

Table 6-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Hematology (Day 28)

Sex	Dose mg/kg	No.		RBC	HGB	HCT	MCV	MCH	MCHC	Reticul.	PLT	PT	APTT	FIB
				X10 ⁴ /μL	g/dL	%	fL	pg	g/dL	%	X10 ⁴ /μL	s	s	mg/dL
Male	0	6	Mean	790	16.1	42.6	54.0	20.4	37.8	2.1	134.1	13.9	21.9	358
			S.D.	37	0.6	1.0	1.9	0.7	0.5	0.5	31.2	1.4	4.1	30
	100	6	Mean	799	16.4	43.0	53.8	20.5	38.1	2.2	120.8	13.7	20.5	370
			S.D.	40	0.6	1.8	1.1	0.5	0.5	0.4	11.0	0.5	3.0	26
	300	6	Mean	807	16.5	43.8	54.2	20.5	37.7	2.3	115.3	15.6	21.7	349
			S.D.	22	0.4	1.3	1.9	0.6	0.4	0.4	12.1	2.3	2.8	25
	1000	6	Mean	802	16.6	44.1	55.1	20.7	37.6	2.2	111.9	15.7	24.7	359
			S.D.	35	0.5	1.1	1.3	0.4	0.2	0.3	9.3	2.7	2.4	22
Female	0	6	Mean	769	15.8	40.9	53.2	20.6	38.8	2.0	130.5	12.5	16.0	272
			S.D.	43	0.6	1.2	1.5	0.5	0.4	0.5	9.6	0.7	1.8	17
	100	6	Mean	801	16.4	42.7	53.4	20.5	38.3	1.9	137.5	12.4	17.8	268
			S.D.	41	0.8	2.2	1.9	0.6	0.3	0.5	18.2	0.7	2.4	26
	300	6	Mean	805	16.6	43.3	53.9	20.6	38.3	1.5	127.0	12.3	18.0	267
			S.D.	25	0.7	1.6	0.8	0.3	0.3	0.3	11.8	0.6	2.0	29
	1000	6	Mean	812	16.2	42.2	51.9	19.9	38.4	1.7	136.1	12.5	18.1	277
			S.D.	25	0.7	1.5	1.6	0.7	0.3	0.3	12.3	0.4	2.0	20

No significant difference in any treated groups from control group.

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

Sex	Dose mg/kg	No.		WBC	Differential leukocyte counts (%)					
				$\times 10^2/\mu\text{L}$	LYM	NE	EOSINO	BASO	MONO	LUC
Male	0	6	Mean	95.2	76.6	19.2	1.3	0.4	1.9	0.7
			S.D.	19.3	5.8	4.9	0.5	0.1	0.5	0.3
	100	6	Mean	76.7	76.8	19.2	0.9	0.4	2.1	0.7
			S.D.	15.8	8.4	7.6	0.4	0.1	1.0	0.2
	300	6	Mean	114.1	77.8	18.3	1.0	0.5	1.9	0.6
			S.D.	30.3	4.1	3.6	0.3	0.1	0.5	0.1
	1000	6	Mean	82.6	75.2	20.3	1.0	0.5	2.1	0.9
			S.D.	25.8	10.1	10.0	0.3	0.2	0.5	0.1
Female	0	6	Mean	69.6	76.2	19.1	1.1	0.3	2.5	0.7
			S.D.	20.5	8.1	6.7	0.5	0.1	1.6	0.4
	100	6	Mean	71.5	77.2	18.8	1.3	0.4	1.6	0.8
			S.D.	11.9	9.5	9.0	0.5	0.2	0.4	0.2
	300	6	Mean	77.2	81.0	14.7	1.3	0.5	1.8	0.8
			S.D.	26.4	6.2	6.0	0.3	0.1	0.7	0.2
	1000	6	Mean	85.7	77.5	18.6	0.9	0.4	1.6	1.0
			S.D.	22.0	5.4	5.6	0.4	0.1	0.5	0.2

LUC : Large unstained cells

No significant difference in any treated groups from control group.

