

ジクロロメタンのラットを用いた
吸入による 13 週間毒性試験報告書

試験番号 : 0257

APPENDIX

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(13-WEEK STUDY)
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(13-WEEK STUDY)
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(13-WEEK STUDY)
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APPENDIX A 1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE (13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day									
	0-0		1-7		2-7		3-7		4-7		5-7	
Control	120±	5	144±	8	171±	11	199±	13	224±	15	238±	17
500 ppm	120±	4	148±	9	176±	15	201±	17	221±	17	241±	18
1000 ppm	120±	4	144±	5	167±	8	188±	14	207±	17	226±	18
2000 ppm	119±	5	142±	8	165±	11	188±	16	206±	19	224±	21
4000 ppm	119±	4	140±	4	163±	7	185±	12	203±	15*	221±	17
8000 ppm	119±	4	119±	6**	129±	7**	143±	7**	156±	7**	170±	7**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

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STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day		7-7		8-7		9-7		10-7		11-7		12-7		13-6	
Control	265±	18	279±	18	289±	19	300±	17	309±	19	319±	19	325±	20		
500 ppm	271±	17	286±	18	296±	18	306±	19	314±	19	320±	19	328±	19		
1000 ppm	254±	21	266±	22	278±	22	285±	24	295±	24	304±	25	309±	23		
2000 ppm	251±	22	263±	23	275±	24	283±	24	290±	22	298±	23	304±	23		
4000 ppm	248±	18	260±	19	270±	19	279±	18	286±	18*	294±	17*	303±	17*		
8000 ppm	189±	9**	198±	9**	210±	10**	215±	10**	220±	10**	226±	11**	231±	12**		

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

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APPENDIX A 2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration		week-day											
	0-0		1-7		2-7		3-7		4-7		5-7		6-7	
Control	100±	3	114±	4	128±	6	139±	6	148±	7	153±	9	158±	10
500 ppm	100±	4	115±	4	129±	4	138±	6	145±	5	154±	5	160±	6
1000 ppm	99±	3	114±	4	128±	7	136±	7	146±	7	152±	7	158±	7
2000 ppm	99±	3	114±	4	127±	6	135±	8	143±	9	151±	10	156±	11
4000 ppm	100±	4	109±	4**	121±	5*	132±	7*	141±	8	147±	9	151±	10
8000 ppm	100±	3	99±	3**	106±	4**	117±	3**	126±	4**	132±	5**	138±	5**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnnett

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STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration		week-day											
	7-7		8-7		9-7		10-7		11-7		12-7		13-6	
Control	164±	10	170±	11	173±	11	177±	12	182±	11	185±	11	188±	13
500 ppm	165±	7	170±	8	176±	9	180±	9	183±	9	185±	8	190±	8
1000 ppm	162±	9	168±	8	171±	7	175±	9	179±	8	180±	11	184±	9
2000 ppm	161±	9	163±	12	168±	11	171±	13	176±	11	178±	14	181±	14
4000 ppm	157±	9	159±	10*	163±	10	166±	10	170±	9*	171±	9*	173±	11*
8000 ppm	143±	5**	148±	5**	153±	5**	156±	5**	160±	6**	163±	6**	166±	7**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

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APPENDIX B 1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	14.0± 0.9	14.8± 1.0	16.5± 1.4	17.6± 1.6	16.8± 1.6	16.8± 1.8	17.2± 1.6
500 ppm	14.4± 0.9	15.5± 1.7	16.8± 1.9	17.7± 1.7	17.8± 1.6	17.3± 1.2	17.6± 1.2
1000 ppm	13.6± 0.6	15.0± 1.0	15.4± 1.7	16.0± 2.0	15.5± 1.8	15.5± 1.6	16.0± 1.7
2000 ppm	14.0± 0.7	14.5± 1.0	16.0± 1.5	16.1± 2.1	15.9± 2.2	16.1± 1.9	16.5± 1.9
4000 ppm	13.0± 0.4*	14.2± 0.9	15.7± 1.1	16.6± 1.8	16.2± 1.7	15.9± 1.4	16.4± 1.5
8000 ppm	8.8± 0.7**	10.2± 0.7**	12.0± 1.0**	13.4± 1.0**	14.3± 1.3**	14.7± 1.2*	15.2± 1.7*

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-6(6)
Control	17.3± 1.4	16.9± 1.1	17.1± 1.1	17.7± 1.2	17.5± 1.1	17.6± 1.0
500 ppm	17.9± 1.5	17.3± 1.1	17.4± 1.3	17.6± 0.8	17.2± 0.8	17.8± 1.0
1000 ppm	16.0± 1.5	16.6± 1.5	16.0± 1.7	16.8± 1.9	16.5± 1.2	16.9± 1.4
2000 ppm	16.0± 1.5	16.3± 1.6	16.2± 1.5	16.1± 1.2*	15.8± 1.1**	16.4± 1.4
4000 ppm	16.4± 1.4	16.3± 1.3	16.0± 1.3	16.6± 1.1	16.4± 1.1	17.3± 1.0
8000 ppm	15.8± 1.0	16.2± 1.0	14.7± 1.0**	15.6± 1.3**	16.5± 1.6	16.9± 1.9
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						
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APPENDIX B 2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE (13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	11.6± 0.6	12.3± 0.8	12.7± 0.7	13.2± 1.1	12.4± 0.9	12.3± 1.1	12.7± 1.1
500 ppm	12.0± 0.6	13.0± 0.9	12.6± 0.8	13.0± 0.8	13.0± 0.9	12.1± 0.8	11.7± 0.9
1000 ppm	11.8± 0.8	12.8± 0.9	12.2± 1.0	12.9± 0.8	12.5± 0.7	12.0± 0.9	12.1± 1.0
2000 ppm	11.8± 0.8	12.7± 0.8	12.6± 1.2	13.0± 1.0	12.6± 1.2	12.2± 1.4	11.7± 1.0
4000 ppm	10.3± 0.6**	11.4± 0.9*	12.2± 0.9	12.5± 1.0	12.1± 1.1	11.5± 0.9	11.6± 0.9
8000 ppm	7.8± 0.5**	9.0± 0.4**	10.4± 0.5**	11.8± 0.5**	11.8± 0.8	12.0± 0.7	12.4± 0.8
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							
(HAN260)							

