

## ADME NTP Study S0652 Triethanolamine

The contract laboratory abbreviation for the test article is TEA.

Sex/Species: adult female F344 rats and B6C3F1 mice.

Vehicles: intravenous, isotonic saline; dermal, acetone.

CASRN 102-71-6

Radiolabeled with carbon-14 on both of the ethyl carbons of all three 2-hydroxyethyl groups; Triethanolamine, [1,2-<sup>14</sup>C]-

### Studies Performed:

- Single 3 mg/kg intravenous dose in rats with sacrifice 72 hours postdose.
- Single 68 and 276 mg/kg dermal doses in rats with covered dose site and sacrifice 72 hours postdose.
- Single 3 mg/kg intravenous dose in mice with sacrifice 72 hours postdose.
- Single 79 and 1120 mg/kg dermal doses in mice with covered dose site and sacrifice 72 hours post dosing.

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Table 1

**Disposition of Radioactivity 72 h after an Intravenous Dose of  
[<sup>14</sup>C]TEA (3 mg/kg) to Female F-344 Rats<sup>a</sup>**

**Cumulative Excretion of Radioactivity**

End of Collection Period	Percent of Dose Recovered in:		Total
	Urine	Feces	
6 h	38.2 ± 26.0		38.2 ± 26.0
24 h	90.5 ± 1.23	0.373 ± 0.106	90.9 ± 1.33
48 h	96.3 ± 1.38	0.580 ± 0.120	96.9 ± 1.50
72 h <sup>b</sup>	98.2 ± 1.85	0.630 ± 0.147	98.9 ± 1.99

**Distribution in Tissues**

Tissue	ng-eq TEA per g Tissue	Tissue/Blood Ratio	% Dose in Total Tissue
Adipose	6.89 ± 0.508	0.857 ± 0.141	0.0167 ± 0.00101
Blood	8.13 ± 0.752	unity	0.0146 ± 0.00145
Brain	21.3 ± 1.43	2.63 ± 0.103	0.00681 ± 0.000588
Heart	41.0 ± 2.97	5.06 ± 0.354	0.00447 ± 0.000231
Kidney	271 ± 16.5	33.6 ± 3.42	0.0597 ± 0.00515
Liver	257 ± 17.3	31.9 ± 5.11	0.272 ± 0.0189
Lung	109 ± 6.21	13.4 ± 0.747	0.0150 ± 0.00102
Muscle	26.9 ± 2.03	3.32 ± 0.215	0.447 ± 0.0332
Skin	15.1 ± 1.61	1.86 ± 0.158	0.0886 ± 0.00939
Spleen	67.8 ± 5.59	8.36 ± 0.710	0.00567 ± 0.0000251
Total in tissues			0.930 ± 0.0384

<sup>a</sup> N=4

<sup>b</sup> includes bladder urine and final cage rinse

**Table 2**

**Cumulative Excretion of Radioactivity following Dermal Administration of [<sup>14</sup>C]TEA to Female F-344 Rats**

End of Collection Period	Percent of Dose Recovered in:		Total
	Urine	Feces	
68 mg/kg <sup>a</sup>			
6 h	0.171 ± 0.172		0.171 ± 0.172
24 h	1.33 ± 0.496	0.0080 ± 0.00446	1.34 ± 0.494
48 h	5.95 ± 2.71	0.0541 ± 0.0493	6.01 ± 2.75
72 h <sup>c</sup>	12.9 ± 5.84	0.247 ± 0.167	13.1 ± 5.70
276 mg/kg <sup>b</sup>			
6 h	0.135 ± 0.0793		0.135 ± 0.0793
24 h	3.03 ± 1.36	0.0148 ± 0.00738	3.04 ± 1.36
48 h	9.90 ± 2.52	0.0664 ± 0.0189	9.96 ± 2.53
72 h <sup>c</sup>	23.8 ± 7.82	0.142 ± 0.0471	23.9 ± 7.87

a N = 4

b N = 3

c includes bladder urine and final cage rinse

**Table 3**  
**Distribution of Radioactivity in Tissues 72 h following Dermal Administration**  
**of [<sup>14</sup>C]TEA to Female F-344 Rats**

Tissue	ng-eq TEA per g Tissue	Tissue/Blood Ratio	% Dose in Total Tissue
68 mg/kg <sup>a</sup>			
Adipose	136 ± 72.0	0.746 ± 0.150	0.0131 ± 0.00703
Blood	174 ± 82.2	unity	0.0124 ± 0.00599
Brain	214 ± 94.9	1.30 ± 0.301	0.00265 ± 0.00107
Heart	682 ± 305	3.98 ± 0.327	0.00293 ± 0.00135
Kidney	4890 ± 2250	28.2 ± 2.05	0.0467 ± 0.0226
Liver	2840 ± 1280	16.9 ± 3.44	0.113 ± 0.0471
Lung	1520 ± 695	8.83 ± 0.867	0.00773 ± 0.00360
Muscle	584 ± 280	3.34 ± 0.440	0.386 ± 0.187
Skin	341 ± 198	2.03 ± 0.707	0.0799 ± 0.0471
Spleen	919 ± 389	5.47 ± 0.658	0.00290 ± 0.00134
Total in tissues			0.668 ± 0.308
276 mg/kg <sup>b</sup>			
Adipose	1200 ± 539	0.713 ± 0.144	0.0282 ± 0.0126
Blood	1700 ± 758	unity	0.0298 ± 0.0142
Brain	1480 ± 685	0.870 ± 0.144	0.00463 ± 0.00234
Heart	6080 ± 2740	3.57 ± 0.223	0.00682 ± 0.00341
Kidney	39300 ± 20600	22.4 ± 2.67	0.0949 ± 0.0543
Liver	19000 ± 8270	11.3 ± 1.42	0.206 ± 0.0998
Lung	12800 ± 5660	7.54 ± 0.569	0.0169 ± 0.00844
Muscle	5060 ± 1630	3.15 ± 0.566	0.820 ± 0.289
Skin	2640 ± 832	1.64 ± 0.299	0.151 ± 0.0520
Spleen	7970 ± 3680	4.66 ± 0.336	0.00627 ± 0.00331
Total in tissues			1.36 ± 0.531

