

ADME NTP Study S0458 Azodicarbonamide

Sex/Species: male F344 rats.
Vehicle: oral, water or corn oil.

CASRN 123-77-3

Radiolabeled with carbon-14 in the carbonyl moiety; Azodicarbonamide, [Carbonyl-¹⁴C]

Studies Performed:

- Single 11.7, 117, or 1170 mg/kg oral gavage dose to rats with sacrifice at 48 hours postdose and water as vehicle. (n = 3)
- Single 1170 mg/kg oral gavage dose to rats with sacrifice 48 days postdose and corn oil as vehicle. (n = 3)

No significant amount (< 0.1% of the net administered dose of ¹⁴C) was expired as ¹⁴CO₂.

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TABLE 1. CUMULATIVE PERCENT OF ADMINISTERED DOSE OF
[Carbonyl-¹⁴C] AZODICARBONAMIDE RECOVERED¹

Nominal Dosage Level (mg/kg)/ Vehicle	Fraction	Interval After Dosing (hr)		Total
		0-24	24-48	
Group 1 11.7/Water	Urine ²	4 ± 0.8	4 ± 0.9	100 ± 14.2
	Feces ²	82 ± 7.0	96 ± 13.3	
Group 2 117/Water	Urine	6 ± 5.0	6 ± 5.0	97 ± 5.0
	Feces	80 ± 7.8	91 ± 3.2	
Group 3 1170/Water	Urine	3 ± 3.1	4 ± 3.4	79 ± 8.3
	Feces	61 ± 15.4	76 ± 11.4	
Group 4 1170/Corn oil	Urine	6 ± 5.0	7 ± 5.5	90 ± 2.4
	Feces	37 ± 7.2	83 ± 5.1	

¹ Values are averages ± standard deviations of 3 animals/interval unless otherwise noted.

² Unknown portion of dose lost during administration to animal #5249; data from this animal not included in calculation of average ± S.D.

PERCENT RADIOCARBON IN THE EXCRETA FROM RATS ADMINISTERED A
SINGLE ORAL DOSE OF [Carbonyl-¹⁴C] AZODICARBONAMIDE

TABLE 2.

Nominal Dosage Level (mg/kg)/ Vehicle	Animal Number	Fraction	Hours After Dosing/ Cumulative Percent of Administered Dose						Total
			4	8	12	24	36	48 ^{1,2}	
Group 1 11.7/ Water	5249 ³	Urine	8.0	9.5	10.1	10.5	10.7	11.4	59.6
		Feces				44.1		48.2	
	5271	Urine	1.8	2.5	2.8	3.0	3.1	3.3	89.5
		Feces				77.7		86.2	
	5276	Urine	1.6	3.1	4.0	4.2	4.3	4.6	109.6
		Feces				87.1		105.0	
Group 2 117/ Water	5258	Urine	3.6	5.0	5.3	6.0	6.2	6.3	93.8
		Feces				71.7		87.5	
	5266	Urine	NS ⁴	NS	0.5	0.9	1.1	1.2	94.9
		Feces				82.2		93.7	
	5272	Urine	4.0	9.8	10.4	10.9	11.1	11.2	102.8
		Feces				87.0		91.6	
Group 3 1170/ Water	5260	Urine	2.6	4.4	5.3	6.5	7.0	7.3	70.1
		Feces				44.6		62.8	
	5268	Urine	NS	NS	0.4	0.6	0.7	0.8	82.6
		Feces				74.7		81.8	
	5278	Urine	1.2	1.6	NS	2.1	2.3	2.4	85.7
		Feces				64.9		83.3	
Group 4 1170/ Corn oil	5259	Urine	0.8	3.2	6.7	11.3	12.9	13.6	91.1
		Feces				34.0		77.5	
	5264	Urine	NS	0.4	NS	3.0	3.5	3.9	91.5
		Feces				44.7		87.6	
	5269	Urine	NS	0.2	1.3	2.7	3.6	4.1	87.1
		Feces				31.1		83.0	

¹Included in the urine fraction is the residual ¹⁴C activity remaining in the urine collection flask; activity = 0.5% or less of the administered dose.

²Included in the feces fraction is the residual ¹⁴C activity entrained by the feed particles on the bottom of the chamber; activity = 0.9% or less of the administered dose.

³Unknown portion of dose lost during test article administration.

⁴NS = No sample.

TABLE 3. SUMMARY OF AZODICARBONAMIDE TISSUE RESIDUE DATA¹

Tissue	Group 1 (11.7 mg/kg)	Group 2 (117 mg/kg)	Group 3 (1170 mg/kg)	Group 4 (1170 mg/kg*)
Liver	0.05 ± 0.012	0.60 ± 0.05	3.37 ± 1.01	5.25 ± 0.20
Kidney	0.04 ± 0.010	0.43 ± 0.09	4.02 ± 0.98	5.04 ± 1.29
Lung	0.03 ± 0.012	0.35 ± 0.11	3.14 ± 0.68	3.78 ± 1.21
Thymus	0.02 ± 0.010	0.17 ± 0.04	1.47 ± 0.77	2.52 ± 0.27
Brain	0.02 ± 0.015	0.33 ± 0.39	1.28 ± 0.13	3.42 ± 3.20
Spleen	0.03 ± 0.012	0.43 ± 0.17	3.25 ± 1.10	4.19 ± 1.23
Testes	0.02 ± 0.010	0.16 ± 0.06	1.28 ± 0.85	1.65 ± 0.44
Heart	0.03 ± 0.006	0.37 ± 0.08	3.12 ± 1.49	4.29 ± 2.70
Urinary bladder	0.07 ± 0.065	0.63 ± 0.60	4.78 ± 4.28	14.5 ± 4.82
Stomach	0.04 ± 0.010	0.28 ± 0.08	3.50 ± 1.89	3.61 ± 0.82
Stomach contents	0.04 ± 0.035	0.08 ± 0.067	1.96 ± 2.27	2.04 ± 0.54
Small intestine	0.05 ± 0.015	0.39 ± 0.19	29.9 ± 28.4	24.7 ± 8.32
Small intestine contents	0.07 ± 0.045	0.36 ± 0.14	15.9 ± 16.8	11.1 ± 3.27
Large intestine	0.71 ± 0.62	2.48 ± 1.48	263 ± 184	384 ± 142
Large intestine contents	1.03 ± 0.76	4.2 ± 3.00	517 ± 458	861 ± 590
Whole blood	0.09 ± 0.023	0.95 ± 0.16	16.2 ± 8.11	23.1 ± 17.9
Plasma	0.03 ± 0.000	0.70 ± 0.73	3.62 ± 0.81	4.37 ± 0.50
Skin	0.04 ± 0.012	1.22 ± 1.63	5.25 ± 1.80	3.88 ± 0.80
Fat	0.02 ± 0.000	0.47 ± 0.58	2.93 ± 1.39	2.03 ± 1.01
Muscle	0.02 ± 0.006	0.24 ± 0.03	2.25 ± 0.83	3.41 ± 1.14

¹Values are mean ± standard deviation of ug equivalents of Azodicarbonamide/g of wet tissue, blood or plasma

*Corn oil vehicle