75.5 ± 2.0	13.7 ± 1.6	1.30 ± 0.21	0.04 ± 0.00	90.6 ± 3.0
48 h	79.5 ± 1.0	15.6 ± 0.8	1.35 ± 0.22	0.04 ± 0.00	96.5 ± 0.9
72 h	80.3 ± 0.8	15.7 ± 0.8	1.36 ± 0.22	0.05 ± 0.01	97.5 ± 0.3
Cagewash	80.6 ± 0.8				97.7 ± 0.4
Total	80.6 ± 0.8	15.7 ± 0.8	1.36 ± 0.22	0.05 ± 0.01	97.7 ± 0.4

Pretreatment with 1-aminobenzotriazole ^b					
End of Collection Period (h)	Percent of Dose Recovered in:				
	Urine	Feces	Volatile Breath	CO ₂	Total
8 h	11.6 ± 6.3	c	6.57 ± 2.95	0.014 ± 0.01	18.2 ± 6.4
24 h	50.3 ± 7.5	11.8 ± 0.8	11.9 ± 3.9	0.024 ± 0.01	74.1 ± 4.1
48 h	60.2 ± 6.6	17.2 ± 3.1	c	c	89.3 ± 1.8
Cagewash	61.8 ± 6.2				90.9 ± 1.6
Total	61.8 ± 6.2	17.2 ± 3.1	11.9 ± 3.9	0.024 ± 0.01	90.9 ± 1.6

^a N=4

^b 100 mg/kg i.p. 4 h prior to administration of [¹⁴C]DAAB

c not measured

Table 2

Cumulative Excretion of Radioactivity after Intravenous Administration of [¹⁴C]DAAB (2 mg/kg) to Male F-344 Rats^a

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces	Volatile Breath	Total
8 h	48.2 ± 12.5	b	0.45 ± 0.07	48.7 ± 12.5
24 h	80.1 ± 3.3	5.2 ± 0.7	0.60 ± 0.08	85.9 ± 3.9
48 h	85.5 ± 2.0	7.3 ± 0.3	0.65 ± 0.09	93.5 ± 1.9
72 h	87.0 ± 1.8	7.7 ± 0.4	0.67 ± 0.10	95.3 ± 1.6
Cagewash	87.4 ± 1.7			95.7 ± 1.6
Total	87.4 ± 1.7	7.7 ± 0.4	0.67 ± 0.10	95.7 ± 1.6

^a N=4

^b not measured

Table 3

Cumulative Excretion of Radioactivity after Dermal Administration of [¹⁴C]DAAB (2 mg/cm²) to Male F-344 Rats^a

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces	Volatile Breath	Total
8 h	0.41 ± 0.17	b	0.05 ± 0.01	0.45 ± 0.18
24 h	1.44 ± 0.38	0.09 ± 0.02	0.13 ± 0.03	1.66 ± 0.42
48 h	2.96 ± 0.76	0.25 ± 0.05	0.24 ± 0.05	3.44 ± 0.86
72 h	4.67 ± 1.19	0.41 ± 0.08	0.36 ± 0.09	5.55 ± 1.44
Cagewash	4.85 ± 1.16			5.62 ± 1.31
Total	4.85 ± 1.16	0.41 ± 0.08	0.36 ± 0.09	5.62 ± 1.31

^a N=3

^b not measured

	% Dose Appearing in:	
Absorbed		
Urine	4.85 ± 1.16	
Feces	0.41 ± 0.08	
Volatile breath	0.36 ± 0.09	
Dose site	0.70 ± 0.24	
Total	6.32 ± 1.46	
Unabsorbed		
Appliance cover	1.07 ± 0.81	
Skin wash	77.0 ± 6.2	
Gauze	1.07 ± 0.90	
Total	79.1 ± 6.7	
Total Recovery	85.5 ± 7.9	

Table 4

Cumulative Excretion of Radioactivity after Dermal Administration of [¹⁴C]DAAB (20 mg/cm²) to Male F-344 Rats^a