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STUDY NO. : 0257
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-6(6)
Control	12.4± 1.1	12.1± 1.3	12.3± 1.3	12.2± 1.0	12.1± 0.9	12.3± 0.9
500 ppm	12.0± 0.8	12.6± 1.4	12.1± 0.8	11.5± 0.6	11.7± 0.7	12.6± 0.8
1000 ppm	12.0± 1.1	12.1± 0.8	11.8± 1.0	12.1± 1.1	11.8± 0.6	12.1± 0.9
2000 ppm	11.3± 0.9	11.5± 1.3	12.0± 1.1	11.7± 1.2	11.7± 1.2	12.0± 0.9
4000 ppm	11.3± 0.9	11.0± 0.8	11.4± 0.7	11.2± 0.9	11.5± 0.8	11.5± 1.1
8000 ppm	12.7± 0.9	12.6± 0.7	12.1± 0.8	12.9± 0.9	13.4± 1.5*	14.0± 1.9*

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

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APPENDIX C 1

HEMATOLOGY : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 013-7
 SEX : MALE

HEMATOLOGY (SUMMARY)
 SURVIVAL ANIMALS (13)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	10	9.17±	0.22	15.9±	0.3	45.1±	1.3	49.2±	0.6	17.4±	0.4	35.3±	1.2	740±	34
500 ppm	10	9.19±	0.62	16.5±	0.5**	45.9±	3.1	49.9±	0.4	18.1±	1.2	36.2±	2.4	763±	64
1000 ppm	10	9.19±	0.30	16.5±	0.3*	46.7±	1.6	50.9±	0.8**	17.9±	0.4	35.2±	0.8	739±	24
2000 ppm	9	9.29±	0.21	16.9±	0.4**	47.6±	1.5*	51.2±	0.8**	18.1±	0.3*	35.4±	0.8	754±	29
4000 ppm	10	9.27±	0.26	16.8±	0.5**	47.6±	2.0*	51.3±	0.8**	18.1±	0.3*	35.3±	0.9	791±	39*
8000 ppm	10	8.85±	0.19	16.6±	0.3**	46.7±	1.4	52.8±	0.8**	18.8±	0.4**	35.6±	0.8	804±	45**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	PROTHROMBIN TIME s e c		APTT s e c	
Control	10	14.0±	2.0	22.1±	1.8
500 ppm	10	14.2±	1.5	22.6±	1.6
1000 ppm	10	13.9±	1.3	21.7±	0.9
2000 ppm	9	13.8±	1.1	21.3±	0.8
4000 ppm	10	13.2±	0.7	21.0±	1.0
8000 ppm	10	12.9±	0.4	18.6±	0.9**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 013-7
 SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	10	3.04±	1.01	0±	0	34±	6	1±	1	0±	0	3±	1	62±	6	0±	0
500 ppm	10	3.73±	1.78	0±	0	30±	5	1±	1	0±	0	4±	2	64±	6	0±	0
1000 ppm	10	3.45±	1.67	0±	0	30±	6	2±	1	0±	0	3±	1	66±	7	0±	0
2000 ppm	9	3.53±	1.67	0±	0	28±	6	2±	1	0±	0	4±	2	66±	8	0±	0
4000 ppm	10	3.74±	1.54	0±	0	30±	8	2±	1	0±	0	4±	2	64±	8	0±	0
8000 ppm	10	2.23±	0.56	0±	0	39±	5	2±	1	0±	0	5±	2	54±	5*	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

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APPENDIX C 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 013-7
 SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ⁹ /μl	
Control	10	8.38±	0.30	15.8±	0.3	44.2±	1.8	52.7±	0.7	18.9±	0.4	35.8±	1.0	679±	60
500 ppm	9	8.51±	0.26	16.4±	0.4*	45.5±	2.0	53.5±	0.9	19.2±	0.2	36.0±	0.9	703±	69
1000 ppm	10	8.51±	0.28	16.4±	0.6*	46.0±	1.8	54.0±	0.8*	19.3±	0.4	35.7±	1.0	711±	68
2000 ppm	10	8.36±	0.32	16.4±	0.5*	45.1±	2.1	54.0±	1.1*	19.6±	0.8	36.3±	1.8	698±	84
4000 ppm	10	8.38±	0.36	16.3±	0.3	45.1±	2.5	53.8±	1.1	19.4±	0.9	36.1±	2.0	764±	61*
8000 ppm	10	8.34±	0.15	16.1±	0.3	45.0±	1.1	53.9±	1.0*	19.4±	0.3	35.9±	1.1	796±	37**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

Group Name	NO. of Animals	PROTHROMBIN TIME		APTT	
		s e c		s e c	
Control	10	11.8±	0.4	16.8±	0.9
500 ppm	9	12.1±	0.5	17.4±	0.8
1000 ppm	10	12.1±	0.3	17.2±	0.9
2000 ppm	10	12.4±	0.5**	17.7±	1.3
4000 ppm	10	12.6±	0.3**	17.7±	0.8
8000 ppm	10	13.1±	0.6**	18.5±	1.5**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
Control	10	1.86±	0.57	0±	0	27±	5	2±	1	0±	0	5±	2	66±	6	0±	0
500 ppm	9	1.80±	0.58	1±	1	29±	6	2±	2	0±	0	4±	2	63±	7	0±	0
1000 ppm	10	1.36±	0.41	0±	0	29±	5	2±	1	0±	0	5±	2	64±	5	0±	0
2000 ppm	10	1.50±	0.72	0±	0	33±	5	1±	1	0±	0	4±	2	61±	5	0±	0
4000 ppm	10	1.68±	0.41	0±	0	30±	5	2±	1	0±	0	4±	1	64±	5	0±	0
8000 ppm	10	1.85±	0.68	0±	0	38±	9**	2±	1	0±	0	5±	2	56±	10**	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

