

1 - クロロ - 2,4 - ジニトロベンゼンのラット及びマウスを用いた
経口投与によるがん原性試験（混餌試験）報告書

APPENDIX

(B1-1～B12-3)

1 3 Week STUDY NO. 0087 ; 0088

APPENDIXES (CONTINUED)

- APPENDIX B 1-1 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 1-2 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 1-3 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 1-4 CLINICAL OBSERVATION (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE
- APPENDIX B 2-1 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 2-2 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 2-3 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 2-4 BODY WEIGHT CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE
- APPENDIX B 3-1 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 3-2 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 3-3 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 3-4 FOOD CONSUMPTION CHANGES (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE
- APPENDIX B 4-1 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:MALE
- APPENDIX B 4-2 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
RAT:FEMALE
- APPENDIX B 4-3 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:MALE
- APPENDIX B 4-4 CHEMICAL INTAKE CHANGES (THIRTEEN-WEEK STUDY:SUMMARY)
MOUSE:FEMALE

APPENDIXES (CONTINUED)

- APPENDIX B 5-1 HEMATOLOGY (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 5-2 HEMATOLOGY (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 5-3 HEMATOLOGY (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 5-4 HEMATOLOGY (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE
- APPENDIX B 6-1 BIOCHEMISTRY (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 6-2 BIOCHEMISTRY (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 6-3 BIOCHEMISTRY (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 6-4 BIOCHEMISTRY (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE
- APPENDIX B 7-1 URINALYSIS (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE
- APPENDIX B 7-2 URINALYSIS (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE
- APPENDIX B 7-3 URINALYSIS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE
- APPENDIX B 7-4 URINALYSIS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE

APPENDIXES (CONTINUED)

- APPENDIX B 8-1 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:MALE:SACRIFICED ANIMALS
- APPENDIX B 8-2 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
RAT:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 8-3 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE:DEAD AND MORIBUND ANIMALS
- APPENDIX B 8-4 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS
- APPENDIX B 8-5 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:MALE:SACRIFICED ANIMALS
- APPENDIX B 8-6 GROSS FINDINGS (THIRTEEN-WEEK STUDIES:SUMMARY)
MOUSE:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 9-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), ABSOLUTE
RAT:MALE
- APPENDIX B 9-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), ABSOLUTE
RAT:FEMALE
- APPENDIX B 9-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), ABSOLUTE
MOUSE:MALE
- APPENDIX B 9-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), ABSOLUTE
MOUSE:FEMALE
- APPENDIX B 10-1 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), RELATIVE
RAT:MALE
- APPENDIX B 10-2 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), RELATIVE
RAT:FEMALE
- APPENDIX B 10-3 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), RELATIVE
MOUSE:MALE
- APPENDIX B 10-4 ORGAN WEIGHT (THIRTEEN-WEEK STUDIES:SUMMARY), RELATIVE
MOUSE:FEMALE

APPENDIXES (CONTINUED)

- APPENDIX B 11-1 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) RAT:MALE:SACRIFICED ANIMALS
- APPENDIX B 11-2 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) RAT:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 11-3 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) MOUSE:MALE:DEAD AND MORIBUND ANIMALS
- APPENDIX B 11-4 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) MOUSE:FEMALE:DEAD AND MORIBUND ANIMALS
- APPENDIX B 11-5 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) MOUSE:MALE:SACRIFICED ANIMALS
- APPENDIX B 11-6 HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS
(THIRTEEN-WEEK STUDIES:SUMMARY) MOUSE:FEMALE:SACRIFICED ANIMALS
- APPENDIX B 12-1 IDENTITY AND PURITY OF CDNB
PERFORMED AT THE JAPAN BIOASSAY LABORATORY
(THIRTEEN-WEEK STUDIES)
- APPENDIX B 12-2 STABILITY OF CDNB
AT THE JAPAN BIOASSAY LABORATORY
(THIRTEEN-WEEK STUDIES)
- APPENDIX B 12-3 RESULTS OF ANALYSIS AND STABILITY OF FORMULATED DIETS
IN THE THIRTEEN-WEEK STUDIES OF CDNB

