

1-ブロモ-3-クロロプロバンのマウスを用いた
吸入による 13 週間毒性試験報告書

試験番号：0398

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(13-WEEK STUDY)
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APPENDIX A 1

BODY WEIGHT CHANGES : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 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	6-7
Control	23.2± 0.9	24.4± 1.4	25.6± 1.3	26.3± 1.3	27.0± 1.4	27.6± 1.9	28.5± 1.5
25ppm	23.2± 0.9	24.4± 1.1	24.9± 0.8	25.5± 1.0	25.8± 1.1	26.8± 1.2	27.3± 1.2
50ppm	23.3± 0.8	24.5± 1.2	25.1± 1.3	25.3± 1.5	25.9± 1.4	26.6± 1.4	27.1± 1.4
100ppm	23.2± 0.8	24.2± 1.1	24.7± 1.1	25.2± 1.1	25.8± 1.0	26.3± 1.2	26.9± 1.1*
200ppm	23.2± 0.9	24.2± 0.9	24.7± 1.1	25.4± 1.0	25.9± 1.3	26.4± 1.4	26.8± 1.7*
400ppm	23.2± 0.9	22.8± 1.3*	23.2± 1.1**	23.8± 1.0**	23.9± 0.7**	24.8± 0.8**	25.4± 0.9**

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

Test of Dunnett

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 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	13-7
Control	29.2± 1.6	29.8± 2.0	30.3± 1.8	31.0± 2.2	31.6± 2.2	32.5± 2.2	32.7± 2.3
25ppm	27.7± 1.2	28.0± 1.1*	29.0± 1.1	29.3± 1.2	29.6± 1.6	30.1± 1.4*	30.5± 1.4
50ppm	28.1± 1.5	28.3± 1.6	29.3± 1.6	29.9± 2.0	30.1± 1.8	30.9± 2.0	31.2± 2.2
100ppm	27.1± 1.2**	27.6± 1.3**	28.2± 1.5*	28.7± 1.7*	29.0± 1.8**	29.4± 1.7**	29.7± 2.5**
200ppm	27.0± 1.6**	27.4± 1.7**	28.2± 1.6*	28.7± 1.6*	29.2± 1.8*	29.8± 1.9**	30.2± 2.1*
400ppm	26.0± 1.3**	26.2± 1.2**	26.7± 1.5**	27.2± 1.4**	27.5± 1.5**	27.8± 1.3**	28.5± 1.1**

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

Test of Dunnett

APPENDIX A 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

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	19.1± 0.6	19.6± 0.7	20.5± 1.2	21.0± 1.2	21.9± 1.3	22.3± 1.2	22.3± 1.5
25ppm	19.1± 0.7	19.9± 1.0	21.0± 1.0	21.2± 1.1	21.8± 0.9	22.8± 0.8	23.3± 0.8
50ppm	19.1± 0.7	19.6± 0.7	20.7± 0.9	21.0± 0.9	21.6± 1.2	22.7± 1.0	22.6± 0.8
100ppm	19.1± 0.7	20.0± 0.7	20.5± 0.6	21.3± 0.9	22.3± 1.0	22.6± 1.3	23.6± 1.3*
200ppm	19.1± 0.7	19.2± 1.0	20.2± 0.8	20.6± 1.0	21.3± 0.9	21.9± 0.7	22.2± 0.9
400ppm	19.1± 0.7	19.0± 0.8	19.4± 0.7*	19.5± 0.6**	19.8± 0.7**	20.5± 0.7**	20.9± 0.8*

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 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	13-7
Control	23.2± 1.7	23.3± 1.7	23.6± 1.4	23.7± 1.1	23.8± 1.7	24.4± 1.3	24.5± 1.6
25ppm	23.4± 1.0	23.6± 0.9	24.0± 0.8	24.8± 0.8	24.1± 0.7	25.4± 1.4	24.8± 0.8
50ppm	23.5± 1.0	23.6± 0.9	23.9± 0.8	24.1± 0.7	24.5± 1.0	25.1± 0.9	24.8± 0.8
100ppm	23.4± 1.0	23.7± 0.8	24.2± 1.0	24.8± 1.0	24.5± 1.0	24.8± 1.0	24.8± 1.1
200ppm	22.2± 1.0	22.7± 1.1	23.2± 1.2	23.9± 0.9	23.5± 1.0	24.1± 0.9	24.5± 1.1
400ppm	21.4± 1.1**	22.1± 0.8	22.1± 1.0*	22.2± 1.0**	22.7± 1.1	23.1± 1.3	23.1± 1.1*
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS 3

APPENDIX B 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.1± 0.5	4.3± 0.2	4.2± 0.2	4.2± 0.3	4.1± 0.4	4.4± 0.3	4.4± 0.3
25ppm	4.1± 0.2	4.0± 0.3	4.0± 0.2	4.0± 0.2	4.1± 0.2	4.1± 0.1*	4.1± 0.2
50ppm	4.1± 0.4	4.0± 0.2	4.0± 0.3	4.1± 0.3	4.2± 0.2	4.2± 0.3	4.3± 0.3
100ppm	4.0± 0.2	4.1± 0.2	4.1± 0.4	4.2± 0.5	4.3± 0.3	4.4± 0.3	4.4± 0.3
200ppm	4.0± 0.1	4.0± 0.4	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.2± 0.3	4.3± 0.3
400ppm	3.5± 0.4**	3.8± 0.2**	3.9± 0.2	3.9± 0.2	4.2± 0.2	4.2± 0.1	4.2± 0.2