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces	Volatile Breath	Total
8 h	0.05 ± 0.01	b	0.03 ± 0.00	0.07 ± 0.01
24 h	0.16 ± 0.01	0.01 ± 0.00	0.05 ± 0.01	0.23 ± 0.01
48 h	0.30 ± 0.02	0.04 ± 0.01	0.07 ± 0.01	0.41 ± 0.01
72 h	0.44 ± 0.03	0.05 ± 0.01	0.08 ± 0.01	0.57 ± 0.02
Cagewash				0.60 ± 0.03
Total	0.46 ± 0.03	0.05 ± 0.01	0.08 ± 0.01	0.60 ± 0.03

^a N=4

^b not measured

	% Dose Appearing in:	
Absorbed		
Urine	0.46 ±	0.03
Feces	0.05 ±	0.01
Volatile breath	0.08 ±	0.01
Dose site	0.17 ±	0.19
Total	0.77 ±	0.19
Unabsorbed		
Appliance cover	0.21 ±	0.33
Skin wash	89.3 ±	5.7
Gauze	0.15 ±	0.19
Total	89.6 ±	5.3
Total Recovery	90.3 ±	5.0

Table 5

**Cumulative Excretion of Radioactivity after Oral
Administration of [¹⁴C]DAAB (20 mg/kg) to Male B6C3F1 Mice^a**

End of Collection Period (h)	Percent of Dose Recovered in:				
	Urine	Feces	Volatile Breath	CO ₂	Total
8 h	4.54 ± 8.82	b	0.73 ± 0.17	0.16 ± 0.03	5.43 ± 8.85
24 h	44.3 ± 21.8	15.2 ± 6.7	0.87 ± 0.20	0.21 ± 0.05	60.6 ± 16.9
48 h	54.6 ± 17.5	18.5 ± 9.6	0.98 ± 0.25	0.23 ± 0.06	74.3 ± 11.8
72 h	60.9 ± 15.0	20.0 ± 10.8	1.03 ± 0.27	0.24 ± 0.07	82.2 ± 10.5
Cagewash	68.3 ± 11.6				89.6 ± 4.40
Total	68.3 ± 11.6	20.0 ± 10.8	1.03 ± 0.27	0.24 ± 0.07	89.6 ± 4.40

^a N=4^b not measured

Table 6**Cumulative Excretion of Radioactivity after Intravenous Administration of [¹⁴C]DAAB (2 mg/kg) to Male B6C3F1 Mice^a**

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces	Volatile Breath	Total
8 h	12.5 ± 17.0		0.55 ± 0.29	13.1 ± 17.2
24 h	27.2 ± 10.5	11.4 ± 3.5	0.74 ± 0.31	39.7 ± 10.9
48 h	36.7 ± 8.5	17.2 ± 6.0	0.93 ± 0.34	54.8 ± 7.4
72 h	43.4 ± 6.5	22.9 ± 5.6	1.02 ± 0.36	69.4 ± 5.2
Cagewash	56.7 ± 7.0			80.6 ± 5.3
Total	56.7 ± 7.0	22.9 ± 5.6	1.02 ± 0.36	80.6 ± 5.3

^a N=4

Table 7

Cumulative Excretion of Radioactivity after Dermal
Administration of [¹⁴C]DAAB (2 mg/cm²) to Male B6C3F1 Mice

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces ^a	Volatile Breath	Total
8 h	0.00 ± 0.00		0.10 ± 0.11	0.10 ± 0.11
24 h	0.59 ± 0.25	0.42 ± 0.06	0.19 ± 0.14	1.20 ± 0.32
48 h	1.02 ± 0.43	1.04 ± 0.31	0.30 ± 0.19	1.92 ± 1.07
72 h	1.92 ± 1.07	2.40 ± 0.84	0.48 ± 0.26	4.80 ± 0.26
Cagewash	3.87 ± 1.32			6.76 ± 1.31
Total	3.87 ± 1.32	2.40 ± 0.84	0.48 ± 0.26	6.76 ± 1.31

