

1, 2 - ジクロロプロパンのマウスを用いた  
吸入による2週間毒性試験報告書

試験番号 : 0425

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## APPENDICES

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## APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day				
		1-2	1-4	1-7	2-4	2-7
		1	1	1	1	1
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	2	0	0	0	0
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-
LATERAL	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	2	0	0	0	0
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-
HUNCHBACK POSITION	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	0	0	0	0	1
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-
PILOERECTION	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	0	0	0	0	1
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-
BRADYPNEA	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	2	0	0	0	0
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-
SUBNORMAL TEMP	Control	0	0	0	0	0
	125ppm	0	0	0	0	0
	250ppm	0	0	0	0	0
	500ppm	2	0	0	0	0
	1000ppm	-	-	-	-	-
	2000ppm	-	-	-	-	-

## APPENDIX B 1

BODY WEIGHT CHANGES : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 2  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day					
	0-0	1-2	1-4	1-7	2-4	2-7
Control	23.3± 1.0	23.6± 0.6	24.2± 0.8	24.6± 0.5	25.1± 0.7	25.5± 0.7
125ppm	23.3± 0.9	23.8± 1.3	24.0± 1.5	23.9± 1.3	24.2± 1.4	24.2± 1.4
250ppm	23.2± 0.9	22.7± 1.9	23.3± 1.3	23.9± 1.0	24.9± 1.1	24.9± 0.9
500ppm	23.3± 1.0	-	-	-	-	-
1000ppm	23.3± 1.1	-	-	-	-	-
2000ppm	23.4± 1.0	-	-	-	-	-

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

Test of Dunnett



## APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 2  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day					
	0-0	1-2	1-4	1-7	2-4	2-7
Control	19.5± 0.7	20.2± 1.1	20.1± 1.3	20.4± 1.5	21.2± 1.3	21.2± 2.0
125ppm	19.5± 0.6	19.2± 0.6	19.8± 0.9	19.7± 0.6	20.5± 0.6	20.9± 1.0
250ppm	19.4± 0.8	19.3± 0.7	19.9± 0.9	20.7± 1.2	21.4± 0.9	21.8± 0.6
500ppm	19.5± 0.7	17.5± 0.5**	18.8 ?	22.0 ?	18.6 ?	16.4 ?
1000ppm	19.4± 0.6	-	-	-	-	-
2000ppm	19.4± 0.6	-	-	-	-	-

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
UNIT : g  
REPORT TYPE : A1 2  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)	
	1-7 (6)	2-7 (7)
Control	4.3± 0.2	4.1± 0.2
125ppm	4.3± 0.3	4.0± 0.4
250ppm	4.2± 0.2	4.3± 0.2
500ppm	-	-
1000ppm	-	-
2000ppm	-	-

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

Test of Dunnett

## APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
UNIT : g  
REPORT TYPE : A1 2  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)	
	1-7(6)	2-7(7)
Control	3.7± 0.4	3.8± 0.4
125ppm	3.8± 0.2	3.6± 0.2
250ppm	3.8± 0.3	3.9± 0.1
500ppm	4.1 ?	2.3 ?
1000ppm	-	-
2000ppm	-	-

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

? : Significant test is not applied, because No. of data in this group is less than 3.

APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV fl	MCH pg	MCHC g/dl	PLATELET 10 <sup>3</sup> /μl
Control	5	10.93± 0.26	16.7± 0.7	51.5± 0.9	47.2± 0.8	15.3± 0.3	32.4± 0.9	1331± 72
125ppm	5	10.70± 0.41	16.2± 0.7	50.5± 1.9	47.2± 1.1	15.1± 0.2	32.1± 0.7	1286± 176
250ppm	3	10.43± 0.65	15.8± 1.0	50.5± 2.5	48.6± 1.0	15.1± 0.1	31.1± 0.8	1295± 90
500ppm	0	-	-	-	-	-	-	-
1000ppm	0	-	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-	-

Significant difference ; \* : P ≤ 0.05      \*\* : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 3



STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	5	0.90±	0.14	0±	1	17±	4	1±	1	0±	0	3±	2	79±	3	0±	0
125ppm	5	1.22±	0.47	1±	1	20±	14	1±	1	0±	0	2±	1	77±	14	0±	0
250ppm	3	1.07±	0.86	1±	1	16±	8	1±	1	0±	0	4±	3	78±	11	0±	0
500ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	3	10.99±	0.38	16.9±	0.5	51.7±	0.9	47.0±	0.8	15.3±	0.1	32.5±	0.5	1243±	124
125ppm	4	10.45±	0.61	16.0±	1.0	50.1±	2.8	47.9±	0.7	15.2±	0.1	31.8±	0.5	1185±	87
250ppm	4	9.90±	0.41	15.0±	0.5*	47.8±	1.0	48.4±	1.2	15.2±	0.2	31.4±	0.5*	1133±	66
500ppm	1	8.78	?	13.0	?	40.4	?	45.9	?	14.9	?	32.4	?	1784	?
1000ppm	0	-		-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	WBC 1 O <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	3	1.28±	0.78	1±	0	29±	14	0±	0	0±	0	1±	0	69±	14	0±	0
125ppm	4	1.22±	1.52	0±	1	14±	6	2±	1	0±	0	1±	2	83±	7	0±	0
250ppm	4	0.80±	0.52	0±	0	14±	3	1±	2	0±	0	5±	3	80±	3	0±	0
500ppm	1	0.74	?	4	?	69	?	0	?	0	?	1	?	26	?	0	?
1000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