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

Test of Dunnett

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 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)	13-7(7)
Control	4.4± 0.3	4.3± 0.3	4.4± 0.4	4.5± 0.3	4.6± 0.3	4.5± 0.4
25ppm	4.3± 0.2	4.3± 0.2	4.3± 0.3	4.2± 0.3*	4.4± 0.2	4.4± 0.2
50ppm	4.4± 0.3	4.6± 0.3	4.6± 0.3	4.4± 0.2	4.5± 0.3	4.5± 0.3
100ppm	4.6± 0.3	4.7± 0.3**	4.6± 0.3	4.5± 0.2	4.6± 0.2	4.6± 0.3
200ppm	4.3± 0.3	4.4± 0.3	4.5± 0.3	4.2± 0.3*	4.5± 0.3	4.4± 0.4
400ppm	4.2± 0.2	4.4± 0.2	4.3± 0.2	4.1± 0.1**	4.3± 0.2	4.3± 0.1
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

APPENDIX B 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.4± 0.3	3.5± 0.3	3.7± 0.2	3.8± 0.3	3.9± 0.2	4.0± 0.3	4.2± 0.3
25ppm	3.5± 0.3	3.7± 0.2	3.8± 0.2	4.0± 0.2	4.1± 0.1	4.2± 0.2	4.2± 0.2
50ppm	3.4± 0.3	3.6± 0.2	3.7± 0.3	3.9± 0.2	4.3± 0.1**	4.4± 0.2**	4.6± 0.1**
100ppm	3.4± 0.3	3.6± 0.2	3.9± 0.3	4.2± 0.4	4.3± 0.4	4.5± 0.3**	4.5± 0.3*
200ppm	3.2± 0.3	3.4± 0.2	3.7± 0.1	3.7± 0.2	3.9± 0.2	4.0± 0.2	4.0± 0.2
400ppm	3.0± 0.4**	3.3± 0.2	3.2± 0.2**	3.4± 0.1*	3.7± 0.2	3.6± 0.2*	3.8± 0.2**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	4.1± 0.3	4.1± 0.3	4.1± 0.2	4.1± 0.4	4.2± 0.3	4.2± 0.3
25ppm	4.3± 0.2	4.3± 0.1	4.4± 0.2**	4.1± 0.2	4.5± 0.4*	4.2± 0.2
50ppm	4.6± 0.1**	4.6± 0.2**	4.7± 0.2**	4.7± 0.3**	4.8± 0.2**	4.7± 0.2**
100ppm	4.5± 0.2**	4.7± 0.3**	4.6± 0.2**	4.4± 0.3	4.6± 0.3*	4.6± 0.4
200ppm	4.1± 0.3	4.3± 0.3	4.3± 0.1	4.0± 0.2	4.2± 0.2	4.2± 0.3
400ppm	3.8± 0.2*	4.0± 0.2	4.0± 0.2	3.9± 0.2	4.0± 0.2	3.9± 0.1
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						

APPENDIX C 1

URINALYSIS : MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH_____								CHI	Protein_____						CHI	Glucose_____						CHI	Ketone body						CHI	Occult blood						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+	4+		
Control	10	0	0	0	0	1	5	4		0	0	9	1	0	0		10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0	0			
25ppm	10	0	1	1	0	1	5	2		0	0	10	0	0	0		10	0	0	0	0	0		1	6	3	0	0	0		10	0	0	0	0			
50ppm	10	0	0	0	0	3	6	1		0	0	9	1	0	0		10	0	0	0	0	0		0	6	4	0	0	0		10	0	0	0	0			
100ppm	10	0	0	0	0	5	2	3		0	0	8	2	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0			
200ppm	10	0	3	0	0	3	4	0	*	0	0	6	4	0	0		10	0	0	0	0	0		0	2	8	0	0	0	**	10	0	0	0	0			
400ppm	10	0	1	2	1	3	3	0		0	0	3	6	1	0	*	10	0	0	0	0	0		0	1	9	0	0	0	**	10	0	0	0	0			

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0398

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0
25ppm	10	10 0 0 0 0
50ppm	10	10 0 0 0 0
100ppm	10	10 0 0 0 0
200ppm	10	10 0 0 0 0
400ppm	10	10 0 0 0 0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX C 2

URINALYSIS : MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				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	2	3	5	0		0	0	5	5	0	0		10	0	0	0	0	0		1	5	4	0	0	0		10	0	0	0	0
25ppm	10	0	0	0	0	1	9	0		0	0	9	1	0	0		10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0	0
50ppm	10	0	0	0	0	5	5	0		0	2	6	2	0	0		10	0	0	0	0	0		1	7	2	0	0	0		10	0	0	0	0
100ppm	10	0	0	0	1	2	7	0		0	2	5	3	0	0		10	0	0	0	0	0		2	5	3	0	0	0		10	0	0	0	0
200ppm	10	0	1	2	1	1	5	0		0	0	5	5	0	0		10	0	0	0	0	0		0	3	6	1	0	0		10	0	0	0	0
400ppm	10	0	1	0	2	2	5	0		0	1	3	6	0	0		10	0	0	0	0	0		0	4	5	1	0	0		10	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0398

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen					CHI
		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0
25ppm	10	10	0	0	0	0	0
50ppm	10	10	0	0	0	0	0
100ppm	10	10	0	0	0	0	0
200ppm	10	10	0	0	0	0	0
400ppm	10	10	0	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

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	9	10.79±	0.27	15.7±	0.4	50.0±	1.0	46.4±	0.7	14.6±	0.2	31.4±	0.3	1369±	63
25ppm	9	10.91±	0.21	15.7±	0.4	50.2±	1.1	46.0±	0.5	14.4±	0.2	31.4±	0.7	1422±	71
50ppm	10	10.99±	0.34	15.8±	0.5	50.4±	1.6	45.9±	0.6	14.3±	0.2	31.3±	0.4	1281±	322
100ppm	10	10.68±	0.29	15.6±	0.4	49.7±	1.1	46.6±	0.8	14.6±	0.3	31.5±	0.7	1324±	150
200ppm	10	10.51±	0.37	15.4±	0.4	49.4±	1.6	47.0±	0.5	14.7±	0.2	31.2±	0.3	1331±	83
400ppm	10	9.94±	0.26**	14.8±	0.4**	48.2±	1.3*	48.5±	0.5**	14.9±	0.1**	30.8±	0.3**	1385±	82

