

## ADME NTP Study K88993 Phthalic acid

The contractor used the abbreviation PA for the test article in the comparison tables.

Sex/Species: male F344 rats.

Vehicle: dermal, absolute ethanol.

CASRN 88-99-3

Radiolabeled with carbon-14 in the phthalyl moiety; Phthalic acid, [<sup>14</sup>C-U-phthalyl]

### Studies Performed:

- Single 7.9 mg/kg dermal dose to rats with covered dose site and sacrifice 7 days postdose. (n = 3)
- Single 79 mg/kg dermal dose to rats with covered dose site and sacrifice 7 days postdose. (n = 2)
- Single 79 mg/kg dermal dose to rats with uncovered dose site and sacrifice 7 days postdose. (n = 2)

The data of the 7-day excretion profile in the urine and feces for the 79 mg/kg dosed rats with covered versus uncovered dose sites was given in a figure and is not shown here. The total recoveries for the 79 mg/kg dosed rats with covered or uncovered dose sites are shown in Table 3.

Phthalic acid is one of nine phthalates that were tested together to determine excretion and tissue distribution after dermal administration. The comparison data is found in the dimethyl phthalate study S0043.

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Table 1. Excretion profile of phthalic acid (low dose level) in the urine and the feces after dermal application to the rat\*

Time (hr)	% Dose Excreted		
	Urine	Feces	Urine & Feces $\Sigma \bar{X}$
24	0.64 ± 0.78	0.08 ± 0.03	0.72
48	0.25 ± 0.33	0.19 ± 0.18	0.44
72	0.44 ± 0.65	0.5 ± 0.63	0.94
96	1.15 ± 1.35	0.32 ± 0.08	1.47
120	1.46 ± 0.89	0.96 ± 1.3	2.42
144	5 ± 4.8	2.4 ± 1.9	7.4
168	2.29 ± 1.9	1.6 ± 0.82	3.69
Total	11.3 ± 3.9	5.8 ± 3.96	17.1

\*Male F-344 rats (200 ± 20 gm) received phthalic acid in ethanol dermally (7.9 mg/Kg). The skin was covered with a perforated plastic cap. Data points are the mean ± S.D. The percentage of dose excreted represents the fraction of the dose found (as the <sup>14</sup>C-equivalent) relative to the total <sup>14</sup>C-equivalent applied.

Table 2. Excretion profile of phthalic acid (medium dose level) in the urine and the feces after dermal application to the rat\*

Time (hr)	% Dose Excreted ( $\bar{X}$ )		
	Urine	Feces	Urine & Feces ( $\Sigma\bar{X}$ )
24	2.7	0.12	2.82
48	1.03	0.32	1.35
72	1.36	0.51	1.87
96	6.57	0.74	5.31
120	9.98	5.6	15.58
144	5.05	9.8	14.85
168	3.8	5.8	9.6
Total	29	22.9	51.9

\*Male F-344 rats (200 ± 20 gm) received phthalic acid in ethanol dermally (79mg/Kg). The skin was covered with a perforated plastic cap. Data points are the mean (n = 2). The percentage of dose excreted represents the fraction of the dose found (as <sup>14</sup>C-equivalent) relative to the total <sup>14</sup>C-equivalent applied.

Table 3. Body tissue distribution after 7 days of dermal exposure to phthalic acid

Tissue	% Dose Found ( $\bar{X} \pm$ S.D., n = 3)			
	Low Dose 7.9 mg/kg		Medium Dose # 79 mg/kg with Cap	Medium Dose # 79 mg/kg Uncapped
Brain	0.01	$\pm$ 0.0049	0.006	0/0008
Lung	0.049	$\pm$ 0.0014	0.0075	0.0002
Liver	0.024	$\pm$ 0.0016	0.0035	0.01
Spleen	0.002	$\pm$ 0.001	0.00015	0.0001
Small Intestine	0.029	$\pm$ 0.022	0.0153	0.0002
Kidney	0.013	$\pm$ 0.011	0.0016	0.0006
Testis	0.0031	$\pm$ 0.0016	0.0076	0.001
Fat	0.09	$\pm$ 0.047	0.0188	0.04
Muscle	0.84	$\pm$ 0.62	0.225	0.15
Skin	0.632	$\pm$ 0.27	0.0003	0.11
Spinal Cord	0.004	$\pm$ 0.001	0.0883	0.0007
Blood	0.031	$\pm$ 0.0143	0.0067	0.0034
Skin Area of Application	61.007	$\pm$ 1.67	17.56	1.843
Plastic Cap	1.05	$\pm$ 1.601	2.683	--
Total Recovery*	81.08	$\pm$ 2.91	72.57	98.04

#Data represented as the mean, n = 2.

\*Total recovery represents the sum of the % dose found in the urine, the feces, the tissues and the plastic cap (if any) after 7 days of exposure.