\*\* :  $P \leq 0.01$

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX E 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

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	5	5.2±	0.2	3.1±	0.1	1.6±	0.1	0.17±	0.01	216±	23	80±	11	25±	6
125ppm	5	5.2±	0.6	3.1±	0.0	1.6±	0.4	0.18±	0.06	198±	33	87±	25	29±	13
250ppm	5	5.1±	0.1	3.1±	0.2	1.7±	0.3	0.20±	0.03	198±	30	110±	7*	27±	7
500ppm	0	-		-		-		-		-		-		-	
1000ppm	0	-		-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

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	5	180±	27	37±	4	16±	2	321±	78	269±	15	1±	1	101±	38
125ppm	5	175±	25	41±	9	19±	7	414±	156	212±	61	1±	1	124±	91
250ppm	5	215±	14	34±	3	19±	4	399±	114	250±	15	0±	1	116±	29
500ppm	0	-		-		-		-		-		-		-	
1000ppm	0	-		-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-		-	

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

\*\* :  $P \leq 0.01$

Test of Dunnett

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	5	33.1±	4.3	149±	1	5.0±	0.3	116±	1	9.0±	0.2	7.2±	1.6
125ppm	5	26.3±	2.9*	149±	1	4.6±	0.5	116±	2	9.2±	0.5	8.1±	0.8
250ppm	5	24.1±	2.6**	149±	1	5.1±	0.6	117±	2	9.0±	0.2	8.7±	1.5
500ppm	0	-		-		-		-		-		-	
1000ppm	0	-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-	

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

Test of Dunnett



## APPENDIX E 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

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	4	5.6±	0.3	3.6±	0.1	1.8±	0.2	0.17±	0.04	211±	31	80±	15	24±	10
125ppm	5	5.3±	0.4	3.6±	0.1	2.3±	0.6	0.17±	0.04	220±	31	79±	13	21±	8
250ppm	4	5.2±	0.3	3.5±	0.1	2.2±	0.6	0.20±	0.03	203±	14	108±	11*	28±	5
500ppm	1	5.2	?	3.4	?	1.9	?	0.22	?	37	?	128	?	8	?
1000ppm	0	-		-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-		-	

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

STUDY NO. : 0425

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS ( 3W)

PAGE : 5

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	4	173±	24	48±	3	18±	2	426±	114	386±	33	1±	1	108±	43
125ppm	5	169±	28	42±	1	17±	2	411±	149	356±	29	1±	1	112±	25
250ppm	4	207±	17	36±	1**	20±	3	356±	104	321±	25*	1±	1	102±	31
500ppm	1	156	?	114	?	65	?	625	?	180	?	2	?	290	?
1000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL074)

BAIS 3

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	4	31.5±	2.4	148±	1	4.7±	0.3	116±	1	9.1±	0.5	6.5±	1.4
125ppm	5	29.2±	2.5	148±	1	4.9±	0.5	116±	2	8.9±	0.2	6.5±	0.9
250ppm	4	20.4±	5.4**	148±	1	4.5±	0.2	117±	2	9.1±	0.3	7.2±	0.6
500ppm	1	47.1	?	147	?	5.2	?	114	?	9.8	?	6.8	?
1000ppm	0	-		-		-		-		-		-	
2000ppm	0	-		-		-		-		-		-	

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

## APPENDIX F 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 1

Organ	Findings	Group Name		Control		125ppm		250ppm		500ppm	
		NO. of Animals		5	(%)	5	(%)	5	(%)	0	(%)
kidney	hydronephrosis			0	( 0)	1	( 20)	0	( 0)	-	( -)

(HPT080)

BAIS 3

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 2

Organ	Findings	Group Name	1000ppm		2000ppm	
		NO. of Animals	0	(%)	0	(%)
kidney	hydronephrosis		-	( -)	-	( -)

(HPT080)

BAIS 3

## APPENDIX F 2

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

( 2-WEEK STUDY )



STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	125ppm 0 (%)	250ppm 0 (%)	500ppm 4 (%)
liver	accentuation of lobular structure		- ( -)	- ( -)	- ( -)	1 ( 25)

(HPT080)

BAIS 3

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 2

Organ_____	Findings_____	Group Name	1000ppm	2000ppm
		NO. of Animals	5 (%)	5 (%)
liver	accentuation of lobular structure		0 ( 0)	0 ( 0)

(HPT080)