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	9	1.51±	0.75	1±	1	16±	3	2±	1	0±	0	5±	2	76±	5	0±	0
25ppm	9	1.67±	0.76	2±	2	16±	5	1±	1	0±	0	5±	1	77±	6	0±	0
50ppm	10	2.06±	1.24	1±	1	16±	4	2±	2	0±	0	5±	2	76±	5	0±	0
100ppm	10	1.38±	0.79	1±	1	14±	3	1±	1	0±	0	4±	2	80±	4	0±	0
200ppm	10	1.53±	1.04	1±	1	12±	3	2±	1	0±	0	6±	2	80±	4	0±	0
400ppm	10	1.25±	0.75	0±	0	18±	5	2±	3	0±	0	5±	2	75±	7	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 3

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	10.75±	0.15	16.0±	0.2	50.3±	1.1	46.8±	0.8	14.9±	0.2	31.9±	0.3	1249±	96
25ppm	10	10.66±	0.19	15.7±	0.3	49.5±	1.0	46.5±	0.6	14.7±	0.1	31.7±	0.4	1265±	84
50ppm	9	10.66±	0.31	15.8±	0.5	49.3±	1.6	46.2±	0.6	14.8±	0.1	32.1±	0.3	1232±	65
100ppm	10	10.54±	0.42	15.7±	0.5	49.3±	1.8	46.8±	0.8	14.9±	0.3	31.8±	0.5	1193±	138
200ppm	9	10.62±	0.24	15.9±	0.3	50.3±	1.4	47.3±	0.6	15.0±	0.1	31.7±	0.5	1214±	84
400ppm	10	10.13±	0.26**	15.6±	0.5	49.2±	1.8	48.5±	0.9**	15.3±	0.2*	31.6±	0.6	1231±	48

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	1.11±	0.74	1±	1	19±	5	1±	1	0±	0	3±	2	77±	6	0±	0
25ppm	10	0.91±	0.58	1±	1	19±	6	1±	1	0±	0	3±	2	77±	5	0±	0
50ppm	9	0.85±	0.60	1±	1	20±	3	0±	1	0±	0	4±	3	75±	4	0±	0
100ppm	10	0.63±	0.75	0±	1	23±	9	0±	1	0±	0	4±	2	73±	8	0±	0
200ppm	9	1.54±	0.67	1±	1	16±	5	2±	1	0±	0	3±	2	78±	4	0±	0
400ppm	10	1.73±	0.82	2±	1	23±	11	3±	2	0±	0	4±	2	69±	10*	0±	0

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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	9	5.0±	0.2	3.0±	0.1	1.5±	0.1	0.16±	0.04	214±	31	82±	9	30±	14
25ppm	10	5.1±	0.2	3.1±	0.1	1.5±	0.2	0.16±	0.03	229±	37	79±	7	28±	9
50ppm	10	5.1±	0.3	3.1±	0.2	1.5±	0.0	0.15±	0.03	221±	39	78±	11	28±	13
100ppm	10	5.0±	0.3	3.0±	0.2	1.5±	0.1	0.13±	0.02	203±	35	80±	12	18±	6*
200ppm	10	4.9±	0.3	3.0±	0.1	1.6±	0.1	0.16±	0.09	207±	40	82±	16	23±	9
400ppm	10	5.0±	0.1	3.0±	0.1	1.6±	0.1	0.15±	0.02	187±	54	86±	10	20±	6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

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	9	173±	23	44±	7	19±	3	229±	68	134±	11	2±	1	66±	17
25ppm	10	168±	19	47±	8	17±	4	252±	79	140±	8	2±	1	78±	35
50ppm	10	166±	22	42±	9	18±	3	249±	68	134±	11	1±	1	80±	36
100ppm	10	158±	22	45±	16	18±	4	204±	62	137±	6	2±	1	71±	61
200ppm	10	157±	27	45±	17	19±	4	208±	70	134±	12	2±	1	69±	31
400ppm	10	156±	10	46±	15	19±	5	229±	54	129±	8	2±	1	66±	29

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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	9	28.1±	4.4	151±	1	4.6±	0.3	121±	1	8.5±	0.2	6.7±	1.0
25ppm	10	30.2±	6.0	151±	2	4.9±	0.6	122±	3	8.6±	0.2	7.2±	1.2
50ppm	10	29.2±	4.0	151±	1	4.7±	0.6	124±	2	8.6±	0.3	6.9±	1.0
100ppm	10	29.7±	6.5	151±	1	4.7±	0.5	125±	5*	8.6±	0.3	6.9±	0.9
200ppm	10	27.4±	3.5	151±	1	4.6±	0.4	131±	3**	8.5±	0.2	6.5±	0.9
400ppm	10	28.1±	4.9	151±	2	5.1±	0.5	139±	5**	8.6±	0.1	7.0±	0.9

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

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX E 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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	10	5.1±	0.1	3.2±	0.1	1.8±	0.1	0.14±	0.01	175±	21	65±	7	16±	6
25ppm	10	5.0±	0.1	3.2±	0.1	1.8±	0.0	0.12±	0.01	147±	22*	70±	9	19±	8
50ppm	10	5.2±	0.2	3.3±	0.1	1.8±	0.0	0.14±	0.03	179±	14	73±	8	15±	6
100ppm	10	5.1±	0.1	3.2±	0.1	1.8±	0.1	0.14±	0.03	201±	28	78±	7**	15±	5
200ppm	9	5.0±	0.2	3.2±	0.1	1.8±	0.1	0.13±	0.03	189±	30	82±	7**	15±	4
400ppm	10	4.9±	0.1	3.1±	0.1	1.8±	0.1	0.14±	0.02	167±	25	86±	10**	17±	4

