

Table 3-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Body weight (Administration period)

Sex	Dose mg/kg		Day of administration								Gain 1-28	
			1	4	7	10	14	17	21	24		28
Male	0	No.	12	12	12	12	12	12	12	12	12	12
		Mean	210	236	264	289	322	343	365	380	398	188
		S.D.	7	9	10	12	16	18	23	25	28	26
	100	No.	6	6	6	6	6	6	6	6	6	6
		Mean	210	235	264	291	322	345	367	380	401	191
		S.D.	7	8	9	8	6	8	5	10	10	7
	300	No.	6	6	6	6	6	6	6	6	6	6
		Mean	209	235	261	285	317	339	364	377	398	189
		S.D.	9	14	19	23	31	34	39	39	46	38
	1000	No.	12	12	12	12	12	12	12	12	12	12
		Mean	209	232	260	286	314	337	358	369	387	178
		S.D.	9	10	12	15	17	20	24	28	29	23
Female	0	No.	12	12	12	12	12	12	12	12	12	12
		Mean	158	168	181	190	206	218	229	236	248	90
		S.D.	7	11	13	16	19	19	22	25	27	22
	100	No.	6	6	6	6	6	6	6	6	6	6
		Mean	157	168	177	187	201	209	221	228	241	84
		S.D.	7	8	9	14	20	20	22	23	31	28
	300	No.	6	6	6	6	6	6	6	6	6	6
		Mean	159	172	182	192	204	215	223	227	238	79
		S.D.	6	9	11	10	13	15	17	18	18	16
	1000	No.	12	12	12	12	12	12	12	12	12	12
		Mean	157	168	180	191	203	210	222	229	239	82
		S.D.	4	5	7	8	11	11	12	12	13	12

Unit : g

No significant difference in any treated groups from control group.

Table 3-2 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Body weight (Recovery period)

Sex	Dose mg/kg		Day of recovery					Gain 1-14
			1	3	7	10	14	
Male	0	No.	6	6	6	6	6	6
		Mean	404	416	436	448	463	60
		S.D.	35	39	42	44	50	16
	1000	No.	6	6	6	6	6	6
		Mean	394	405	424	434	452	58
		S.D.	38	37	41	41	46	11
Female	0	No.	6	6	6	6	6	6
		Mean	253	261	269	271	273	21
		S.D.	27	30	33	33	38	11
	1000	No.	6	6	6	6	6	6
		Mean	231	237	249	254	259	28
		S.D.	16	15	18	18	14	7

Unit : g
No significant difference between treated group and control group.

Table 4-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Food consumption (Administration period)

Sex	Dose mg/kg		Day of administration								
			1	4	7	10	14	17	21	24	28
Male	0	No.	12	12	12	12	12	12	12	12	12
		Mean	24	23	26	25	27	26	26	24	25
		S.D.	2	2	2	2	2	2	2	2	2
	100	No.	6	6	6	6	6	6	6	6	6
		Mean	24	23	25	25	26	25	25	24	25
		S.D.	1	1	2	2	1	1	1	1	1
	300	No.	6	6	6	6	6	6	6	6	6
		Mean	23	23	25	24	26	26	26	24	25
		S.D.	2	3	4	4	5	5	4	4	5
	1000	No.	12	12	12	12	12	12	12	12	12
		Mean	24	22	25	24	26	26	25	24	24
		S.D.	2	2	2	2	2	2	2	3	2
Female	0	No.	12	12	12	12	12	12	12	12	12
		Mean	19	17	17	17	18	18	18	17	19
		S.D.	2	2	1	1	2	1	2	2	2
	100	No.	6	6	6	6	6	6	6	6	6
		Mean	18	16	17	16	17	17	18	16	18
		S.D.	3	2	1	3	3	2	2	3	2
	300	No.	6	6	6	6	6	6	6	6	6
		Mean	20	17	18	17	18	17	17	16	18
		S.D.	2	2	2	1	2	2	2	2	2
	1000	No.	12	12	12	12	12	12	12	12	12
		Mean	18	16	17	17	18	17	18	17	18
		S.D.	1	2	1	2	1	2	2	1	2

Unit : g/rat/day

No significant difference in any treated groups from control group.

