

## ADME NTP Study S0046 Diisobutyl phthalate

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

Sex/Species: male F344 rats.

Vehicle: dermal, absolute ethanol.

CASRN 84-69-2

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

### Studies Performed:

- Single 37.49 mg/kg dermal dose to rats with covered dose site and sacrifice 7 days postdose. (n = 3 )

Diisobutyl phthalate 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 di-isobutyl phthalate in the urine and the feces after dermal application to the rat\*

Time (hr)	% Dose Excreted		
	Urine	Feces	Urine & Feces ( $\Sigma\bar{X}$ )
24	6.3 ± 0.9	1 ± 0.4	7.3
48	9.1 ± 2.23	1.75 ± 4	10.85
72	7.9 ± 1.33	1.56 ± 0.3	9.46
96	6.8 ± 1.11	1.39 ± 0.196	8.19
120	4.8 ± 0.3	1.06 ± 0.14	5.86
144	4.87 ± 0.13	0.94 ± 0.18	5.81
168	2.46 ± 0.25	0.591 ± 0.3	3.05
Total	42.4 ± 5.39	8.3 ± 0.54	50.7

\*Male F-344 rats (200 ± 20gm) received di-isobutyl phthalate in ethanol dermally (37.49 mg/Kg). The skin was covered with a perforated plastic cap. Data points are the mean ± standard deviation. The percentage of dose represents the fraction of the dose found (as  $^{14}\text{C}$ -equivalent) relative to the total  $^{14}\text{C}$ -equivalent applied.

Table 2. Tissue distribution of di-isobutylphthalate after 7 days of dermal exposure

Tissue	% Dose Found ( $\bar{X} \pm$ S.D.)
Brain	0.02 $\pm$ 0.01
Lung	0.02 $\pm$ 0.02
Liver	0.045 $\pm$ 0.017
Spleen	0.002 $\pm$ 0.001
Small Intestine	0.016 $\pm$ 0.008
Kidney	0.023 $\pm$ 0.003
Testis	0.005 $\pm$ 0.001
Fat	0.112 $\pm$ 0.031
Muscle	0.224 $\pm$ 0.089
Skin	0.191 $\pm$ 0.12
Spinal Cord	0.008 $\pm$ 0.005
Blood	0.039 $\pm$ 0.006
Skin of Application	35.574 $\pm$ 13.616
Plastic Cap	5.92 $\pm$ 0.532
Total Recovery*	92.94 $\pm$ 7.38

\*The total recovery represents the sum of the % dose found in the urine, the feces, the tissues and the plastic cap in 7 days.

\*Dose applied was 37.49 mg/kg.