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

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	10	136±	20	54±	12	21±	4	236±	78	216±	14	2±	1	84±	69
25ppm	10	143±	25	63±	19	24±	5	292±	136	214±	24	2±	1	113±	121
50ppm	10	144±	21	62±	17	24±	4	299±	98	224±	22	1±	1	144±	127
100ppm	10	146±	19	60±	13	23±	4	309±	90	210±	34	2±	1	142±	106*
200ppm	9	153±	15	42±	4*	18±	2	204±	57	201±	18	1±	1	62±	22
400ppm	10	147±	15	46±	16	18±	3	220±	77	193±	16	2±	1	58±	30

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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	10	23.4±	2.4	151±	2	4.5±	0.3	122±	1	8.6±	0.1	5.9±	0.6
25ppm	10	24.2±	5.1	151±	2	4.2±	0.5	122±	2	8.6±	0.2	6.9±	1.4
50ppm	10	24.3±	3.7	151±	2	4.5±	0.3	124±	3	8.6±	0.3	6.1±	1.0
100ppm	10	25.5±	3.1	151±	1	4.2±	0.5	127±	3*	8.7±	0.2	6.4±	0.6
200ppm	9	23.0±	2.2	151±	2	4.7±	0.4	133±	4**	8.7±	0.2	5.8±	0.7
400ppm	10	19.1±	3.0*	151±	1	4.8±	0.4	138±	5**	8.6±	0.2	6.6±	0.9

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

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX F 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE

ALL ANIMALS (13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		25ppm		50ppm		100ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
spleen	black zone		0	(0)	0	(0)	1	(10)	1	(10)
kidney	hydronephrosis		2	(20)	0	(0)	0	(0)	1	(10)

(HPT080)

BAIS 3

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	200ppm		400ppm	
			10	(%)	10	(%)
spleen	black zone		1	(10)	0	(0)
kidney	hydronephrosis		0	(0)	1	(10)

(HPT080)

BAIS 3

APPENDIX F 2

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE

ALL ANIMALS (13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		25ppm		50ppm		100ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
spleen	black zone		1	(10)	1	(10)	0	(0)	2	(20)

(HPT080)

BAIS 3

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 4

Organ	Findings	Group Name		200ppm		400ppm	
		NO. of Animals	10	(%)	10	(%)	
spleen	black zone		1	(10)		1	(10)

(HPT080)

BAIS 3

APPENDIX G 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	29.2± 2.5	0.036± 0.006	0.009± 0.002	0.234± 0.018	0.158± 0.012	0.154± 0.007
25ppm	10	27.1± 1.5	0.033± 0.005	0.009± 0.001	0.214± 0.031	0.153± 0.009	0.148± 0.009
50ppm	10	27.8± 1.9	0.034± 0.007	0.010± 0.002	0.216± 0.042	0.155± 0.013	0.158± 0.009
100ppm	10	26.3± 2.1**	0.031± 0.008	0.008± 0.002	0.238± 0.026	0.151± 0.011	0.156± 0.011
200ppm	10	26.6± 2.0*	0.029± 0.004*	0.008± 0.002	0.216± 0.037	0.148± 0.008	0.155± 0.007
400ppm	10	25.2± 1.5**	0.027± 0.004**	0.010± 0.003	0.219± 0.021	0.148± 0.007	0.154± 0.010

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.448±	0.077	0.047±	0.006	1.144±	0.068	0.430±	0.013
25ppm	10	0.417±	0.014	0.045±	0.005	1.097±	0.049	0.433±	0.015
50ppm	10	0.430±	0.018	0.047±	0.014	1.158±	0.076	0.432±	0.008
100ppm	10	0.516±	0.281	0.046±	0.009	1.124±	0.092	0.433±	0.015
200ppm	10	0.423±	0.030	0.041±	0.004	1.147±	0.089	0.432±	0.015
400ppm	10	0.513±	0.204	0.037±	0.004**	1.163±	0.038	0.420±	0.013

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

(13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	20.7± 1.2	0.037± 0.005	0.011± 0.002	0.007± 0.001	0.126± 0.008	0.146± 0.009
25ppm	10	21.2± 0.8	0.036± 0.006	0.012± 0.002	0.006± 0.001	0.129± 0.006	0.149± 0.005
50ppm	10	20.9± 0.7	0.037± 0.006	0.012± 0.002	0.007± 0.002	0.132± 0.008	0.151± 0.011
100ppm	10	21.0± 0.8	0.036± 0.005	0.012± 0.003	0.007± 0.002	0.129± 0.010	0.151± 0.009
200ppm	10	20.9± 1.0	0.034± 0.003	0.010± 0.001	0.007± 0.002	0.127± 0.006	0.151± 0.009
400ppm	10	20.1± 1.0	0.034± 0.006	0.010± 0.002	0.006± 0.001	0.123± 0.008	0.147± 0.009

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.292±	0.016	0.049±	0.007	0.895±	0.062	0.441±	0.016
25ppm	10	0.296±	0.015	0.050±	0.006	0.939±	0.068	0.452±	0.012
50ppm	10	0.294±	0.015	0.049±	0.008	0.934±	0.068	0.452±	0.013
100ppm	10	0.302±	0.014	0.051±	0.007	0.934±	0.063	0.449±	0.019
200ppm	10	0.307±	0.023	0.047±	0.005	0.950±	0.061	0.447±	0.012
400ppm	10	0.314±	0.019*	0.041±	0.006*	0.934±	0.042	0.425±	0.020