Table 6-3 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Hematology (Week 2 of recovery)

Sex	Dose mg/kg	No.		RBC	HGB	HCT	MCV	MCH	MCHC	Reticul.	PLT	PT	APTT	FIB
				X10 ⁴ /μL	g/dL	%	fL	pg	g/dL	%	X10 ⁴ /μL	s	s	mg/dL
Male	0	6	Mean	836	16.5	42.6	51.0	19.8	38.8	2.0	117.3	13.9	20.2	373
			S.D.	40	0.6	1.4	2.2	0.8	0.3	0.4	8.0	1.2	2.0	29
	1000	6	Mean	862	17.1	43.7	50.8	19.8	39.0	1.8	118.1	14.4	21.8	381
			S.D.	15	0.4	1.2	0.7	0.2	0.3	0.3	9.9	1.4	3.6	31
Female	0	6	Mean	807	16.1	41.2	51.1	20.0	39.2	1.8	130.1	11.8	15.6	276
			S.D.	36	0.6	1.7	2.7	0.8	0.6	0.3	7.6	0.5	2.4	20
	1000	6	Mean	850*	16.6	42.3	49.8	19.6	39.2	1.4	137.0	12.2	17.3	281
			S.D.	23T	0.3	0.6	1.3	0.5	0.3	0.2	9.1	0.7	3.1	22

* : p<0.05 (Significant difference from control group)
T : Student's t-test

Table 6-4 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Hematology (Week 2 of recovery)

Sex	Dose mg/kg	No.		WBC	Differential leukocyte counts (%)					
				$\times 10^3/\mu\text{L}$	LYM	NE	EOSINO	BASO	MONO	LUC
Male	0	6	Mean	105.8	73.5	21.8	1.5	0.4	2.3	0.6
			S.D.	31.4	5.9	6.0	0.2	0.1	0.6	0.2
	1000	6	Mean	98.1	78.7	16.6	1.1	0.5	2.4	0.7
			S.D.	36.1	4.8	4.5	0.4	0.2	0.5	0.3
Female	0	6	Mean	68.3	79.9	15.8	1.0	0.3	2.1	0.9
			S.D.	12.4	6.6	6.0	0.3	0.1	1.2	0.2
	1000	6	Mean	81.2	75.7	19.3	1.4	0.4	2.1	1.2
			S.D.	22.4	5.1	6.0	0.5	0.1	0.7	0.5

LUC : Large unstained cells
No significant difference between treated group and control group.

Table 7-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Blood chemistry (Day 28)

Sex	Dose mg/kg	No.		AST	ALT	LDH	γ -GTP	ALP	T-CHO	TG	PL	T-BIL	GLU
				IU/L	IU/L	IU/L	IU/L	IU/L	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL
Male	0	6	Mean	59	27	53	1	774	51	31	91	0.1	135
			S.D.	6	2	9	0	60	11	9	13	0.1	17
	100	6	Mean	56	27	51	1	631	59	38	103	0.1	141
			S.D.	3	5	8	0	114	9	19	10	0.1	4
	300	6	Mean	59	27	51	1	628	49	36	92	0.0	139
			S.D.	5	2	7	0	156	9	18	13	0.1	10
	1000	6	Mean	58	27	65	1	604*	59	31	100	0.1	140
			S.D.	5	2	19	1	97D	10	10	9	0.1	15
Female	0	6	Mean	65	27	68	2	452	51	9	93	0.1	112
			S.D.	9	10	17	1	93	10	2	14	0.0	12
	100	6	Mean	58	22	60	1	428	51	8	98	0.1	122
			S.D.	5	2	13	0	107	17	4	28	0.1	13
	300	6	Mean	58	24	53	1	366	56	10	101	0.1	119
			S.D.	6	3	10	0	55	21	4	27	0.1	16
	1000	6	Mean	55	25	59	1	405	63	12	112	0.1	124
			S.D.	6	2	9	1	74	13	6	24	0.1	14

* : p<0.05 (Significant difference from control group)

D : Dunnett's test

Table 7-2

A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Blood chemistry (Day 28)

Sex	Dose mg/kg	No.		BUN	CRNN	Na	K	Cl	Ca	P	TP	ALB	A/G
				mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	g/dL	g/dL	
Male	0	6	Mean	11	0.23	142	4.9	107	9.8	8.0	5.9	2.9	0.93
			S.D.	2	0.03	1	0.3	1	0.3	0.8	0.2	0.1	0.02
	100	6	Mean	11	0.21	142	5.2	108	10.0	7.9	6.0	2.8	0.91
			S.D.	1	0.01	2	0.3	1	0.3	0.6	0.3	0.1	0.04
	300	6	Mean	12	0.23	142	5.0	107	9.9	8.0	5.7	2.8	0.93
			S.D.	1	0.03	1	0.3	2	0.3	0.4	0.2	0.1	0.05
	1000	6	Mean	11	0.22	142	5.0	107	10.0	7.9	6.1	2.9	0.93
			S.D.	1	0.01	1	0.3	1	0.2	0.5	0.2	0.1	0.07
Female	0	6	Mean	15	0.27	142	4.5	109	9.9	7.4	6.1	3.0	0.98
			S.D.	2	0.03	1	0.1	1	0.3	0.6	0.2	0.1	0.04
	100	6	Mean	14	0.25	142	4.7	110	9.9	7.3	5.9	3.0	1.01
			S.D.	2	0.03	1	0.4	1	0.3	0.4	0.2	0.1	0.03
	300	6	Mean	16	0.29	141	4.5	109	10.0	7.9	6.0	3.0	1.00
			S.D.	1	0.02	1	0.2	2	0.3	0.6	0.2	0.1	0.06
	1000	6	Mean	15	0.26	142	4.5	108	10.1	7.9	6.3	3.1	0.97
			S.D.	2	0.03	2	0.3	1	0.2	0.3	0.3	0.1	0.07