APPENDIX D 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 014-1
 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g / dl		ALBUMIN g / dl		A/G RATIO		T-BILIRUBIN mg / dl		GLUCOSE mg / dl		T-CHOLESTEROL mg / dl		TRIGLYCERIDE mg / dl	
Control	10	6.6±	0.2	3.7±	0.1	1.3±	0.1	0.20±	0.01	184±	19	52±	5	91±	17
500 ppm	10	6.6±	0.2	3.8±	0.1	1.3±	0.0	0.21±	0.01	178±	12	45±	4*	76±	15
1000 ppm	10	6.5±	0.2	3.7±	0.1	1.3±	0.0	0.20±	0.03	180±	23	47±	5	86±	17
2000 ppm	9	6.5±	0.2	3.8±	0.1	1.4±	0.1	0.22±	0.02	178±	21	43±	4**	78±	11
4000 ppm	10	6.6±	0.2	3.8±	0.1	1.3±	0.1	0.22±	0.03	170±	18	44±	4**	72±	16*
8000 ppm	10	6.4±	0.2*	3.6±	0.1	1.3±	0.1	0.23±	0.03	154±	13**	43±	7**	40±	7**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

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BAIS 3

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 014-1
 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	10	107±	7	73±	7	26±	3	149±	17	330±	24	1±	1	89±	5
500 ppm	10	94±	7*	80±	13	28±	5	168±	33	336±	29	1±	1	91±	9
1000 ppm	10	98±	8	77±	15	26±	4	147±	24	339±	39	1±	1	88±	4
2000 ppm	9	93±	9**	78±	16	26±	4	160±	38	342±	18	0±	1	87±	7
4000 ppm	10	90±	10**	74±	12	25±	3	166±	41	328±	23	1±	1	94±	11
8000 ppm	10	86±	12**	64±	3*	23±	2	158±	47	326±	16	1±	1	86±	14

Significant defference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 014-1
SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	17.6±	1.4	0.5±	0.1	142±	2	3.7±	0.4	106±	1	10.1±	0.2	5.4±	1.0
500 ppm	10	17.8±	1.5	0.5±	0.0	143±	1	3.6±	0.4	105±	2	10.2±	0.1	5.7±	1.0
1000 ppm	10	18.3±	1.8	0.5±	0.1	143±	1	3.7±	0.4	106±	1	10.0±	0.1	5.7±	1.1
2000 ppm	9	18.1±	1.4	0.5±	0.1	143±	1	3.7±	0.4	106±	1	10.0±	0.1	6.1±	0.7
4000 ppm	10	17.5±	1.4	0.5±	0.1	142±	1	3.7±	0.4	107±	1	10.0±	0.2	6.0±	1.0
8000 ppm	10	16.0±	1.8	0.4±	0.1	142±	2	3.8±	0.3	107±	1	10.0±	0.2	6.5±	0.7

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

APPENDIX D 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 014-1
SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g / dl		ALBUMIN g / dl		A/G RATIO		T-BILIRUBIN mg / dl		GLUCOSE mg / dl		T-CHOLESTEROL mg / dl		TRIGLYCERIDE mg / dl	
Control	10	6.5±	0.3	3.7±	0.1	1.3±	0.1	0.29±	0.07	140±	13	73±	6	40±	6
500 ppm	9	6.5±	0.1	3.7±	0.1	1.3±	0.1	0.26±	0.03	121±	11**	63±	8	39±	6
1000 ppm	10	6.4±	0.2	3.7±	0.1	1.3±	0.0	0.30±	0.05	123±	10*	62±	10*	35±	3
2000 ppm	10	6.4±	0.2	3.7±	0.2	1.4±	0.0*	0.34±	0.10	122±	11**	54±	9**	35±	4
4000 ppm	10	6.2±	0.2**	3.5±	0.2*	1.3±	0.1	0.35±	0.08	119±	15**	53±	9**	32±	5**
8000 ppm	10	6.0±	0.2**	3.3±	0.1**	1.2±	0.1**	0.35±	0.06	123±	12**	44±	9**	35±	3

Significant defference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 014-1
SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U / l		GPT I U / l		LDH I U / l		ALP I U / l		G-GTP I U / l		CPK I U / l	
Control	10	142±	13	72±	6	26±	6	214±	44	212±	30	2±	1	110±	15
500 ppm	9	123±	16*	68±	8	24±	4	179±	29	240±	31	2±	1	101±	15
1000 ppm	10	120±	16**	72±	8	24±	5	226±	43	230±	30	2±	0	111±	16
2000 ppm	10	108±	17**	68±	10	22±	5	205±	60	221±	24	2±	1	101±	17
4000 ppm	10	105±	15**	66±	4	23±	3	198±	54	234±	24	2±	1	98±	17
8000 ppm	10	92±	14**	67±	6	22±	3	201±	44	253±	24**	2±	1	93±	15

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0257
 ANIMAL : RAT F344
 SAMPLING DATE : 014-1
 SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	17.4±	2.1	0.5±	0.1	142±	1	3.7±	0.4	108±	2	10.0±	0.2	5.2±	1.4
500 ppm	9	18.4±	1.9	0.5±	0.0	143±	1	3.6±	0.2	109±	1	10.0±	0.2	5.7±	1.6
1000 ppm	10	18.3±	1.1	0.5±	0.1	142±	2	3.5±	0.2	108±	1	9.9±	0.2	5.6±	1.1
2000 ppm	10	17.7±	2.0	0.5±	0.1	143±	1	3.7±	0.3	109±	2	9.9±	0.2	6.0±	0.8
4000 ppm	10	17.7±	1.3	0.5±	0.1	142±	1	3.8±	0.3	109±	1	9.8±	0.2	5.9±	1.3
8000 ppm	10	15.4±	1.9	0.5±	0.1	142±	1	3.7±	0.2	109±	2	9.6±	0.4**	6.0±	1.2