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX H 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	29.2± 2.5	0.123± 0.015	0.032± 0.007	0.802± 0.046	0.541± 0.039	0.529± 0.035
25ppm	10	27.1± 1.5	0.122± 0.012	0.032± 0.002	0.791± 0.093	0.566± 0.027	0.550± 0.052
50ppm	10	27.8± 1.9	0.121± 0.022	0.035± 0.007	0.779± 0.149	0.557± 0.036	0.568± 0.028
100ppm	10	26.3± 2.1**	0.117± 0.024	0.032± 0.006	0.906± 0.070*	0.576± 0.038	0.596± 0.040**
200ppm	10	26.6± 2.0*	0.108± 0.011	0.031± 0.008	0.813± 0.141	0.559± 0.048	0.587± 0.044*
400ppm	10	25.2± 1.5**	0.107± 0.015	0.039± 0.012	0.872± 0.093	0.590± 0.046	0.611± 0.043**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.539± 0.295	0.163± 0.024	3.924± 0.163	1.480± 0.125
25ppm	10	1.543± 0.085	0.165± 0.020	4.060± 0.206	1.604± 0.129
50ppm	10	1.552± 0.087	0.168± 0.048	4.168± 0.151*	1.559± 0.117
100ppm	10	1.974± 1.092*	0.174± 0.031	4.278± 0.235**	1.655± 0.119*
200ppm	10	1.596± 0.096	0.153± 0.012	4.322± 0.211**	1.636± 0.145*
400ppm	10	2.038± 0.782**	0.148± 0.017	4.634± 0.259**	1.677± 0.123**

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX H 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	20.7± 1.2	0.181± 0.021	0.053± 0.009	0.033± 0.006	0.609± 0.044	0.708± 0.027
25ppm	10	21.2± 0.8	0.168± 0.025	0.056± 0.009	0.030± 0.006	0.610± 0.026	0.702± 0.030
50ppm	10	20.9± 0.7	0.176± 0.030	0.057± 0.009	0.034± 0.007	0.630± 0.033	0.721± 0.045
100ppm	10	21.0± 0.8	0.169± 0.018	0.056± 0.012	0.034± 0.010	0.617± 0.042	0.719± 0.034
200ppm	10	20.9± 1.0	0.162± 0.018	0.050± 0.008	0.034± 0.009	0.610± 0.031	0.723± 0.030
400ppm	10	20.1± 1.0	0.169± 0.025	0.052± 0.008	0.031± 0.006	0.615± 0.034	0.731± 0.043

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.416± 0.065	0.237± 0.019	4.334± 0.183	2.142± 0.146
25ppm	10	1.398± 0.083	0.238± 0.028	4.434± 0.207	2.138± 0.069
50ppm	10	1.410± 0.066	0.235± 0.030	4.471± 0.245	2.169± 0.080
100ppm	10	1.444± 0.082	0.241± 0.029	4.452± 0.189	2.145± 0.086
200ppm	10	1.469± 0.086	0.224± 0.015	4.548± 0.171	2.145± 0.104
400ppm	10	1.566± 0.060**	0.205± 0.028*	4.654± 0.112**	2.121± 0.147

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

(HCL042)

BAIS 3

APPENDIX I 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : ALL ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 1

		Group Name	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study	10				10				10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<10>				<10>				<10>				<10>			
	eosinophilic change:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		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)
	respiratory metaplasia:gland		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	desquamation:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
nasopharynx			<10>				<10>				<10>				<10>			
	eosinophilic change		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)
{Hematopoietic system}																		
spleen			<10>				<10>				<10>				<10>			
	deposit of melanin		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(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. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	200ppm				400ppm			
		No. of Animals on Study				No. of Animals on Study			
		Grade				Grade			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}									
nasal cavit		<10>				<10>			
	eosinophilic change:olfactory epithelium	0	0	0	0	9	0	0	0 **
		(0)	(0)	(0)	(0)	(90)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium	0	0	0	0	3	0	0	0
		(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	respiratory metaplasia:gland	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	desquamation:olfactory epithelium	0	0	0	0	3	0	0	0
		(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	atrophy:olfactory epithelium	0	0	0	0	6	0	0	0 *
		(0)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
	hyperplasia:respiratory epithelium	0	0	0	0	6	0	0	0 *
		(0)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
nasopharynx		<10>				<10>			
	eosinophilic change	0	0	0	0	4	0	0	0
		(0)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
{Hematopoietic system}									
spleen		<10>				<10>			
	deposit of melanin	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 : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study				10				10				10			
		Grade				1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																	
spleen	follicular hyperplasia	<10>				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)
{Digestive system}																	
stomach	edema	<10>				0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	erosion:forestomach	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:forestomach	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0 *
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
liver	granulation	<10>				5	0	0	0	6	0	0	0	7	0	0	0
		(50)	(0)	(0)	(0)	(60)	(0)	(0)	(0)	(60)	(0)	(0)	(0)	(70)	(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. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 4

Organ	Findings	Group Name		200ppm				400ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}											
spleen	follicular hyperplasia			<10>				<10>			
				0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}											
stomach	edema			<10>				<10>			
				0	0	0	0	2	0	0	0
				(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	inflammatory infiltration			2	0	0	0	6	0	0	0 *
				(20)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
	erosion:forestomach			1	0	0	0	4	0	0	0
				(10)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
	hyperplasia:forestomach			6	2	0	0 **	1	5	4	0 **
				(60)	(20)	(0)	(0)	(10)	(50)	(40)	(0)
liver	granulation			<10>				<10>			
				5	0	0	0	3	0	0	0
				(50)	(0)	(0)	(0)	(30)	(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. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 5