^a N=4

	% Dose Appearing in:
Absorbed	
Urine	3.87 ± 1.32
Feces	2.40 ± 0.84
Volatile breath	0.48 ± 0.26
Dose site	0.28 ± 0.05
Total	7.04 ± 1.30
Unabsorbed	
Appliance cover	1.01 ± 1.58
Skin wash	78.0 ± 3.69
Gauze	0.41 ± 0.35
Total	79.4 ± 2.2
Total Recovery	86.4 ± 2.8

Table 8

Cumulative Excretion of Radioactivity after Dermal Administration of [¹⁴C]DAAB (20 mg/cm²) to Male B6C3F1 Mice^a

End of Collection Period (h)	Percent of Dose Recovered in:			
	Urine	Feces	Volatile Breath	Total
8 h	0.01 ± 0.01		0.02 ± 0.01	0.02 ± 0.01
24 h	0.08 ± 0.01	0.07 ± 0.06	0.04 ± 0.01	0.20 ± 0.05
48 h	0.18 ± 0.01	0.17 ± 0.05	0.07 ± 0.01	0.42 ± 0.04
72 h	0.26 ± 0.01	0.36 ± 0.07	0.09 ± 0.01	0.71 ± 0.08
Cagewash	0.55 ± 0.05			1.00 ± 0.11
Total	0.55 ± 0.05	0.36 ± 0.07	0.09 ± 0.01	1.00 ± 0.11

^a N=4

	% Dose Appearing in:
Absorbed	
Urine	0.55 ± 0.05
Feces	0.36 ± 0.07
Volatile breath	0.09 ± 0.01
Dose site	0.19 ± 0.17
Total	1.19 ± 0.23
Unabsorbed	
Appliance cover	0.12 ± 0.05
Skin wash	63.0 ± 6.2
Gauze	0.18 ± 0.15
Total	63.3 ± 6.2
Total Recovery	64.5 ± 6.3

Table 9

Tissue Distribution of Radioactivity 24 h after Oral Administration of [¹⁴C]DAAB (20 mg/kg) to Male F-344 Rats^a

Tissue	ng-eq DAAB per g Tissue	Tissue/Blood Ratio	% Dose in Total Tissue
Adipose	438 ± 113	0.320 ± 0.098	0.155 ± 0.041
Blood	1380 ± 80	unity	0.361 ± 0.016
Kidney	1910 ± 150	1.38 ± 0.10	0.067 ± 0.006
Liver	912 ± 30	0.662 ± 0.047	0.184 ± 0.002
Muscle	123 ± 11	0.089 ± 0.010	0.297 ± 0.030
Skin	229 ± 11	0.166 ± 0.006	0.196 ± 0.007
Spleen	671 ± 25	0.485 ± 0.008	0.007 ± 0.001

^a N=3

Table 10a

Tissue Distribution of Radioactivity 24 h after Oral Administration of [¹⁴C]DAAB (20 mg/kg) to Female F-344 Rats^a

Tissue	ng-eq DAAB per g Tissue	Tissue/Blood Ratio	% Dose in Total Tissue
Adipose	803 ± 443	0.579 ± 0.256	0.273 ± 0.150
Blood	1370 ± 300	unity	0.346 ± 0.075
Kidney	2430 ± 440	1.80 ± 0.15	0.084 ± 0.016
Liver	1090 ± 140	0.830 ± 0.195	0.182 ± 0.025
Muscle	137 ± 17	0.104 ± 0.027	0.319 ± 0.039
Skin	253 ± 43	0.191 ± 0.043	0.210 ± 0.034
Spleen	976 ± 184	0.722 ± 0.076	0.012 ± 0.002

Table 10b

Cumulative Excretion of Radioactivity 24 h after Oral Administration of [¹⁴C]DAAB (20 mg/kg) to Female F-344 Rats^a