Table 4-2 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Food consumption (Recovery period)

Sex	Dose mg/kg		Day of recovery			
			3	7	10	14
Male	0	No.	6	6	6	6
		Mean	30	31	31	30
		S.D.	3	3	3	2
	1000	No.	6	6	6	6
		Mean	27	29	29	29
		S.D.	2	2	2	3
Female	0	No.	6	6	6	6
		Mean	22	22	21	20
		S.D.	2	3	2	3
	1000	No.	6	6	6	6
		Mean	21	21	20	20
		S.D.	2	2	2	1

Unit : g/rat/day
 No significant difference between treated group and control group.

Table 5-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Urinalysis (Week 4)

Sex	Dose mg/kg	No.	pH									1) Protein					2) Ketone body					3) Glucose							
			5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	-	+-	+	++	+++	++++	-	+-	+	++	+++	++++	-	+-	+	++	+++	++++
Male	0	12	0	0	0	1	2	1	3	3	2	0	3	8	1	0	0	1	4	7	0	0	0	12	0	0	0	0	0
	100	6	0	0	0	0	0	1	1	3	1	0	3	2	1	0	0	3	1	2	0	0	0	6	0	0	0	0	0
	300	6	0	0	0	4	0	0	1	1	0	0	0	6	0	0	0	0	2	3	1	0	0	6	0	0	0	0	0
	1000	12	0	0	0	0	2	0	4	6	0	0	2	9	1	0	0	2	3	7	0	0	0	12	0	0	0	0	0
Female	0	12	0	0	0	3	3	3	3	0	0	5	3	4	0	0	0	4	4	4	0	0	0	12	0	0	0	0	0
	100	6	0	0	0	2	1	1	1	1	0	0	2	4	0	0	0	0	3	3	0	0	0	6	0	0	0	0	0
	300	6	0	0	2	3	0	0	1	0	0	0	2	4	0	0	0	0	1	5	0	0	0	6	0	0	0	0	0
	1000	12	0	0	1	6	1	3	1	0	0	0	2	8	2	0	0	0	4	8	0	0	0	12	0	0	0	0	0
1)	-	<10 mg/dL	+-	10 - 25 mg/dL	+	26 - 85 mg/dL	++	86 - 250 mg/dL	+++	251 - 600 mg/dL	++++	>600 mg/dL																	
2)	-	<5 mg/dL	+-	5 - 7.5 mg/dL	+	7.6 - 30 mg/dL	++	31 - 70 mg/dL	+++	71 - 125 mg/dL	++++	>125 mg/dL																	
3)	-	<30 mg/dL	+-	30 - 60 mg/dL	+	61 - 125 mg/dL	++	126 - 250 mg/dL	+++	251 - 750 mg/dL	++++	>750 mg/dL																	

Table 5-2 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Urinalysis (Week 4)

Sex	Dose mg/kg	No.	4) Occult blood				5) Bilirubin					6) Urobilinogen					7) Color			
			-	+-	+	++	+++	-	+	++	+++	++++	+-	+	++	+++	++++	LY	Y	DY
Male	0	12	12	0	0	0	0	12	0	0	0	0	10	2	0	0	0	0	12	0
	100	6	6	0	0	0	0	6	0	0	0	0	5	1	0	0	0	0	6	0
	300	6	6	0	0	0	0	6	0	0	0	0	4	2	0	0	0	0	6	0
	1000	12	12	0	0	0	0	12	0	0	0	0	8	4	0	0	0	0	12	0
Female	0	12	12	0	0	0	0	12	0	0	0	0	10	2	0	0	0	0	12	0
	100	6	6	0	0	0	0	6	0	0	0	0	6	0	0	0	0	0	6	0
	300	6	6	0	0	0	0	6	0	0	0	0	5	1	0	0	0	0	6	0
	1000	12	12	0	0	0	0	12	0	0	0	0	5	7	0	0	0	0	12	0