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX E 1

URINALYSIS : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH_____							CHI	Protein_____					CHI	Glucose_____					CHI	Ketone body					CHI	Bilirubin				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+	3+
Control	10	0	0	1	0	4	3	2		0	3	4	3	0	0		10	0	0	0	0	0		7	1	2	0	0	0		10	0	0	0	
500 ppm	10	0	0	1	1	4	3	1		0	1	6	3	0	0		10	0	0	0	0	0		3	6	1	0	0	0		10	0	0	0	
1000 ppm	10	0	0	1	3	4	2	0		0	2	5	3	0	0		10	0	0	0	0	0		6	3	1	0	0	0		10	0	0	0	
2000 ppm	10	0	0	0	3	3	4	0		0	3	5	2	0	0		10	0	0	0	0	0		5	4	1	0	0	0		10	0	0	0	
4000 ppm	10	0	0	1	2	5	1	1		0	2	8	0	0	0		10	0	0	0	0	0		4	6	0	0	0	0	*	10	0	0	0	
8000 ppm	10	0	0	0	2	2	4	2		0	4	5	1	0	0		10	0	0	0	0	0		5	4	0	1	0	0		10	0	0	0	

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
500 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
1000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
2000 ppm	10	9	0	0	0	0	1	10	0	0	0	0	0
4000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
8000 ppm	10	9	1	0	0	0	0	10	0	0	0	0	0

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS3

APPENDIX E 2

URINALYSIS : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animats	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		+	2+
Control	10	0	0	0	1	3	6	0		2	6	2	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0
500 ppm	10	0	0	1	3	3	3	0		2	7	1	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0
1000 ppm	10	0	0	1	0	3	6	0		1	8	1	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0
2000 ppm	10	0	0	0	0	4	6	0		1	8	1	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0
4000 ppm	10	0	0	1	1	2	6	0		2	5	3	0	0	0		10	0	0	0	0	0		8	2	0	0	0	0		10	0	0	0
8000 ppm	10	0	0	0	0	4	6	0		1	8	1	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0257
ANIMAL : RAT F344
SAMPLING DATE : 013-5
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
500 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
1000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
2000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
4000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
8000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS3

APPENDIX F 1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name		Control		500 ppm		1000 ppm		2000 ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
Liver	herniation			1	(10)	0	(0)	1	(10)	1	(10)

(HPT080)

BAIS 3

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

Organ_____	Findings_____	Group Name	4000 ppm	8000 ppm
		NO. of Animals	10 (%)	10 (%)
Liver	herniation		0 (0)	0 (0)

(HPT080)

BAIS 3

APPENDIX F 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name		Control		500 ppm		1000 ppm		2000 ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
Liver	herniation			0	(0)	2	(20)	1	(10)	0	(0)

(HPT080)

BALS3

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

Organ	Findings	Group Name		4000 ppm		8000 ppm	
		NO. of Animals		10	(%)	10	(%)
Liver	herniation			2	(20)	1	(10)

(HPT080)

BAIS3

APPENDIX G 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE
(13-WEEK STUDY)

STUDY NO. : 0257
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body Weight		THYMUS		ADRENALS		TESTES		HEART		LUNGS	
Control	10	304±	16	0.230±	0.028	0.056±	0.005	2.830±	0.142	0.927±	0.057	0.972±	0.049
500 ppm	10	304±	19	0.226±	0.028	0.056±	0.006	2.833±	0.120	0.951±	0.043	0.988±	0.059
1000 ppm	10	288±	23	0.223±	0.031	0.054±	0.006	2.773±	0.109	0.911±	0.042	0.932±	0.052
2000 ppm	10	283±	21*	0.219±	0.026	0.052±	0.007	2.768±	0.098	0.908±	0.074	0.906±	0.032**
4000 ppm	10	282±	16*	0.218±	0.018	0.050±	0.004	2.743±	0.106	0.923±	0.054	0.927±	0.042
8000 ppm	10	218±	12**	0.139±	0.017**	0.058±	0.006	2.645±	0.069**	0.764±	0.045**	0.826±	0.035**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0257
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.752±	0.093	0.523±	0.030	7.715±	0.407	1.827±	0.058
500 ppm	10	1.808±	0.105	0.519±	0.031	7.792±	0.613	1.827±	0.042
1000 ppm	10	1.696±	0.121	0.503±	0.032	7.393±	0.635	1.810±	0.046
2000 ppm	10	1.678±	0.124	0.483±	0.027*	7.293±	0.646	1.818±	0.036
4000 ppm	10	1.685±	0.088	0.507±	0.026	7.516±	0.396	1.810±	0.073
8000 ppm	10	1.491±	0.088**	0.394±	0.029**	6.192±	0.395**	1.771±	0.048
Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett									

(HCL040)

BAIS 3

APPENDIX G 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	173± 12	0.177± 0.022	0.060± 0.006	0.106± 0.016	0.629± 0.033	0.728± 0.042
500 ppm	10	175± 8	0.194± 0.020	0.061± 0.007	0.103± 0.013	0.633± 0.033	0.752± 0.031
1000 ppm	10	170± 8	0.179± 0.022	0.055± 0.006	0.100± 0.013	0.618± 0.040	0.734± 0.019
2000 ppm	10	167± 14	0.174± 0.025	0.057± 0.007	0.097± 0.017	0.622± 0.036	0.737± 0.057
4000 ppm	10	161± 9*	0.173± 0.020	0.055± 0.005	0.093± 0.011	0.588± 0.026*	0.718± 0.039
8000 ppm	10	157± 6**	0.139± 0.011**	0.066± 0.009	0.096± 0.015	0.586± 0.038*	0.723± 0.024