End of Collection Period (h)	Percent of Dose Recovered in:		
	Urine	Feces	Total
8 h	35.9 ± 29.0		35.9 ± 29.0
24 h	76.3 ± 8.78	2.21 ± 2.21	78.5 ± 8.96
Cagewash	85.3 ± 4.90		87.5 ± 6.0
Total	85.3 ± 4.90	2.21 ± 2.21	87.5 ± 6.0

^a N=4

Table 11a. Concentration of Total Radioactivity in Blood Extracts Following 20 mg/kg Oral Gavage Administration of [¹⁴C]DAAB to Male Rats (ng-equivalents DAAB/g blood)

Time (h)	Rat 1	Rat 2	Rat 3	Rat 4
0.25	5666.665	5035.22	6066.129	4277.29
0.5	8390.02	8645.491	8800.62	5482.802
1	9036.513	8651.691	9624	7995.981
2	6440.068	4501.659	5321.169	4783.666
4	1655.224	1857.35	1481.192	2125.501
6	845.3645	1237.423	891.8848	714.0749
24	196.9298	45.99832	81.84566	93.55539

Curator's note: concentrations are *sic erat scriptum*. However, 2-3 significant figures above the decimal place are shown for some of these numbers elsewhere in the original report.

N=4 male F344 rats.

SD = standard deviation; h = hours

Table 11b. Concentration of DAAB in Blood Extracts Following 20 mg/kg Oral Gavage Administration of [¹⁴C]DAAB to Male Rats (ng DAAB/g blood)

Time (h)	Rat 1	Rat 2	Rat 3	Rat 4	Mean	SD
0.25	186	140.9862	172.2781	73.56939	143.2084	50.10222
0.5	343	88.18401	85.36601	19.18981	133.935	142.9764
1	169	32.87643	40.4208	19.98995	65.57179	69.4662
2	199	13.05481	12.77081	1.913466	56.68477	95.01847
4	62	18.0163	12.29389	10.62751	25.73442	24.38325
6	35	17.5714	18.81877	0.785482	18.04391	13.97839
24	nd	nd	nd	nd	nd	nd

Curator's note: concentrations are *sic erat scriptum*. However, 2-3 significant figures above the decimal place are shown for some of these numbers elsewhere in the original report.

N=4 male F344 rats.

SD = standard deviation; h = hours; nd = not detected

**Table 12a. Concentration of Total Radioactivity in Blood Extracts
Following 20 mg/kg Oral Gavage Administration of [¹⁴C]DAAB to Female Rats
(ng-equivalents DAAB/g blood)**

Time (h)	Rat 1	Rat 2	Rat 3	Rat 4	Mean	SD
0.25	5796.693	5237.418	7171.093	5499.337	5926.135	860.8455
0.5	**	9177.084	10569.32	10860.28	10202.23	899.6421
1	9487.563	10525.19	13261.59	11057.3	11082.91	1592.01
2	6760.059	6483.507	8269.503	6621.132	7033.55	831.6678
4	1885.668	1816.907	2235.742	2213.137	2037.864	217.4565
6	909.3564	960.5505	1105.537	985.9087	990.338	83.13783
24	133.3395	104.6598	145.8631	146.3327	132.5488	19.54216

** Sample lost

Curator's note: concentrations are *sic erat scriptum*. However, 2-3 significant figures above the decimal place are shown for some of these numbers elsewhere in the original report.

N=4 female F344 rats.

SD = standard deviation; h = hours

**Table 12b. Concentration of DAAB in Blood Extracts
Following 20 mg/kg Oral Gavage Administration of [¹⁴C]DAAB to Female Rats
(ng DAAB/g blood)**

Time (h)	Mean	SD
0.25	305.4071	165.341
0.5	199.4481	201.2806
1	92.66362	175.82
2	33.82205	175.8673
4	7.259067	176.0083
6	14.00089	175.3831
24	nd	nd

Curator's note: concentrations are *sic erat scriptum*. However, 2-3 significant figures above the decimal place are shown for some of these numbers elsewhere in the original report.

N=2 female F344 rats.

SD = standard deviation; h = hours; nd = not detected