a N = 4

b N = 3

**Table 4**

**Distribution of Radioactivity 72 h following Dermal Administration of [<sup>14</sup>C]TEA to Female F-344 Rats**

	Percent of Dose	
	68 mg/kg	276 mg/kg
<u>Absorbed</u>		
Tissues	0.668 ± 0.308	1.36 ± 0.531
Dose site	5.62 ± 2.32	3.12 ± 0.881
Feces	0.247 ± 0.167	0.142 ± 0.0471
Urine	12.9 ± 5.84	23.8 ± 7.82
Total	19.4 ± 5.43	28.4 ± 9.08
<u>Unabsorbed</u>		
Appliance	6.35 ± 4.11	2.99 ± 2.01
Skin Gauze	22.9 ± 4.04	10.2 ± 4.39
Skin Wash	37.2 ± 9.13	41.4 ± 3.54
Total	66.5 ± 5.26	54.6 ± 6.96

**Table 5**

**Disposition of Radioactivity 72 h after an Intravenous Dose of [<sup>14</sup>C]TEA (3 mg/kg) to Female B6C3F1 Mice<sup>a</sup>**

**Cumulative Excretion of Radioactivity**

End of Collection Period	Percent of Dose Recovered in:		Total
	Urine	Feces	
6 h	6.76 ± 8.29		6.76 ± 8.29
24 h	26.0 ± 17.2	14.3 ± 7.56	40.3 ± 10.3
48 h	42.6 ± 22.8	23.7 ± 13.1	66.2 ± 14.6
72 h <sup>b</sup>	61.9 ± 14.6	27.6 ± 10.4	89.5 ± 4.62

**Distribution in Tissues**

Tissue	ng-eq TEA per g Tissue	Tissue/Blood Ratio	% Dose in Total Tissue
Adipose	17.1 ± 2.7	4.65 ± 1.29	0.0384 ± 0.00623
Blood	3.79 ± 0.578	unity	0.00631 ± 0.000932
Brain	15.0 ± 1.12	4.02 ± 0.490	0.00835 ± 0.00158
Heart	32.7 ± 1.01	8.77 ± 1.28	0.00587 ± 0.000527
Kidney	106 ± 11.4	28.2 ± 3.75	0.0489 ± 0.00467
Liver	215 ± 33.8	57.7 ± 13.5	0.305 ± 0.0484
Lung	68.4 ± 5.45	18.2 ± 1.94	0.0123 ± 0.00193
Muscle	14.4 ± 1.27	3.87 ± 0.720	0.221 ± 0.0145
Skin	12.1 ± 1.19	3.24 ± 0.627	0.0658 ± 0.00797
Spleen	48.4 ± 2.15	12.9 ± 1.54	0.00425 ± 0.000225
Total in tissues			0.716 ± 0.0685

a N=4

b includes bladder urine and final cage rinse

**Table 6**

**Excretion of Radioactivity following Dermal Administration  
of [<sup>14</sup>C]TEA to Female B6C3F1 Mice**

End of Collection Period	Percent of Dose Recovered in:		Total
	Urine	Feces	
79 mg/kg <sup>a</sup>			
6 h	3.04 ± 4.84		3.04 ± 4.84
24 h	22.5 ± 8.28	5.03 ± 3.09	27.5 ± 6.52
48 h	39.7 ± 4.96	7.07 ± 4.65	46.8 ± 7.28
72 h <sup>c</sup>	48.2 ± 5.09	7.8 ± 4.73	56.0 ± 8.05
1120 mg/kg <sup>b</sup>			
6 h	0.000105 ± 0.00009		0.000105 ± 0.00009
24 h	39.7 ± 21.5	8.75 ± 6.02	48.4 ± 20.5
48 h	57.1 ± 18.1	11.8 ± 7.05	68.9 ± 13.1
72 h <sup>c</sup>	67.7 ± 14.9	13.0 ± 7.60	80.7 ± 7.96

a N = 4

b N = 3

c includes bladder urine and final cage rinse

**Table 7****Distribution of Radioactivity 72 h following Dermal Administration of [<sup>14</sup>C]TEA to Female B6C3F1 Mice**

	Percent of Dose	
	79mg/kg	1120mg/kg
<u>Absorbed</u>		
Blood	0.00590 ± 0.00144	0.00627 ± 0.000412
Dose site	1.35 ± 0.317	0.576 ± 0.118
Feces	7.80 ± 4.73	13.0 ± 7.60
Urine	48.2 ± 5.09	67.7 ± 14.9
Total	57.3 ± 8.34	81.3 ± 8.02
<u>Unabsorbed</u>		
Appliance	0.481 ± 0.301	1.68 ± 2.02
Skin Gauze	2.30 ± 2.00	0.824 ± 0.737
Skin Wash	11.8 ± 4.65	4.24 ± 2.13
Total	14.6 ± 2.84	6.75 ± 3.41