No significant difference in any treated groups from control group.

Table 7-3 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Blood chemistry (Week 2 of recovery)

Sex	Dose mg/kg	No.		AST	ALT	LDH	γ -GTP	ALP	T-CHO	TG	PL	T-BIL	GLU
				IU/L	IU/L	IU/L	IU/L	IU/L	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL
Male	0	6	Mean	60	28	59	1	576	56	50	99	0.1	149
			S.D.	5	5	16	0	156	8	16	9	0.0	20
	1000	6	Mean	60	32	59	1	486	62	51	107	0.1	151
			S.D.	7	6	10	1	42	12	11	16	0.0	21
Female	0	6	Mean	60	24	45	1	274	68	17	122	0.1	117
			S.D.	8	3	9	0	47	13	9	22	0.0	20
	1000	6	Mean	62	24	49	1	383	66	17	119	0.1	115
			S.D.	7	1	15	1	128	11	4	15	0.0	11

No significant difference between treated group and control group.

Table 7-4 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Blood chemistry (Week 2 of recovery)

Sex	Dose mg/kg	No.		BUN	CRNN	Na	K	Cl	Ca	P	TP	ALB	A/G
				mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	g/dL	g/dL	
Male	0	6	Mean	15	0.24	144	4.6	107	9.9	7.3	6.1	2.8	0.84
			S.D.	1	0.03	2	0.3	1	0.3	0.5	0.1	0.1	0.05
	1000	6	Mean	14	0.24	143	4.5	107	9.7	7.4	6.0	2.8	0.88
			S.D.	2	0.02	3	0.3	3	0.3	0.5	0.3	0.1	0.03
Female	0	6	Mean	16	0.30	143	4.5	109	10.1	7.3	6.4	3.1	0.94
			S.D.	1	0.04	1	0.2	1	0.2	0.5	0.2	0.1	0.08
	1000	6	Mean	15	0.28	144	4.6	110	10.0	7.2	6.3	3.0	0.92
			S.D.	2	0.02	1	0.3	1	0.3	0.3	0.4	0.2	0.04

No significant difference between treated group and control group.

Table 8-1 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
Absolute and relative organ weight (Day 28)

Male

Dose mg/kg		Body weight	Brain	Thymus	Heart	Liver	Spleen	Kidney (R+L)	Adrenal (R+L)	
		g	g(g/100g BW)	mg(mg/100g BW)	g(g/100g BW)	g(g/100g BW)	g(g/100g BW)	g(g/100g BW)	mg(mg/100g BW)	
Absolute	0	No.	6	6	6	6	6	6	6	
		Mean	374	2.05	431	1.21	11.68	0.62	2.88	59
		S.D.	24	0.05	130	0.06	1.34	0.05	0.25	8
	100	No.	6	6	6	6	6	6	6	6
		Mean	376	2.01	478	1.25	12.40	0.66	2.86	55
		S.D.	11	0.09	76	0.07	1.09	0.09	0.14	6
	300	No.	6	6	6	6	6	6	6	6
		Mean	370	2.00	559	1.25	11.71	0.71	2.83	61
		S.D.	40	0.09	92	0.18	2.70	0.13	0.45	13
	1000	No.	6	6	6	6	6	6	6	6
		Mean	360	1.99	447	1.18	11.77	0.60	2.83	62
		S.D.	26	0.07	71	0.08	0.89	0.12	0.26	11
Relative	0	No.	6	6	6	6	6	6	6	
		Mean		0.55	115	0.33	3.12	0.16	0.77	16
		S.D.		0.03	35	0.04	0.19	0.01	0.05	2
	100	No.	6	6	6	6	6	6	6	6
		Mean		0.54	127	0.33	3.30	0.18	0.76	15
		S.D.		0.03	19	0.02	0.30	0.02	0.04	2
	300	No.	6	6	6	6	6	6	6	6
		Mean		0.54	152	0.34	3.13	0.19*	0.76	16
		S.D.		0.04	26	0.03	0.38	0.02D	0.06	3
	1000	No.	6	6	6	6	6	6	6	6
		Mean		0.55	125	0.33	3.27	0.17	0.79	17
		S.D.		0.03	21	0.03	0.13	0.03	0.04	2