4) - : <0.03 mg/dL +- : 0.03 - 0.05 mg/dL + : 0.06 - 0.15 mg/dL ++ : 0.16 - 0.75 mg/dL +++ : >0.75 mg/dL
5) - : <0.5 mg/dL + : 0.5 - 1.5 mg/dL ++ : 1.6 - 5.0 mg/dL +++ : 5.1 - 10.0 mg/dL ++++ : >10.0 mg/dL
6) +- : <2.0 mg/dL + : 2.0 - 3.5 mg/dL ++ : 3.6 - 7.0 mg/dL +++ : 7.1 - 12.0 mg/dL ++++ : >12.0 mg/dL
7) LY : Light yellow Y : Yellow DY : Dark yellow

Table 5-3 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Urinalysis (Week 4)

Sex	Dose mg/kg	No.	URINE SEDIMENT																																
			RBC				WBC				SEC				SREC				Cast		CRYSTALLIZATION														
			-	+-	+	++	+++	-	+-	+	++	+++	-	+-	+	++	+++	-	+-	+	++	+++	-	+-	+	++	+++	-	+-	+	++	+++			
Male	0	12	12	0	0	0	0	12	0	0	0	0	0	12	0	0	0	12	0	0	0	0	12	0	0	12	0	0	0	0	12	0	0	0	0
	100	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	0	0	6	0	0	6	0	0	0	0	6	0	0	0	0
	300	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	0	0	6	0	0	6	0	0	0	0	5	1	0	0	0
	1000	12	12	0	0	0	0	12	0	0	0	0	0	11	1	0	0	11	1	0	0	0	12	0	0	12	0	0	0	0	11	1	0	0	0
Female	0	12	12	0	0	0	0	12	0	0	0	0	0	12	0	0	0	12	0	0	0	0	12	0	0	12	0	0	0	0	12	0	0	0	0
	100	6	6	0	0	0	0	5	1	0	0	0	0	6	0	0	0	6	0	0	0	0	6	0	0	6	0	0	0	0	5	1	0	0	0
	300	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	0	0	6	0	0	6	0	0	0	0	6	0	0	0	0
	1000	12	12	0	0	0	0	12	0	0	0	0	0	12	0	0	0	12	0	0	0	0	12	0	0	11	1	0	0	0	10	2	0	0	0

SEC : Squamous Epithelial Cell - : Negative
 SREC : Small Round Epithelial Cell +- : Slight
 PS : Phosphate Salts + : Mild
 CO : Calcium Oxalate ++ : Moderate
 +++ : Severe

Table 5-4 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Water intake and urinalysis (Week 4)

Sex	Dose mg/kg	No.		Water intake mL/24h	Urine volume mL/24h	Osmolality mOsm/kg
Male	0	12	Mean	30	6.5	2136
			S.D.	5	3.0	382
	100	6	Mean	37	9.1	1734
			S.D.	5	3.0	354
	300	6	Mean	31	7.6	2068
			S.D.	5	1.4	285
	1000	12	Mean	38*	8.3	2082
			S.D.	9D	3.4	490
Female	0	12	Mean	28	5.4	2183
			S.D.	7	4.3	648
	100	6	Mean	30	6.0	2027
			S.D.	11	2.8	493
	300	6	Mean	29	5.3	2241
			S.D.	9	4.2	686
	1000	12	Mean	32	4.8	2325
			S.D.	7	2.1	445

* : $p < 0.05$ (Significant difference from control group)
 D : Dunnett's test

Table 5-5 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Urinalysis (Week 2 of recovery)

Sex	Dose mg/kg	No.	pH									1) Protein					2) Ketone body					3) Glucose							
			5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	-	+	+	++	+++	++++	-	+	+	++	+++	++++	-	+	+	++	+++	++++
Male	0	6	0	0	0	0	0	0	1	4	1	0	4	2	0	0	0	1	2	3	0	0	0	6	0	0	0	0	0
	1000	6	0	0	0	0	0	0	0	3	3	1	3	2	0	0	0	3	0	3	0	0	0	6	0	0	0	0	0
Female	0	6	0	0	0	0	2	2	0	1	1	3	0	3	0	0	0	3	0	3	0	0	0	6	0	0	0	0	0
	1000	6	0	0	0	2	0	1	0	3	0	2	3	1	0	0	0	1	2	3	0	0	0	6	0	0	0	0	0