BAIS 3

## APPENDIX F 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		125ppm		250ppm		500ppm	
			5	(%)	5	(%)	5	(%)	1	(%)
thymus	atrophic		0	( 0)	0	( 0)	0	( 0)	1	(100)
spleen	black zone		0	( 0)	1	( 20)	0	( 0)	0	( 0)
gl stomach	ulcer		0	( 0)	0	( 0)	0	( 0)	1	(100)
liver	yellow zone		0	( 0)	0	( 0)	0	( 0)	1	(100)
kidney	hydronephrosis		1	( 20)	0	( 0)	0	( 0)	0	( 0)

(HPT080)

BAIS 3

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	1000ppm		2000ppm	
			0	(%)	0	(%)
thymus	atrophic		-	( -)	-	( -)
spleen	black zone		-	( -)	-	( -)
gl stomach	ulcer		-	( -)	-	( -)
liver	yellow zone		-	( -)	-	( -)
kidney	hydronephrosis		-	( -)	-	( -)

(HPT080)

BAIS 3

## APPENDIX G 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	21.3± 0.6	0.039± 0.006	0.010± 0.002	0.181± 0.031	0.125± 0.009	0.140± 0.005
125ppm	5	20.8± 1.1	0.039± 0.008	0.012± 0.002	0.194± 0.026	0.121± 0.007	0.136± 0.009
250ppm	5	21.5± 0.9	0.032± 0.005	0.009± 0.003	0.183± 0.039	0.121± 0.004	0.137± 0.010
500ppm	0	-	-	-	-	-	-
1000ppm	0	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-

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

Test of Dunnett

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS ( 3W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	0.348±	0.012	0.040±	0.003	0.895±	0.033	0.440±	0.005
125ppm	5	0.399±	0.149	0.043±	0.013	0.886±	0.053	0.421±	0.013**
250ppm	5	0.365±	0.017	0.041±	0.003	0.972±	0.056*	0.432±	0.006
500ppm	0	-		-		-		-	
1000ppm	0	-		-		-		-	
2000ppm	0	-		-		-		-	

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

Test of Dunnett

(HCL040)

BAIS 3



## APPENDIX G 2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS ( 3W)

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	17.4± 1.3	0.054± 0.007	0.012± 0.002	0.020± 0.002	0.106± 0.015	0.130± 0.007
125ppm	5	17.4± 0.6	0.066± 0.006*	0.013± 0.001	0.021± 0.005	0.109± 0.011	0.128± 0.003
250ppm	5	18.8± 0.5*	0.060± 0.006	0.012± 0.002	0.024± 0.005	0.110± 0.007	0.130± 0.005
500ppm	1	13.6 ?	0.004 ?	0.012 ?	0.010 ?	0.107 ?	0.115 ?
1000ppm	0	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-

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

Test of Dunnett

? : Significant test is not applied,because No. of data in this group is less than 3.

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	5	0.334±	0.214	0.048±	0.015	0.742±	0.073	0.438±	0.011
125ppm	5	0.233±	0.012	0.041±	0.003	0.759±	0.037	0.431±	0.006
250ppm	5	0.256±	0.011	0.049±	0.005	0.893±	0.028**	0.447±	0.009
500ppm	1	0.272	?	0.022	?	0.958	?	0.411	?
1000ppm	0	-		-		-		-	
2000ppm	0	-		-		-		-	

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

Test of Dunnett

? : Significant test is not applied, because No. of data in this group is less than 3.

(HCL040)

BAIS 3

## APPENDIX H 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	5	21.3± 0.6	0.182± 0.026	0.048± 0.011	0.852± 0.160	0.585± 0.036	0.656± 0.029
125ppm	5	20.8± 1.1	0.187± 0.030	0.056± 0.009	0.937± 0.138	0.582± 0.020	0.653± 0.030
250ppm	5	21.5± 0.9	0.148± 0.023	0.044± 0.011	0.854± 0.179	0.563± 0.022	0.638± 0.029
500ppm	0	-	-	-	-	-	-
1000ppm	0	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.634± 0.066	0.186± 0.016	4.203± 0.088	2.067± 0.060
125ppm	5	1.939± 0.771	0.210± 0.068	4.264± 0.259	2.026± 0.104
250ppm	5	1.702± 0.150	0.191± 0.013	4.529± 0.282	2.013± 0.101
500ppm	0	-	-	-	-
1000ppm	0	-	-	-	-
2000ppm	0	-	-	-	-

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

Test of Dunnett

## APPENDIX H 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	5	17.4± 1.3	0.311± 0.022	0.068± 0.009	0.114± 0.010	0.607± 0.052	0.750± 0.065
125ppm	5	17.4± 0.6	0.380± 0.029**	0.072± 0.007	0.119± 0.028	0.626± 0.053	0.733± 0.026
250ppm	5	18.8± 0.5*	0.320± 0.033	0.066± 0.009	0.128± 0.029	0.585± 0.049	0.693± 0.019
500ppm	1	13.6 ?	0.029 ?	0.088 ?	0.074 ?	0.787 ?	0.846 ?
1000ppm	0	-	-	-	-	-	-
2000ppm	0	-	-	-	-	-	-

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

Test of Dunnett

? : Significant test is not applied,because No. of data in this group is less than 3.



STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 3W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	5	1.899± 1.150	0.271± 0.068	4.263± 0.132	2.529± 0.171
125ppm	5	1.337± 0.057	0.233± 0.016	4.352± 0.120	2.473± 0.064
250ppm	5	1.362± 0.072	0.260± 0.027	4.754± 0.156**	2.381± 0.074
500ppm	1	2.000 ?	0.162 ?	7.044 ?	3.022 ?
1000ppm	0	-	-	-	-
2000ppm	0	-	-	-	-

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

Test of Dunnett

? : Significant test is not applied,because No. of data in this group is less than 3.

## APPENDIX I 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY,  
MOUSE : MALE : DEAD AND MORIBUND ANIMALS

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 1

		Group Name	Control				125ppm				250ppm				500ppm			
		No. of Animals on Study	0				0				0				5			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit	desquamation:olfactory epithelium		< 0>				< 0>				< 0>				< 5>			
		-	-	-	-	-	-	-	-	-	-	-	-	-	5	0	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	(100)	( 0 )	( 0 )	( 0 )
lung	hemorrhage		< 0>				< 0>				< 0>				< 5>			
		-	-	-	-	-	-	-	-	-	-	-	-	-	1	0	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 20 )	( 0 )	( 0 )	( 0 )
{Hematopoietic system}																		
spleen	congestion		< 0>				< 0>				< 0>				< 5>			
		-	-	-	-	-	-	-	-	-	-	-	-	-	5	0	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	(100)	( 0 )	( 0 )	( 0 )
{Digestive system}																		
liver	degeneration:central		< 0>				< 0>				< 0>				< 5>			
		-	-	-	-	-	-	-	-	-	-	-	-	-	2	3	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 40 )	( 60 )	( 0 )	( 0 )
{Urinary system}																		
kidney	hydronephrosis		< 0>				< 0>				< 0>				< 5>			
		-	-	-	-	-	-	-	-	-	-	-	-	-	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	b : Number of animals with lesion																	
( c )	c : b / a * 100																	

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 2

		Group Name	1000ppm				2000ppm			
		No. of Animals on Study	5				5			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			< 5>				< 5>			
	desquamation:olfactory epithelium		4	0	0	0	1	0	0	0
			( 80)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)
lung			< 5>				< 5>			
	hemorrhage		2	0	0	0	0	2	0	0
			( 40)	( 0)	( 0)	( 0)	( 0)	( 40)	( 0)	( 0)
{Hematopoietic system}										
spleen			< 5>				< 5>			
	congestion		5	0	0	0	5	0	0	0
			(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)
{Digestive system}										
liver			< 5>				< 5>			
	degeneration:central		2	3	0	0	4	1	0	0
			( 40)	( 60)	( 0)	( 0)	( 80)	( 20)	( 0)	( 0)
{Urinary system}										
kidney			< 5>				< 5>			
	hydronephrosis		1	0	0	0	0	0	0	0
			( 20)	( 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

## APPENDIX I 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY,  
MOUSE : MALE : SACRIFICED ANIMALS

( 2-WEEK STUDY )

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 3#)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	Control 5				125ppm 5				250ppm 5				500ppm 0			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit	hemorrhage		< 5>				< 5>				< 5>				< 0>			
			0	0	0	0	0	0	0	0	1	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( -)	( -)	( -)	( -)
	disarrangement:olfactory epithelium		0	0	0	0	0	0	0	0	5	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)	( -)	( -)	( -)	( -)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	0	0	0	0	1	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( -)	( -)	( -)	( -)
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	4	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 80)	( 0)	( 0)	( 0)	( -)	( -)	( -)	( -)
{Digestive system}																		
liver	granulation		< 5>				< 5>				< 5>				< 0>			
			0	0	0	0	0	0	0	0	2	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 40)	( 0)	( 0)	( 0)	( -)	( -)	( -)	( -)
{Urinary system}																		
kidney	hydronephrosis		< 5>				< 5>				< 5>				< 0>			
			0	0	0	0	0	1	0	0	1	0	0	0	-	-	-	-
			( 0)	( 0)	( 0)	( 0)	( 0)	( 20)	( 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	b : Number of animals with lesion																	
( c )	c : b / a * 100																	

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 2

		Group Name	1000ppm				2000ppm			
		No. of Animals on Study	0				0			
Organ	Findings	Grade	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			< 0>				< 0>			
	hemorrhage		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
	disarrangement:olfactory epithelium		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
	respiratory metaplasia:olfactory epithelium		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
	atrophy:olfactory epithelium		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
{Digestive system}										
liver			< 0>				< 0>			
	granulation		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
{Urinary system}										
kidney			< 0>				< 0>			
	hydronephrosis		-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )

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

## APPENDIX I 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY,  
MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

( 2-WEEK STUDY )



STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study Grade	Control 0				125ppm 0				250ppm 0				500ppm 4			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			< 0>				< 0>				< 0>				< 4>			
	desquamation:olfactory epithelium		-	-	-	-	-	-	-	-	-	-	-	-	3	0	0	0
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 75 )	( 0 )	( 0 )	( 0 )
{Hematopoietic system}																		
thymus			< 0>				< 0>				< 0>				< 3>			
	karyorrhexis		-	-	-	-	-	-	-	-	-	-	-	-	3	0	0	0
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 100 )	( 0 )	( 0 )	( 0 )
spleen			< 0>				< 0>				< 0>				< 4>			
	congestion		-	-	-	-	-	-	-	-	-	-	-	-	4	0	0	0
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 100 )	( 0 )	( 0 )	( 0 )
	deposit of melanin		-	-	-	-	-	-	-	-	-	-	-	-	1	0	0	0
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 25 )	( 0 )	( 0 )	( 0 )
{Digestive system}																		
liver			< 0>				< 0>				< 0>				< 4>			
	necrosis:central		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 0 )	( 25 )	( 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

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 4

		Group Name	1000ppm				2000ppm			
		No. of Animals on Study	5				5			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			< 5>				< 5>			
	desquamation:olfactory epithelium		5	0	0	0	5	0	0	0
			(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)
{Hematopoietic system}										
thymus			< 5>				< 5>			
	karyorrhexis		0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
spleen			< 5>				< 5>			
	congestion		5	0	0	0	5	0	0	0
			(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)
	deposit of melanin		0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Digestive system}										
liver			< 5>				< 5>			
	necrosis:central		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 b : Number of animals with lesion  
 ( c ) c : b / a \* 100

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 5

		Group Name	Control				125ppm				250ppm				500ppm			
		No. of Animals on Study	0				0				0				4			
Organ	Findings	Grade	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver			< 0>				< 0>				< 0>				< 4>			
	fatty change		-	-	-	-	-	-	-	-	-	-	-	-	3	1	0	0
			( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( 75)	( 25)	( 0)	( 0)
	mineralization		-	-	-	-	-	-	-	-	-	-	-	-	1	0	0	0
			( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( 25)	( 0)	( 0)	( 0)
	degeneration:central		-	-	-	-	-	-	-	-	-	-	-	-	0	2	0	0
			( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( -)	( 0)	( 50)	( 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																	

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 3W)

PAGE : 6

Organ	Findings	1000ppm				2000ppm			
		5				5			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>									
{Digestive system}									
liver									
	fatty change	< 5>				< 5>			
		0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	mineralization	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	degeneration:central	1	4	0	0	3	2	0	0
		( 20)	( 80)	( 0)	( 0)	( 60)	( 40)	( 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

(HPT150)

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## APPENDIX I 4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY,  
MOUSE : FEMALE : SACRIFICED ANIMALS

( 2-WEEK STUDY )

STUDY NO. : 0425  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 3W)

PAGE : 3

		Group Name	Control				125ppm				250ppm				500ppm			
		No. of Animals on Study	5				5				5				1			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			< 5>				< 5>				< 5>				< 1>			
	disarrangement:olfactory epithelium		0	0	0	0	0	0	0	0	4	0	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 80 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )
	respiratory metaplasia:olfactory epithelium		0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 60 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	4	1	0	0	0	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 80 )	( 20 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )
{Hematopoietic system}																		
thymus			< 5>				< 5>				< 5>				< 1>			
	karyorrhexis		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 )	( 100 )	( 0 )	( 0 )	( 0 )
spleen			< 5>				< 5>				< 5>				< 1>			
	deposit of melanin		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Circulatory system}																		
heart			< 5>				< 5>				< 5>				< 1>			
	necrosis:focal		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 )	( 100 )	( 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

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 3W)

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study				1000ppm				2000ppm			
		Grade				0				0			
		1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}													
nasal cavit		< 0>				< 0>							
	disarrangement:olfactory epithelium	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
	respiratory metaplasia:olfactory epithelium	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
	atrophy:olfactory epithelium	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
{Hematopoietic system}													
thymus		< 0>				< 0>							
	karyorrhexis	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
spleen		< 0>				< 0>							
	deposit of melanin	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
{Circulatory system}													
heart		< 0>				< 0>							
	necrosis:focal	-	-	-	-	-	-	-	-	-	-	-	-
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )

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

STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 3W)

PAGE : 5

		Group Name	Control				125ppm				250ppm				500ppm			
		No. of Animals on Study	5				5				5				1			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach			< 5>				< 5>				< 5>				< 1>			
	hyperkeratosis:forestomach		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)	(100)	( 0)	( 0)	( 0)
liver			< 5>				< 5>				< 5>				< 1>			
	mineralization		0	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)	(100)	( 0)	( 0)
{Urinary system}																		
kidney			< 5>				< 5>				< 5>				< 1>			
	hydronephrosis		0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 20)	( 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 b : Number of animals with lesion  
 ( c ) c : b / a \* 100