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS3

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

(HCL040)	BAIS 3
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APPENDIX H 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	304± 16	0.076± 0.010	0.018± 0.002	0.931± 0.041	0.305± 0.015	0.320± 0.010
500 ppm	10	304± 19	0.074± 0.007	0.018± 0.002	0.932± 0.035	0.313± 0.010	0.325± 0.013
1000 ppm	10	288± 23	0.078± 0.008	0.019± 0.002	0.968± 0.060	0.318± 0.019	0.325± 0.014
2000 ppm	10	283± 21*	0.077± 0.006	0.018± 0.002	0.982± 0.071	0.321± 0.011	0.321± 0.016
4000 ppm	10	282± 16*	0.077± 0.005	0.018± 0.002	0.976± 0.048	0.328± 0.018**	0.330± 0.007
8000 ppm	10	218± 12**	0.064± 0.005**	0.027± 0.003**	1.216± 0.084**	0.351± 0.016**	0.379± 0.017**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.576± 0.014	0.172± 0.009	2.537± 0.059	0.601± 0.024
500 ppm	10	0.594± 0.014	0.171± 0.005	2.558± 0.045	0.602± 0.034
1000 ppm	10	0.590± 0.021	0.175± 0.012	2.570± 0.043	0.632± 0.043
2000 ppm	10	0.593± 0.022	0.171± 0.008	2.576± 0.082	0.645± 0.042*
4000 ppm	10	0.599± 0.022	0.180± 0.008	2.673± 0.105**	0.644± 0.025*
8000 ppm	10	0.684± 0.033**	0.181± 0.010	2.838± 0.060**	0.814± 0.045**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX H 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 10				500 ppm 10				1000 ppm 10				2000 ppm 10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]																		
heart	granulation		<10>				<10>				<10>				<10>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]																		
liver	herniation		<10>				<10>				<10>				<10>			
			1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]																		
kidney	basophilic change		<10>				<10>				<10>				<10>			
			1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic body		9	0	0	0	9	0	0	0	10	0	0	0	10	0	0	0
			(90)	(0)	(0)	(0)	(90)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
[Special sense organs/appandage]																		
Harder gl	lymphocytic infiltration		<10>				<10>				<10>				<10>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b : Number of animals with lesion

(c) c : b / a * 100

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

		4000 ppm				8000 ppm			
		10				10			
		Grade				Grade			
Organ_____	Findings_____	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Circulatory system]									
heart		<10>				<10>			
	granulation	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Digestive system]									
liver		<10>				<10>			
	herniation	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]									
kidney		<10>				<10>			
	basophilic change	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic body	10	0	0	0	2	0	0	0 **
		(100)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
[Special sense organs/appandage]									
Harder gl		<10>				<10>			
	lymphocytic infiltration	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

APPENDIX I 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	173± 12	0.103± 0.009	0.035± 0.004	0.062± 0.011	0.365± 0.020	0.422± 0.016
500 ppm	10	175± 8	0.111± 0.009	0.035± 0.004	0.059± 0.008	0.363± 0.020	0.432± 0.023
1000 ppm	10	170± 8	0.105± 0.009	0.032± 0.004	0.059± 0.006	0.365± 0.022	0.433± 0.016
2000 ppm	10	167± 14	0.104± 0.009	0.035± 0.005	0.058± 0.010	0.374± 0.015	0.443± 0.019
4000 ppm	10	161± 9*	0.107± 0.009	0.034± 0.002	0.058± 0.007	0.366± 0.019	0.447± 0.017*
8000 ppm	10	157± 6**	0.089± 0.007**	0.042± 0.006**	0.061± 0.010	0.374± 0.019	0.462± 0.017**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.647± 0.031	0.204± 0.011	2.418± 0.063	0.994± 0.063
500 ppm	10	0.645± 0.038	0.207± 0.006	2.480± 0.074	0.979± 0.049
1000 ppm	10	0.653± 0.023	0.205± 0.009	2.431± 0.069	1.013± 0.046
2000 ppm	10	0.665± 0.036	0.210± 0.008	2.478± 0.088	1.025± 0.078
4000 ppm	10	0.667± 0.030	0.217± 0.009**	2.507± 0.077	1.046± 0.062
8000 ppm	10	0.719± 0.042**	0.211± 0.012	2.838± 0.099**	1.071± 0.038*

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX I 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0257
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 10				500 ppm 10				1000 ppm 10				2000 ppm 10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
bone marrow	granulation		<10>				<10>				<10>				<10>			
			2	1	0	0	3	0	0	0	0	1	0	0	1	0	0	0
			(20)	(10)	(0)	(0)	(30)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(10)	(0)	(0)	(0)
[Digestive system]																		
liver	herniation		<10>				<10>				<10>				<10>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		2	0	0	0	1	0	0	0	2	0	0	0	4	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
[Urinary system]																		
kidney	mineralization:tubule		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Endocrine system]																		
thyroid	ultimibranhial body remanet		< 9>				<10>				< 9>				<10>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0257
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	4000 ppm				8000 ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]										
bone marrow			<10>				<10>			
	granulation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Digestive system]										
liver			<10>				<10>			
	herniation		2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	granulation		2	0	0	0	0	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]										
kidney			<10>				<10>			
	mineralization:tubule		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Endocrine system]										
thyroid			< 8>				<10>			
	ultimibranhial body remanet		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0257
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 5

Organ_____	Findings_____	Group Name	Control				500 ppm				1000 ppm				2000 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
[Special sense organs/appandage]																		
Harder gl			<10>				<10>				<10>				<10>			
	Lymphocytic infiltration		0	0	0	0	2	0	0	0	0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS3