Organ	Findings	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study				10				10				10			
		Grade				10				10				10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																	
liver		<10>				<10>				<10>				<10>			
	perivascular inflammation	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
		(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Urinary system}																	
kidney		<10>				<10>				<10>				<10>			
	basophilic change	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)
	hydronephrosis	0	0	2	0	0	0	0	0	0	0	0	0	0	0	1	0
		(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)
{Endocrine system}																	
thyroid		<10>				<10>				<10>				<10>			
	cyst	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)
{Reproductive system}																	
epididymis		<10>				<10>				<10>				<10>			
	spermatogenic granuloma	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)

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. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 6

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ_____	Findings_____	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
{Digestive system}										
liver			<10>				<10>			
	perivascular inflammation		2	0	0	0	0	0	0	0
			(20)	(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)
	hydronephrosis		0	0	0	0	0	0	1	0
			(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)
{Endocrine system}										
thyroid			<10>				<10>			
	cyst		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}										
epididymis			<10>				<10>			
	spermatogenic granuloma		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 ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

APPENDIX I 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE: ALL ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0398
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 7

		Group Name	Control				25ppm				50ppm				100ppm			
		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
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit		<10>																
	eosinophilic change:olfactory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		2	0	0	0	1	0	0	0	3	0	0	0	2	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	desquamation:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
nasopharynx		<10>																
	eosinophilic change		0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Hematopoietic system}																		
spleen		<10>																
	deposit of melanin		1	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(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. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 8

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			<10>				<10>			
	eosinophilic change:olfactory epithelium		1	0	0	0	4	6	0	0 **
			(10)	(0)	(0)	(0)	(40)	(60)	(0)	(0)
	eosinophilic change:respiratory epithelium		2	0	0	0	6	4	0	0 **
			(20)	(0)	(0)	(0)	(60)	(40)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	desquamation:olfactory epithelium		0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	4	1	0	0 *
			(0)	(0)	(0)	(0)	(40)	(10)	(0)	(0)
	hyperplasia:respiratory epithelium		0	0	0	0	4	0	0	0
		(0)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	
nasopharynx			<10>				<10>			
	eosinophilic change		1	0	0	0	9	1	0	0 **
			(10)	(0)	(0)	(0)	(90)	(10)	(0)	(0)
{Hematopoietic system}										
spleen			<10>				<10>			
	deposit of melanin		1	0	0	0	1	0	0	0
			(10)	(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. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 9

		Group Name	Control				25ppm				50ppm				100ppm			
		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
Organ_____	Findings_____		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Digestive system}																		
tongue	inflammation		<10>				<10>				<10>				<10>			
			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)	(0)	(0)	(0)	(0)	(0)
stomach	edema		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory infiltration		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)	(0)	(10)	(0)	(0)	(0)
	erosion: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)	(0)	(10)	(0)	(0)	(0)
	hyperplasia:forestomach		0	0	0	0	0	0	0	1	0	0	0	7	2	0	0	**
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(70)	(20)	(0)	(0)	
liver	necrosis:focal		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		6	0	0	0	2	0	0	0	3	0	0	0	5	0	0	0
		(60)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(50)	(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 ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 10

Organ	Findings	200ppm				400ppm			
		No. of Animals on Study				No. of Animals on Study			
		Grade				Grade			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}									
tongue	inflammation	<10>				<10>			
		0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
stomach	edema	<10>				<10>			
		1	0	0	0	3	0	0	0
		(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammatory infiltration	3	0	0	0	9	0	0	0 **
		(30)	(0)	(0)	(0)	(90)	(0)	(0)	(0)
	erosion:forestomach	1	0	0	0	4	0	0	0
		(10)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
liver	hyperplasia:forestomach	4	5	0	0 **	3	3	4	0 **
		(40)	(50)	(0)	(0)	(30)	(30)	(40)	(0)
	necrosis:focal	<10>				<10>			
		1	0	0	0	0	0	0	0
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation	6	0	0	0	6	0	0	0
		(60)	(0)	(0)	(0)	(60)	(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 ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 11

Organ_____	Findings_____	Group Name	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study	10				10				10				10			
		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>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Digestive system}																		
liver			<10>				<10>				<10>				<10>			
	fibrosis:focal		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)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	basophilic change		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																		
pituitary			<10>				<10>				<10>				<10>			
	Rathke pouch		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)	(10)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>				<10>				<10>			
	cyst		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(10)	(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. : 0398
 ANIMAL : MOUSE Crj:BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	200ppm				400ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}										
liver	fibrosis:focal		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}										
kidney	basophilic change		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}										
pituitary	Rathke pouch		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid	cyst		<10>				<10>			
			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
 Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