(HPT150)

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STUDY NO. : 0425  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 3W)

PAGE : 6

Organ_____	Findings_____	Group Name	1000ppm				2000ppm				
		No. of Animals on Study	0				0				
		Grade	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>											
{Digestive system}											
stomach			< 0>				< 0>				
	hyperkeratosis:forestomach		-	-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
liver			< 0>				< 0>				
	mineralization		-	-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )
{Urinary system}											
kidney			< 0>				< 0>				
	hydronephrosis		-	-	-	-	-	-	-	-	-
			( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )

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

(HPT150)

BAIS3

## APPENDIX J 1

IDENTITY AND IMPURITY OF 1,2 - DICHLOROPROPANE IN THE 2-WEEK INHALATION STUDY

## IDENTITY OF 1,2-DICHLOROPROPANE IN THE 2-WEEK INHALATION STUDY

Test Substance : 1,2-Dichloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : LDR4974

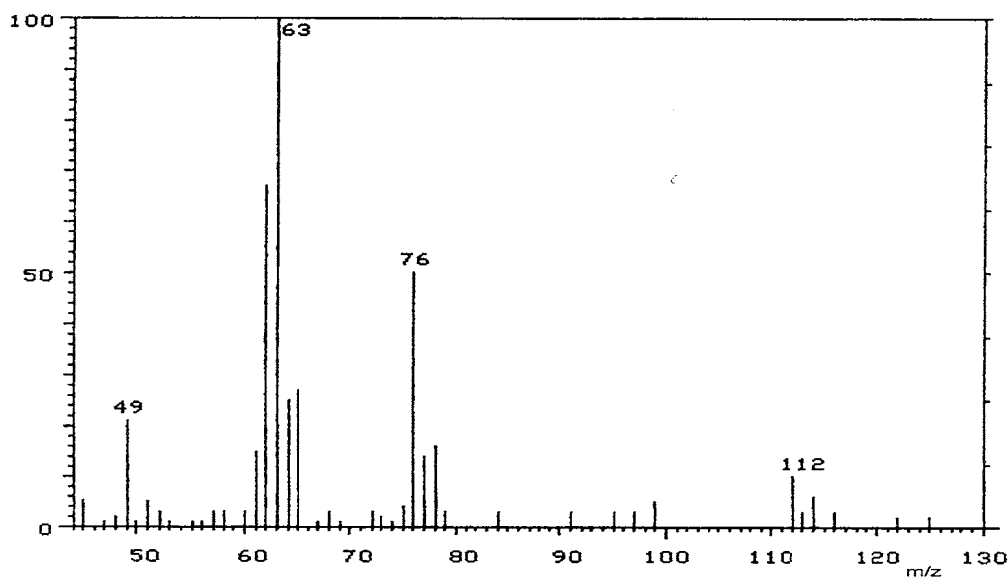
## 1. Spectral Data

Mass Spectrometry

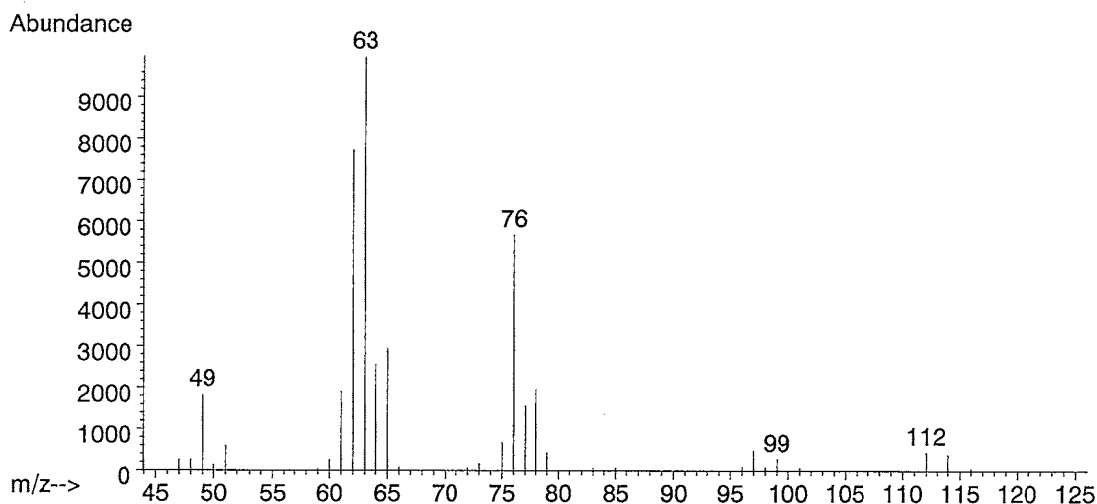
Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance



Mass Spectrum of Literature Data\*

Results: The mass spectrum was consistent with literature spectrum.