STUDY NO. : 0257
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 SACRIFICED ANIMALS (13W)

PAGE : 6

Organ	Findings	Group Name No. of Animals on Study Grade	4000 ppm				8000 ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Special sense organs/appandage]

Harder gl	Lymphocytic infiltration	<10>				<10>			
		1	0	0	0	0	0	0	0
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS3

APPENDIX J 1

IDENTITY OF DICHLOROMETHANE IN THE 13-WEEK INHALATION STUDY

IDENTITY OF DICHLOROMETHANE IN THE 13-WEEK INHALATION STUDY

A. Lot No. APR5259

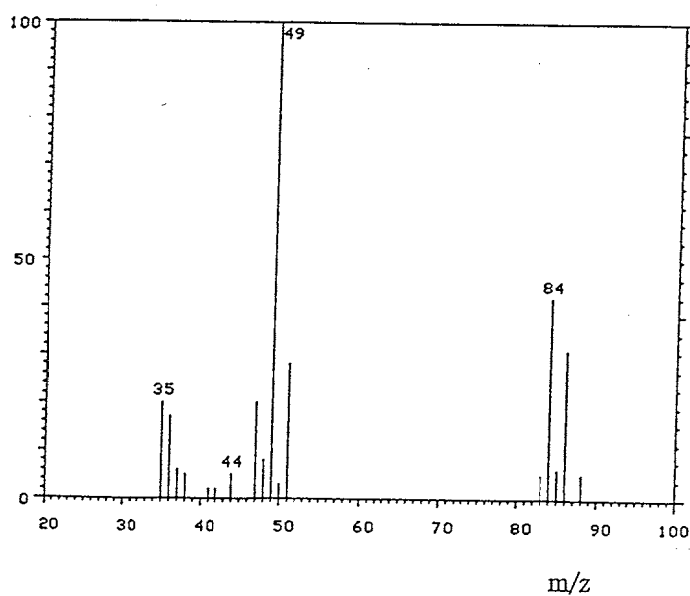
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results: The mass spectrum was consistent with literature spectrum.

<u>Determined Values</u>	<u>Literature Values</u> *
Fragment Peak(m/z)	Fragment Peak(m/z)
35	35
49	49
84	84

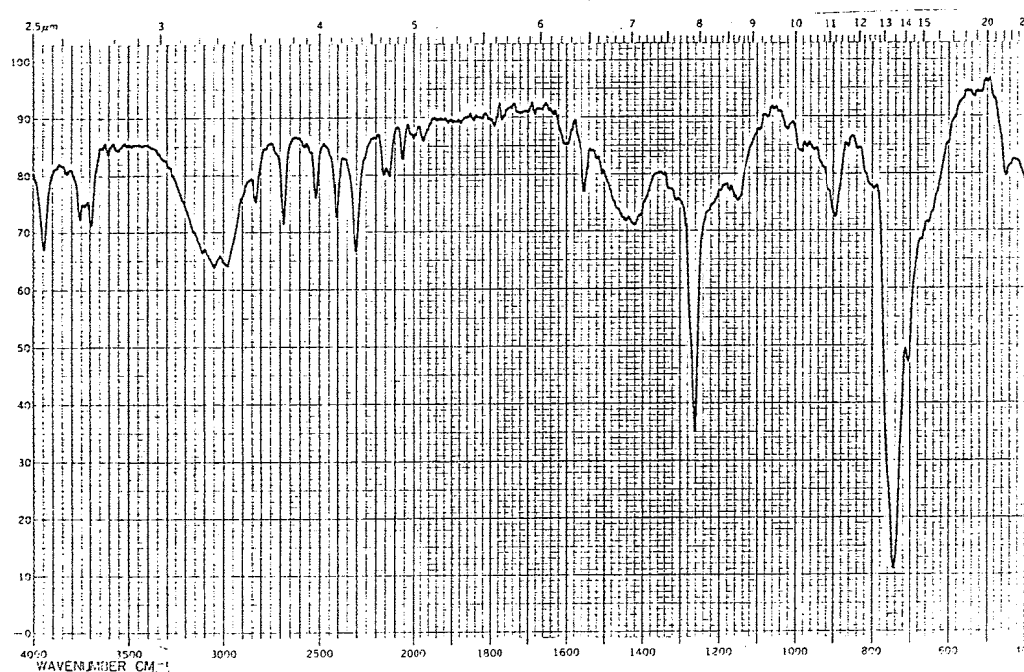
(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

<u>Determined Values</u>	<u>Literature Values*</u>
Wave Number(cm^{-1})	Wave Number(cm^{-1})
430~480	
650~840	650~850
870~940	870~940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

B. Lot No. APR5260

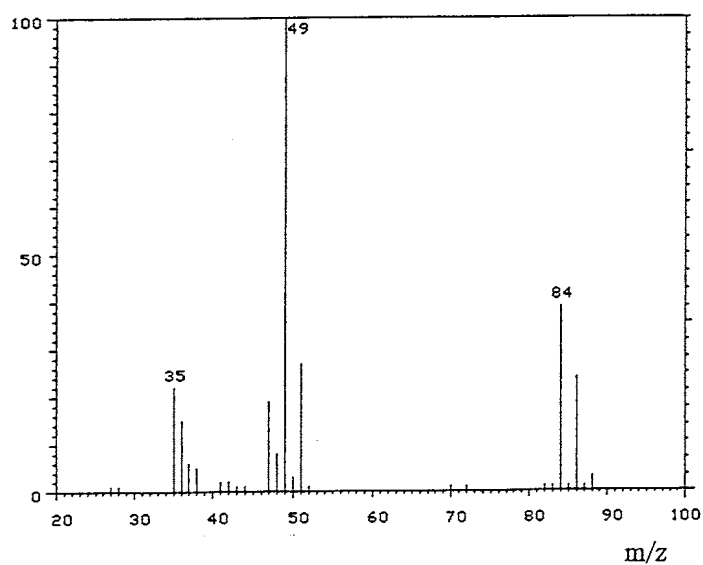
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Results: The mass spectrum was consistent with literature spectrum.

