

ADME NTP Study S0041 C.I. Pigment Yellow 74

Sex/Species: male F344 rats.

Vehicle: oral, corn oil.

CASRN 6358-31-2

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

Studies Performed:

- Single 14.1 mg/kg oral gavage dose to rats with sacrifice 0, 1, 4, 24, or 48 hours postdose. (n = 3 per group)
- Vehicle control oral gavage dose to rats with sacrifice at 48 hours postdose (n=1; control for low dose).
- Single 131 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 low dose, only the stomach, stomach contents, small intestines, large intestines, and intestinal contents were tested. An earlier low dose study (not shown) had found < 0.1% of the dose present in the samples of plasma, whole blood, liver, kidney, lung, muscle, or brain.

For the high dose rats, no detectable pigment (< 0.1% of the dose) was present in the samples of plasma, whole blood, liver, kidney, lung, muscle, or brain. Pigment was found in the gut contents and tissue (stomach, stomach contents, intestines, and intestinal contents). The remaining carcasses were not assayed at either dose level.

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Table 1

Disposition of C. I. Pigment Yellow #74
in Rats Dosed Orally with 14.1 mg/kg

Time (hr) After Dosing	Percent of Dose				
	Rat No.	Gut Contents + Rinse	Feces	Tissues Collected	Total
0	14	—	—	—	87.6 ^{a,b}
	15	—	—	—	97.9 ^a
	16	—	—	—	89.1 ^a
					91.5 _± 5.6 ^c
1	1	109	<0.1	2.9	112
	2	112	<0.1	2.1	114
	3	112	<0.1	2.7	115
		111 _± 2		2.6 _± 0.4	114 _± 2
4	4	104	<0.1	1.9	106
	5	9	<0.1	2.5	—
	6	102	<0.1	1.9	104
		103 _± 1		2.1 _± 0.3	105 _± 1
24	7	7.2	83.4	<0.1	90.6
	8	31.7	61.4	0.1	93.2
	9	37.5	66.5	<0.1	104
		25.5 _± 16.1	70.4 _± 11.5		95.9 _± 7.1
48	10	0.6	107	<0.1	108
	11	2.4	62.6	<0.1	65.0
	12	3.3	88.3	<0.1	91.6
		2.1 _± 1.4	86.0 _± 22.3		88.2 _± 21.7

^aStomach and small intestines plus contents only.

^bA small portion of this sample was spilled. Nevertheless, the value is included in further calculations.

^cOffset numbers are averages \pm std. dev.

^dA large portion of this sample was spilled. This value is not included in further calculations.

Tissues collected includes only gastrointestinal tissues.

Table 2

Disposition of C. I. Pigment Yellow #74
in Rats Dosed Orally with 131 mg/kg

Rat No.	Dose (mg)	Percent of Dose					Total	
		Gut Contents + Rinse	Feces	Urine + Rinse ^a	Tissues Collected			
1	18.7	75.8	<0.1	<0.1	1.2	77.0	1 hr	
2	20.0	79.4	0.1	<0.1	1.6	81.1		
3	17.2	69.3	<0.1	0.1	1.1	70.5		
		74.8±5.1 ^b			1.3±0.3	76.2±5.3		
4	19.6	81.4	<0.1	0.2	0.5	82.1	4 hr	
5	19.8	88.6	<0.1	<0.1	0.8	89.5		
6	18.3	82.2	<0.1	0.1	0.6	82.9		
		84.1±3.9			0.6±0.2	84.8±4.1		
7	19.6	19.3	51.0	0.1	0.1	70.5	24 hr	
8	19.4	32.0	47.1	0.1	0.1	79.3		
9	19.1	17.8	64.7	<0.1	0.1	82.6		
		23.0±7.8	54.3±9.2			77.4±6.3		

^aThe pigment recovered was in the rinse of the cages.

^bThe offset numbers are averages ± std. dev.