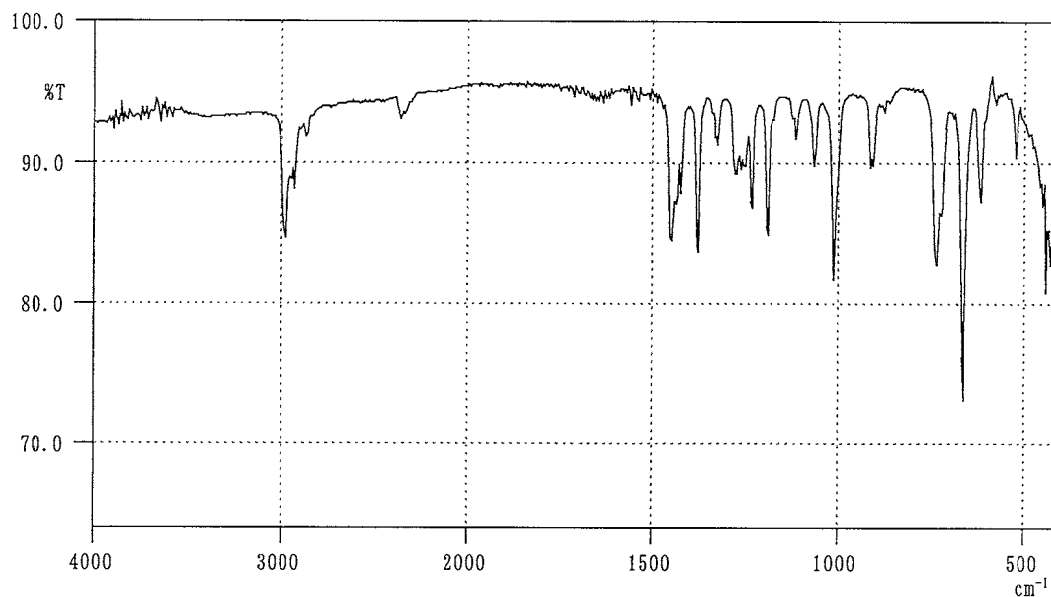
(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 10229)

## Infrared Spectrometry

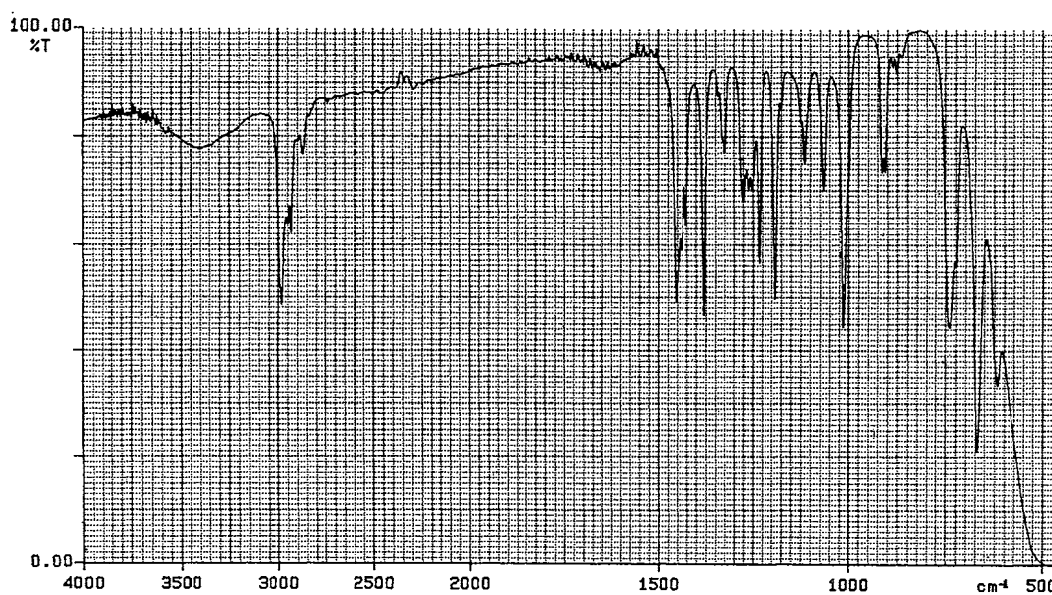
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4  $\text{cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data\*

Results: The infrared spectrum was consistent with literature spectrum.

(\*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Conclusions: The test substance was identified as 1,2-dichloropropane by the mass spectrum and the infrared spectrum.

## APPENDIX J 2

### STABILITY OF 1,2 - DICHLOROPROPANE IN THE 2-WEEK INHALATION STUDY

## STABILITY OF 1,2-DICHLOROPROPANE IN THE 2-WEEK INHALATION STUDY

Test Substance : 1,2-Dichloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : LDR4974

1. Sample : This lot was used from 2001.4.10 to 2001.4.23. Test substance was stored in a dark place at room temperature.