<u>Determined Values</u>	<u>Literature Values</u> *
Fragment Peak(m/z)	Fragment Peak(m/z)
35	35
49	49
84	84

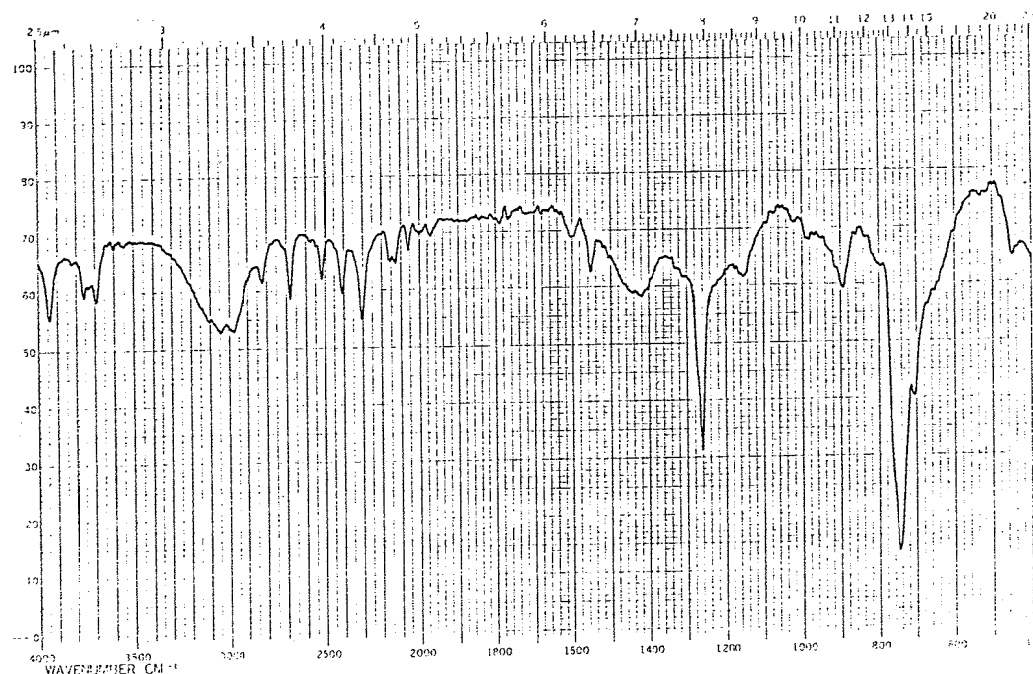
(*EPA/NIH Mass Spectral Data Base (1978) Vol. 1, p. 33.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium



Infrared Spectrum of Test Substance

Results: The infrared spectrum was consistent with literature spectrum.

<u>Determined Values</u>	<u>Literature Values</u> *
Wave Number(cm^{-1})	Wave Number(cm^{-1})
430~480	
650~840	650~850
870~940	870~940
970~1000	970~1000
1120~1180	1130~1180
1200~1340	1200~1350
1370~1500	1380~1500
1530~1570	1540~1570
1580~1630	1580~1630
2040~2090	2050~2090
2100~2190	2120~2190
2250~2360	2280~2370
2380~2460	2400~2460
2500~2550	2500~2560
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3670~3750
3730~3800	3750~3800
3900~4000	3900~4000

(*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The test substance was identified as dichloromethane, by the mass spectrum and the infrared spectrum.

APPENDIX J 2

STABILITY OF DICHLOROMETHANE IN THE 13-WEEK INHALATION STUDY

STABILITY OF DICHLOROMETHANE IN THE 13-WEEK INHALATION STUDY

A. Lot No. APR5259

1. Sample: This lot was used from 1994.1.19 to 1994.2.4. Test substance was stored in a dark place at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium

Results: The result of infrared spectrum did not change when before and after the lot of study.

<u>1994.01.11(date analyzed)</u>	<u>1994.02.08(date analyzed)</u>
Wave Number(cm^{-1})	Wave Number(cm^{-1})
430~ 480	430~ 480
650~ 840	650~ 840
870~ 940	870~ 940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone(0.2 mm ϕ \times 50 m)

Column Temperature : 60 $^{\circ}\text{C}$

Flow Rate : 1 ml/min

Detector : FID(Flame Ionization Detector)

Injection Volume : 1 μl

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.1.11 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.2.8. No new trace impurity peak in the test substance analyzed at 1994.2.8 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	Area Count
1994.01.11	1	3.303	64234
	2	3.41	10
1994.02.08	1	3.302	64221
	2	3.407	8

4. Conclusions: The test substance was stable for about 1 month in a dark place at room temperature.

B. Lot No. APR5260

1. Sample: This lot was used from 1994.2.7 to 1994.4.19 Test substance was stored in a dark place at room temperature.

2. Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr Liquid Cell

Slit : Medium

Results: The result of infrared spectrum did not change when before and after the lot of study.