1) - : <10 mg/dL +- : 10 - 25 mg/dL + : 26 - 85 mg/dL ++ : 86 - 250 mg/dL +++ : 251 - 600 mg/dL ++++ : >600 mg/dL
2) - : <5 mg/dL +- : 5 - 7.5 mg/dL + : 7.6 - 30 mg/dL ++ : 31 - 70 mg/dL +++ : 71 - 125 mg/dL ++++ : >125 mg/dL
3) - : <30 mg/dL +- : 30 - 60 mg/dL + : 61 - 125 mg/dL ++ : 126 - 250 mg/dL +++ : 251 - 750 mg/dL ++++ : >750 mg/dL

Table 5-6 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Urinalysis (Week 2 of recovery)

Sex	Dose mg/kg	No.	4) Occult blood					5) Bilirubin					6) Urobilinogen					7) Color		
			-	+-	+	++	+++	-	+	++	+++	++++	+-	+	++	+++	++++	LY	Y	DY
Male	0	6	5	1	0	0	0	6	0	0	0	0	6	0	0	0	0	0	6	0
	1000	6	5	1	0	0	0	6	0	0	0	0	6	0	0	0	0	0	6	0
Female	0	6	6	0	0	0	0	5	1	0	0	0	5	1	0	0	0	0	6	0
	1000	6	5	1	0	0	0	6	0	0	0	0	6	0	0	0	0	0	6	0

4) - : <0.03 mg/dL +- : 0.03 - 0.05 mg/dL + : 0.06 - 0.15 mg/dL ++ : 0.16 - 0.75 mg/dL +++ : >0.75 mg/dL
5) - : <0.5 mg/dL + : 0.5 - 1.5 mg/dL ++ : 1.6 - 5.0 mg/dL +++ : 5.1 - 10.0 mg/dL ++++ : >10.0 mg/dL
6) +- : <2.0 mg/dL + : 2.0 - 3.5 mg/dL ++ : 3.6 - 7.0 mg/dL +++ : 7.1 - 12.0 mg/dL ++++ : >12.0 mg/dL
7) LY : Light yellow Y : Yellow DY : Dark yellow

Table 5-7 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Urinalysis (Week 2 of recovery)

Sex	Dose mg/kg	No.	URINE SEDIMENT																															
			RBC			WBC			SEC			SREC			Cast		CRYSTALLIZATION																	
			-	+-	+ ++ +++	-	+-	+ ++ +++	-	+-	+ ++ +++	-	+-	+ ++ +++	-	+-	+	-	+-	+ ++ +++	-	+-	+ ++ +++											
Male	0	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	0	6	0	0	4	2	0	0	0	6	0	0	0	0
	1000	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	6	0	0	5	1	0	0	0	6	0	0	0	0	
Female	0	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	5	1	0	0	0	6	0	0	0	0	0	0	0	
	1000	6	6	0	0	0	0	6	0	0	0	0	0	6	0	0	0	6	0	0	5	1	0	0	0	6	0	0	0	0	0	0	0	

SEC : Squamous Epithelial Cell - : Negative
 SREC : Small Round Epithelial Cell +- : Slight
 PS : Phosphate Salts + : Mild
 CO : Calcium Oxalate ++ : Moderate
 +++ : Severe

Table 5-8

A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Water intake and urinalysis (Week 2 of recovery)

Sex	Dose mg/kg	No.		Water intake mL/24h	Urine volume mL/24h	Osmolality mOsm/kg
Male	0	6	Mean	35	15.2	2000
			S.D.	5	4.4	230
	1000	6	Mean	38	12.9	1716
			S.D.	6	4.6	291
Female	0	6	Mean	32	9.0	2122
			S.D.	8	3.9	542
	1000	6	Mean	29	7.8	2064
			S.D.	4	3.5	557

No significant difference between treated group and control group.