## 2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone ( 0.53 mm $\phi$   $\times$  60 m)

Column Temperature: 100° C

Flow Rate : 15 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1  $\mu$ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
2001.03.26	1	3.692	100
2001.04.25	1	3.688	100

Results: Gas chromatography indicated one major peak (peak No.1) analyzed on 2001.3.26 and one major peak (peak No.1) analyzed on 2001.4.25. No new trace impurity peak in the test substance analyzed on 2001.4.25 was detected.

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

## APPENDIX K 1

CONCENTRATION OF 1,2 - DICHLOROPROPANE IN THE INHALATION CHAMBER OF  
THE 2-WEEK INHALATION STUDY

CONCENTRATION OF 1,2-DICHLOROPROPANE IN THE INHALATION CHAMBER  
OF THE 2-WEEK INHALATION STUDY

Group Name	Concentration(ppm)
	Mean $\pm$ S.D.
Control	0.0 $\pm$ 0.0
125ppm	125.3 $\pm$ 0.6
250ppm	250.4 $\pm$ 0.9
500ppm	500.5 $\pm$ 1.5
1000ppm	989.8
2000ppm	1996.7



## APPENDIX K 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION  
STUDY OF 1,2 - DICHLOROPROPANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF  
1,2-DICHLOROPROPANE

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Change(time/h) Mean
Control	21.7 ± 0.1	58.6 ± 0.7	104.5 ± 0.4	12.1
125ppm	21.8 ± 0.1	58.3 ± 0.6	104.5 ± 0.2	12.1
250ppm	21.7 ± 0.1	58.8 ± 0.8	104.3 ± 0.2	12.0
500ppm	21.1 ± 0.1	57.6 ± 0.9	104.2 ± 0.3	12.0
1000ppm	21.3 ± 0.4	57.6 ± 1.6	104.7 ± 0.4	12.1
2000ppm	21.8 ± 0.4	55.6 ± 3.0	105.2 ± 0.1	12.1

## APPENDIX L 1

### METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF 1,2 - DICHLOROPROPANE

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE  
2-WEEK INHALATION STUDY OF 1,2-DICHLOROPROPANE

Item	Method
<b>Hematology</b>	
Red blood cell (RBC)	Light scattering method <sup>1)</sup>
Hemoglobin (Hgb)	Cyanmethemoglobin method <sup>1)</sup>
Hematocrit (Hct)	Calculated as $RBC \times MCV/10$ <sup>1)</sup>
Mean corpuscular volume (MCV)	Light scattering method <sup>1)</sup>
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb/RBC \times 10$ <sup>1)</sup>
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb/Hct \times 100$ <sup>1)</sup>
Platelet	Light scattering method <sup>1)</sup>
White blood cell (WBC)	Light scattering method <sup>1)</sup>
Differential WBC	Pattern recognition method <sup>2)</sup> (Wright staining)
<b>Biochemistry</b>	
Total protein (TP)	Biuret method <sup>3)</sup>
Albumin (Alb)	BCG method <sup>3)</sup>
A/G ratio	Calculated as $Alb/(TP - Alb)$ <sup>3)</sup>
T-bilirubin	Alkaline azobilirubin method <sup>3)</sup>
Glucose	GlcK·G-6-PDH method <sup>3)</sup>
T-cholesterol	CE·COD·POD method <sup>3)</sup>
Triglyceride	LPL·GK·GPO·POD method <sup>3)</sup>
Phospholipid	PLD·ChOD·POD method <sup>3)</sup>
Glutamic oxaloacetic transaminase (GOT)	JSCC method <sup>3)</sup>
Glutamic pyruvic transaminase (GPT)	JSCC method <sup>3)</sup>
Lactate dehydrogenase (LDH)	SFBC method <sup>3)</sup>
Alkaline phosphatase (ALP)	GSCC method <sup>3)</sup>
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -Glutamyl-p-nitroanilide method <sup>3)</sup>
Creatine phosphokinase (CPK)	JSCC method <sup>3)</sup>
Urea nitrogen	Urease·GLDH method <sup>3)</sup>
Sodium	Ion selective electrode method <sup>3)</sup>
Potassium	Ion selective electrode method <sup>3)</sup>
Chloride	Ion selective electrode method <sup>3)</sup>
Calcium	OCPC method <sup>3)</sup>
Inorganic phosphorus	PNP·XOD·POD method <sup>3)</sup>

1) Automatic blood cell analyzer (ADVIA 120 : Bayer Corporation, USA)

2) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation, Japan)

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd., Japan)

## APPENDIX L 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK  
INHALATION STUDY OF 1,2 - DICHLOROPROPANE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY  
IN THE 2-WEEK INHALATION STUDY OF 1,2-DICHLOROPROPANE

Item	Unit	Decimal place
<b>Hematology</b>		
Red blood cell (RBC)	$\times 10^6 / \mu\text{L}$	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	$\times 10^3 / \mu\text{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu\text{L}$	2
Differential WBC	%	0
<b>Biochemistry</b>		
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 transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1