<u>1994.02.01(date analyzed)</u>	<u>1994.04.28(date analyzed)</u>
Wave Number(cm^{-1})	Wave Number(cm^{-1})
430~480	430~480
650~840	650~840
870~940	870~940
970~1000	970~1000
1120~1180	1120~1180
1200~1340	1200~1340
1370~1500	1370~1500
1530~1570	1530~1570
1580~1630	1580~1630
2040~2090	2040~2090
2100~2190	2100~2190
2250~2360	2250~2360
2380~2460	2380~2460
2500~2550	2500~2550
2650~2730	2650~2730
2800~2860	2800~2860
2900~3200	2900~3200
3650~3730	3650~3730
3730~3800	3730~3800
3900~4000	3900~4000

3. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone(0.2 mm ϕ \times 50 m)

Column Temperature : 60 °C

Flow Rate : 1 ml/min

Detector : FID(Flame Ionization Detector)

Injection Volume : 1 μ l

Results: Gas chromatography indicated one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.2.1 and one major peak (peak No.1) and one impurity (peak No.2 < 1% of total area) analyzed at 1994.4.28. No new trace impurity peak in the test substance analyzed at 1994.4.28 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	Area Count
1994.02.01	1	3.305	65049
	2	3.41	7
1994.04.28	1	3.302	64232
	2	3.407	9

4. Conclusions: The test substance was stable for about 3 months in a dark place at room temperature.

APPENDIX K 1

CONCENTRATION OF DICHLOROMETHANE IN THE INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY

CONCENTRATION OF DICHLOROMETHANE IN INHALATION CHAMBER

Group Name	Concentration(ppm)	
	Mean	± S.D.
Control	0.0	± 0.0
500ppm	502.5	± 1.3
1,000ppm	1,003.1	± 3.6
2,000ppm	2,004.3	± 6.3
4,000ppm	3,993.8	± 13.2
8,000ppm	8,007.6	± 9.7

APPENDIX K 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER
IN THE 13-WEEK INHALATION STUDY OF DICHLOROMETHANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF DICHLOROMETHANE

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Room Air Change(time/h) Mean
Control	22.1 ± 0.1	54.8 ± 0.9	211.9 ± 0.6	12.0
500ppm	22.0 ± 0.2	52.4 ± 0.8	212.7 ± 0.9	12.0
1,000ppm	22.1 ± 0.1	52.4 ± 0.6	211.8 ± 0.4	11.9
2,000ppm	21.9 ± 0.2	53.0 ± 0.5	212.2 ± 0.5	12.0
4,000ppm	22.0 ± 0.2	51.9 ± 0.7	212.7 ± 0.6	12.0
8,000ppm	21.8 ± 0.2	53.2 ± 0.7	211.9 ± 0.3	12.0

APPENDIX L 1

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY OF DICHLOROMETHANE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE
13-WEEK INHALATION STUDY OF DICHLOROMETHANE

Item	Method
Hematology Red blood cell (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean corpuscular volume (MCV) Mean corpuscular hemoglobin (MCH) Mean corpuscular hemoglobin concentration (MCHC) Platelet Prothrombin time Activated partial thromboplastin time (APTT) White blood cell (WBC) Differential WBC	Light scattering method ¹⁾ Cyanmethemoglobin method ¹⁾ Calculated as $RBC \times MCV/10$ ¹⁾ Light scattering method ¹⁾ Calculated as $Hgb/RBC \times 10$ ¹⁾ Calculated as $Hgb/Hct \times 100$ ¹⁾ Light scattering method ¹⁾ Quick one stage method ²⁾ Ellagic acid activated method ²⁾ Light scattering method ¹⁾ Pattern recognition method ³⁾ (May-Grunwald-Giemsa staining)
Biochemistry Total protein (TP) Albumin (Alb) A/G ratio T-bilirubin Glucose T-cholesterol Triglyceride Phospholipid Glutamic oxaloacetic transaminase (GOT) Glutamic pyruvic transaminase (GPT) Lactate dehydrogenase (LDH) Alkaline phosphatase (ALP) γ -Glutamyl transpeptidase (γ -GTP) Creatine phosphokinase (CPK) Urea nitrogen Creatinine Sodium Potassium Chloride Calcium Inorganic phosphorus	Biuret method ⁴⁾ BCG method ⁴⁾ Calculated as $Alb/(TP - Alb)$ ⁴⁾ Michaelson method ⁴⁾ Enzymatic method (HK-G-6-PDH) ⁴⁾ Enzymatic method (CEH-COD-POD) ⁴⁾ Enzymatic method (GK-GPO-POD) ⁴⁾ Enzymatic method (PLD-COD-POD) ⁴⁾ UV-Rate method ⁴⁾ UV-Rate method ⁴⁾ UV-Rate method ⁴⁾ p-Nitrophenylphosphate method ⁴⁾ L- γ -Glutamyl-p-nitroanilide method ⁴⁾ UV-Rate method ⁴⁾ Enzymatic method (Urease-GLDH) ⁴⁾ Jaffe method ⁴⁾ Flame photometry ⁵⁾ Flame photometry ⁵⁾ Coulometric titration ⁵⁾ OCPC method ⁴⁾ Enzymatic method (SPL-PGM-G-6-PDH) ⁴⁾
Urinalysis pH, Protein, Glucose, Ketone body, Bilirubin, Occult Blood, Urobilinogen	Urinalysis reagent paper method ⁶⁾

1) Automatic blood cell analyzer (Technicon H-1 : Technicon Instruments Corporation, USA)

2) Automatic coagulometer (Sysmex CA-5000 : Toa Medical Electronics Co., Ltd., Japan)

3) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi, Ltd., Japan)

4) Automatic analyzer (Hitachi 705 : Hitachi, Ltd., Japan)

5) Flame photometer (Hitachi 750 : Hitachi, Ltd., Japan)

6) Ames reagent strips for urinalysis (Multistix : Miles-Sankyo Co., Ltd., Japan)

APPENDIX L 2

UNISTS AND DECIMAL PLACE FOR HEMAYOLOGY AND
BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY
OF DICHLOROMETHANE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE
13--WEEK INHALATION STUDY OF DICHLOROMETHANE

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6 / \mu L$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu L$	0
Prothrombin time	sec	1
Activated partial thromboplastin time (APTT)	sec	1
White blood cell (WBC)	$\times 10^3 / \mu L$	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio	—	1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Triglyceride	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
γ - Glutamyl transpeptidase (γ - GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Creatinine	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1