

ADME NTP Study S0031 C.I. Pigment Red 23

Sex/Species: male F344 rats.

Vehicle: oral, corn oil.

CASRN 6471-49-4

No radiolabel was used. Concentration was determined by HPLC using a UV detector.

Studies Performed:

- Single 12.6 mg/kg oral gavage dose to rats with sacrifice 1, 4, or 24 hours postdose. (n = 3 per group)
- Vehicle control oral gavage dose to rats with sacrifice at 24 hours postdose. (n=1; control for low dose)
- Single 60.6 mg/kg oral gavage dose to rats with sacrifice 1, 4, or 24 hours postdose. (n = 3 per group)
- Vehicle control oral gavage dose to rats with sacrifice at 24 hours postdose (n=1; control for high dose).

For the high dose study which was performed first, no detectable pigment (< 0.001% of the dose) was present in the samples of plasma, whole blood, liver, kidney, lung, voluntary muscle, or brain. Pigment was found in the gut contents and tissue (stomach, stomach contents, intestines, and intestinal contents), feces, and urine cage rinse. The remaining carcasses were not assayed.

For the low dose, only feces, stomach, stomach contents, small intestines, large intestines, and intestinal contents were tested.

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Table 1

Disposition of C. I. Pigment Red #23
in Rats Dosed Orally with 12.6 mg/kg

Rat No.	Dose (mg)	Percent of Dose			
		Gut Contents + Rinse	Feces	Tissues Collected	Total
1	0.774	69.44	< 0.01	1.34	70.78
2	0.860	92.01	< 0.01	1.42	93.43
3	0.860	93.03 84.8 ± 13.3 ^a	< 0.01	1.74 1.50 ± 0.21	94.77 86.3 ± 13.5
4	0.946	86.10	< 0.01	0.78	86.88
5	0.946	88.60	< 0.01	0.50	89.10
6	0.860	83.08 85.9 ± 2.8	< 0.01	1.01 0.77 ± 0.25	84.09 86.7 ± 2.5
7	0.860	23.44	33.97	0.06	57.47
8	0.860	8.71	61.27	0.04	70.02
9	0.946	16.03 16.1 ± 7.4	42.09 45.8 ± 14.0	0.24 0.11 ± 0.11	58.36 62.0 ± 7.0

^aThe offset numbers are averages ± std. dev., rounded off to three significant figures, where applicable

Rats 1-3 were sacrificed at 1 hour, rats 4-6 were sacrificed at 4 hours, and rats 7-10 were sacrificed at 24 hours postdose.

Table 2

Disposition of C. I. Pigment Red #23
in Rats Dosed Orally with 60.6 mg/kg

Rat No.	Dose (mg)	Percent of Dose				
		Gut Contents + Rinse	Feces	Urine + Rinse ^a	Tissues Collected	Total
1	10.5	51.79	<0.001	0.012	0.546	52.35
2	10.4	63.57	<0.001	0.018	1.177	64.76
3	8.8	67.28	<0.001	0.083	0.754	68.12
		60.9+8.1 ^b		0.038+0.039	0.826+0.322	61.7+8.3
4	10.4	65.19	<0.001	0.126	0.260	65.58
5	9.3	79.95	<0.001	0.044	0.545	80.54
6	10.7	49.83	<0.001	0.115	0.922	50.87
		65.0+15.1		0.095+0.045	0.576+0.332	65.7+14.8
7	9.0	25.77	70.28	0.068	0.342	96.46
8	10.1	24.76	51.35	0.072	0.283	76.46
9	9.6	26.28	57.89	0.042	0.165	84.38
		25.6+0.77	59.8+9.6	0.061+0.016	0.263+0.090	85.8+10.1

^aAll of the pigment recovered was in the rinse of the cage.

^bThe offset numbers are averages \pm std. dev., rounded off to three significant figures, where applicable.

Rats 1-3, 4-6, and 7-9 were sacrificed at 1, 4, and 24 hours postdose, respectively.