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

Table 8-2 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Absolute and relative organ weight (Day 28)
 Male

Dose			Testis (R+L) g(g/100g BW)	Epididymis (R+L) mg(mg/100g BW)
mg/kg				
Absolute	0	No.	6	6
		Mean	3.21	862
		S.D.	0.18	49
	100	No.	6	6
		Mean	3.18	863
		S.D.	0.27	94
	300	No.	6	6
		Mean	3.05	844
		S.D.	0.52	66
	1000	No.	6	6
		Mean	3.01	836
		S.D.	0.32	96
Relative	0	No.	6	6
		Mean	0.86	232
		S.D.	0.05	26
	100	No.	6	6
		Mean	0.85	230
		S.D.	0.07	23
	300	No.	6	6
		Mean	0.82	229
		S.D.	0.08	16
	1000	No.	6	6
		Mean	0.84	233
		S.D.	0.09	30

No significant difference in any treated groups from control group.

Table 8-3 A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks
 Absolute and relative organ weight (Day 28)
 Female

Dose mg/kg		Body weight	Brain	Thymus	Heart	Liver	Spleen	Kidney (R+L)	Adrenal (R+L)	
		g	g(g/100g BW)	mg(mg/100g BW)	g(g/100g BW)	g(g/100g BW)	g(g/100g BW)	g(g/100g BW)	mg(mg/100g BW)	
Absolute	0	No.	6	6	6	6	6	6	6	
		Mean	231	1.92	484	0.83	6.90	0.50	1.78	69
		S.D.	24	0.06	190	0.10	1.01	0.09	0.16	11
	100	No.	6	6	6	6	6	6	6	6
		Mean	224	1.91	444	0.82	6.68	0.53	1.74	67
		S.D.	25	0.09	181	0.10	1.10	0.14	0.19	9
	300	No.	6	6	6	6	6	6	6	6
		Mean	219	1.88	437	0.77	6.63	0.48	1.58	68
		S.D.	15	0.06	103	0.09	0.95	0.11	0.14	7
	1000	No.	6	6	6	6	6	6	6	6
		Mean	228	1.89	470	0.84	7.62	0.55	1.76	72
		S.D.	8	0.07	145	0.06	0.28	0.09	0.12	5
Relative	0	No.	6	6	6	6	6	6	6	
		Mean	0.84	206	0.36	2.97	0.22	0.77	30	
		S.D.	0.08	62	0.01	0.16	0.03	0.03	5	
	100	No.	6	6	6	6	6	6	6	
		Mean	0.86	194	0.37	2.98	0.24	0.78	30	
		S.D.	0.07	53	0.02	0.25	0.04	0.05	4	
	300	No.	6	6	6	6	6	6	6	
		Mean	0.86	200	0.35	3.02	0.22	0.72	31	
		S.D.	0.04	46	0.02	0.24	0.04	0.04	1	
	1000	No.	6	6	6	6	6	6	6	
		Mean	0.83	206	0.37	3.35*	0.24	0.77	32	
		S.D.	0.02	59	0.02	0.13D	0.04	0.05	3	

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

Table 8-4

A 28-day oral toxicity study of paracetaldehyde in rats with a recovery period of 2 weeks

Absolute and relative organ weight (Day 28)

Female

Dose			Ovary (R+L) mg(mg/100g BW)	Uterus mg(mg/100g BW)
mg/kg				
Absolute	0	No.	6	6
		Mean	91.7	432
		S.D.	14.6	112
	100	No.	6	6
		Mean	89.3	487
		S.D.	15.6	195
	300	No.	6	6
		Mean	74.9	419
		S.D.	5.9	156
	1000	No.	6	6
		Mean	92.7	438
		S.D.	14.3	95
Relative	0	No.	6	6
		Mean	39.8	186
		S.D.	6.4	40
	100	No.	6	6
		Mean	39.9	213
		S.D.	4.3	62
	300	No.	6	6
		Mean	34.4	189
		S.D.	3.2	60
	1000	No.	6	6
		Mean	40.7	192
		S.D.	6.1	41

No significant difference in any treated groups from control group.