APPENDIX J 1

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

Test Substance : 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : CKK5616

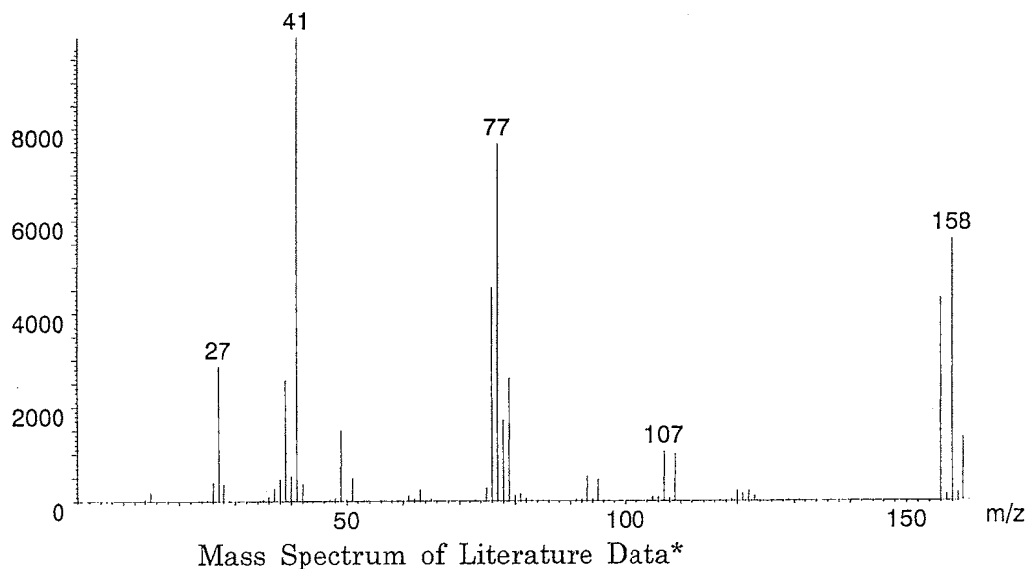
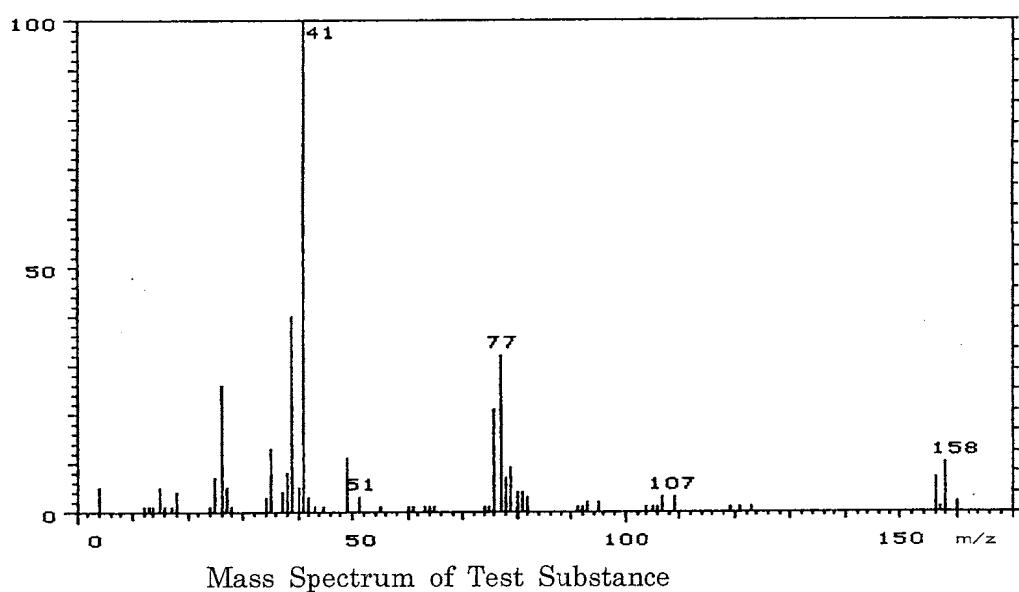
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Results: The mass spectrum was consistent with literature spectrum.

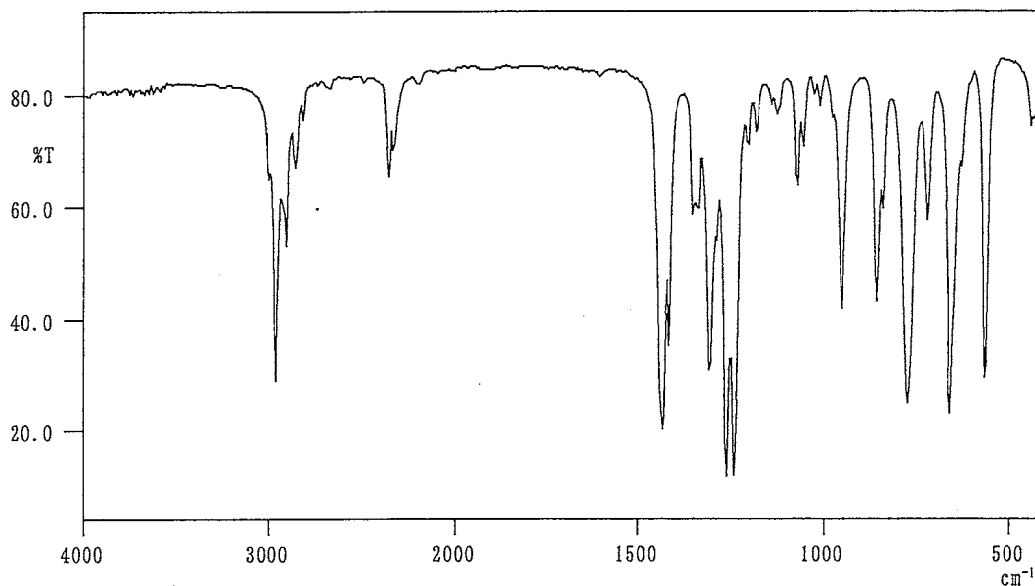
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.
John Wiley and Sons, Inc. (U.S.), Entry Number 41048)

Infrared Spectrometry

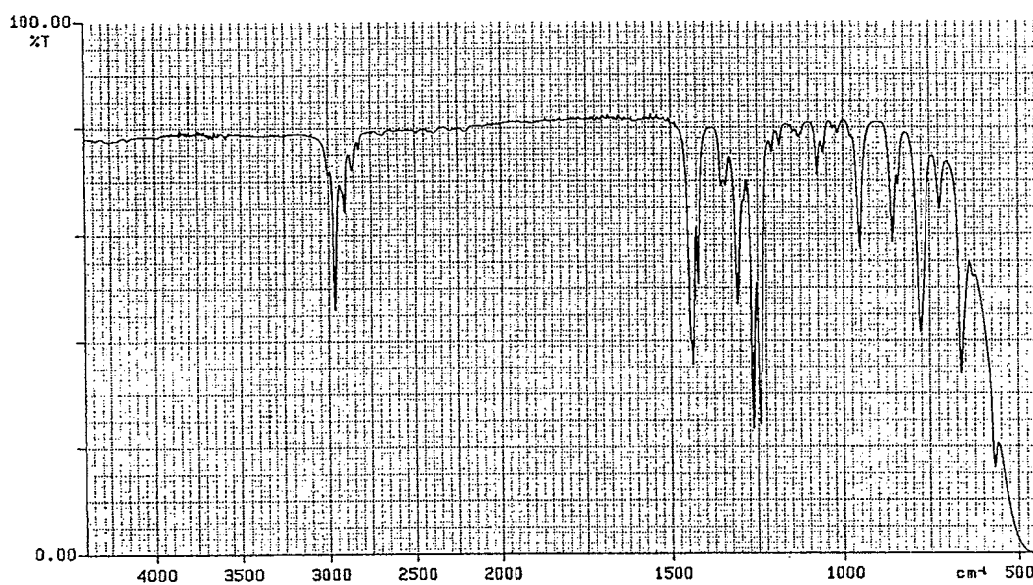
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 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-bromo-3-chloropropane by the mass spectrum and the infrared spectrum.

APPENDIX J 2

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

Test Substance : 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : CKK5616

1. Sample : This lot was used from 1999.9.16 to 1999.12.14. 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 ϕ \times 60 m)

Column Temperature: 100° C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1999.09.08	1	2.012	0.041
	2	7.061	99.959
1999.12.21	1	2.011	0.036
	2	7.041	99.964

Results: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No.1 < 0.1% of total area) analyzed on 1999.9.8 and one major peak (peak No.2) and one impurity (peak No.1 < 0.1% of total area) analyzed on 1999.12.21. No new trace impurity peak in the test substance analyzed on 1999.12.21 was detected.

3. Conclusions: The test substance was stable for about 15 weeks in a dark place at room temperature.

APPENDIX K 1

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE
INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE INHALATION CHAMBER
OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm)		
	Mean \pm S.D.		
0ppm(Control)	0.0	\pm	0.0
25ppm	25.1	\pm	0.4
50ppm	50.4	\pm	0.7
100ppm	100.4	\pm	1.2
200ppm	200.3	\pm	1.9
400ppm	399.7	\pm	3.0

APPENDIX K 2

ENVORONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13 -WEEK INHALATION SYUDY
OF 1-BROMO-3-CHLOROPROPANE

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Change(time/h) Mean
0ppm(Control)	21.9 ± 0.2	58.9 ± 1.0	104.3 ± 1.1	12.0
25ppm	21.7 ± 0.1	58.3 ± 0.5	104.1 ± 1.2	12.0
50ppm	21.7 ± 0.2	59.1 ± 1.5	103.9 ± 1.1	12.0
100ppm	21.6 ± 0.2	57.6 ± 0.8	104.0 ± 1.1	12.0
200ppm	21.6 ± 0.1	57.7 ± 0.6	104.1 ± 1.0	12.0
400ppm	21.6 ± 0.1	57.5 ± 0.8	104.3 ± 1.1	12.0

APPENDIX L 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE
13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method ¹⁾
Hemoglobin (Hgb)	Cyanmethemoglobin method ¹⁾
Hematocrit (Hct)	Calculated as $RBC \times MCV / 10$ ¹⁾
Mean corpuscular volume (MCV)	Light scattering method ¹⁾
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb / RBC \times 10$ ¹⁾
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb / Hct \times 100$ ¹⁾
Platelet	Light scattering method ¹⁾
White blood cell (WBC)	Light scattering method ¹⁾
Differential WBC	Pattern recognition method ²⁾ (Wright staining)
Biochemistry	
Total protein (TP)	Biuret method ³⁾
Albumin (Alb)	BCG method ³⁾
A/G ratio	Calculated as $Alb / (TP - Alb)$ ³⁾
T-bilirubin	Alkaline azobilirubin method ³⁾
Glucose	GlcK • G-6-PDH method ³⁾
T-cholesterol	CE • COD • POD method ³⁾
Triglyceride	LPL • GK • GPO • POD method ³⁾
Phospholipid	PLD • ChOD • POD method ³⁾
Glutamic oxaloacetic transaminase (GOT)	JSCC method ³⁾
Glutamic pyruvic transaminase (GPT)	JSCC method ³⁾
Lactate dehydrogenase (LDH)	SFBC method ³⁾
Alkaline phosphatase (ALP)	GSCC method ³⁾
γ -Glutamyl transpeptidase (γ -GTP)	L- γ -Glutamyl-p-nitroanilide method ³⁾
Creatine phosphokinase (CPK)	JSCC method ³⁾
Urea nitrogen	Urease • GLDH method ³⁾
Sodium	Ion selective electrode method ³⁾
Potassium	Ion selective electrode method ³⁾
Chloride	Ion selective electrode method ³⁾
Calcium	OCPC method ³⁾
Inorganic phosphorus	PNP • XOD • POD method ³⁾
Urinalysis	
pH, Protein, Glucose, Ketone body, Occult Blood, Urobilinogen	Urinalysis reagent paper method ⁴⁾

1) Automatic blood cell analyzer (Technicon H•1 : Bayer Corporation)

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

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

4) Ames reagent strips for urinalysis (Uro-Labstix : Bayer Corporation)

APPENDIX L 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

Item	Unit	Decimal place
Hematology		
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
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 transaminase (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
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1