APPENDIX B 1-1

CLINICAL OBSERVATION : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	1	0	0	0	0	0	0	0	0	0	0	0
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	9	9	8	8	8	9	9	9	9	9	9	9	9
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	1	1	1	1	0	0	0	0	0	0
	4000 ppm	0	0	2	3	2	2	2	2	2	2	2	2	3	3
ABNORMAL TESTIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	1	0	0	0	0	0	0	0

APPENDIX B 1-2

CLINICAL OBSERVATION : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	5	9	9	9	8	8	8	8	8	8	8	8	8
LOSS OF HAIR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	2	2
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	3	5	5	5	5	5	5	5	5	5	5	6	6
	4000 ppm	0	6	10	10	10	10	10	10	10	10	10	10	10	10
LACRYMATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	100 ppm	0	0	0	0	0	0	0	0	1	0	0	0	1	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	1	1	0	0	0	0	1	2	1
GUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	1
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	2
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 2

APPENDIX B 1-3

CLINICAL OBSERVATION : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	2	2	2	3	3	3	3	3	3	3	3
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	1	1	2	1	0	0	0	0	0	1	1
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	5	4	3	3	3	3	3	3	4	4	4	3	3
TREMOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	2	1	1	3	3	2	1	1	1	1	1	1
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	2	2	2	2	1	1	1	1	2	2	2	2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
SOILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	4	4	3	3	3	3	3	3	3	3	3	3	3
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	10	9	8	8	8	7	7	7	7	7	6	5	3
LOSS OF HAIR	Control	0	1	3	4	4	6	6	8	10	10	10	10	10	10
	100 ppm	0	2	2	5	6	7	7	7	7	7	7	8	8	8
	250 ppm	0	1	1	3	3	5	5	5	6	6	6	6	6	6
	640 ppm	0	1	1	1	1	2	2	2	2	2	3	4	4	4
	1600 ppm	0	1	3	3	5	6	7	7	7	7	7	7	7	7
	4000 ppm	0	1	1	2	2	3	3	3	3	3	3	4	4	5
TRAUMA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	1	1	0	0	0	0	0	0	0	1

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 3

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	2	2	2	1	1	1	1	1	1	1	1	1
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	3	3	3	3	1	1	2	2	3	3	3
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	1	2	2	1	0	0	0	0	0	0	0

(HAN190)

BAIS2

APPENDIX B 1-4

CLINICAL OBSERVATION : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 4

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	1	1	2	2	2	2	2	2	2	2	2	2	2
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	1
HUNCHBACK POSITION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	4	5	3	2	2	2	2	2	2	2	1	1	1
TREMOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	0	0	0	0	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	2	2	1	1	1	1	1	1	1	1	1	1

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE : 5

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
SOILED	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	2	0	1	1	1	1	2	2	1	1	1
PILOERECTION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	7	8	7	7	5	3	2	2	2	2	2	2	2
LOSS OF HAIR	Control	0	1	2	2	4	5	6	6	7	7	7	7	7	8
	100 ppm	0	1	1	2	2	3	4	5	5	5	7	7	7	7
	250 ppm	0	0	1	3	2	2	4	5	6	6	8	8	8	8
	640 ppm	0	1	4	5	6	8	8	9	9	9	9	9	9	9
	1600 ppm	0	1	2	4	6	7	7	8	8	8	8	8	8	7
	4000 ppm	0	2	2	1	1	1	2	2	2	2	2	2	3	4
TRAUMA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SOILED PERI GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	0	0	0	2	0	0	0	0	0	0

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 6

Clinical sign	Group Name	Administration Week-day													
		0-0	1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EYE OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	0	0	0	0	0	0	0	0	1	1
SUBNORMAL TEMP	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4000 ppm	0	0	1	0	1	0	0	0	0	0	0	0	0	0

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day											
	0-0		1-7		2-7		3-7		4-7		5-7		6-7	
Control	131±	4	165±	5	195±	7	215±	8	233±	11	247±	15	260±	15
100 ppm	131±	4	163±	6	193±	10	214±	13	230±	14	246±	15	256±	17
250 ppm	131±	4	162±	6	191±	8	210±	9	225±	9	239±	12	250±	15
640 ppm	131±	4	163±	4	193±	6	213±	9	231±	11	248±	11	261±	11
1600 ppm	131±	4	156±	5*	185±	7	203±	10	220±	14	238±	14	249±	17
4000 ppm	131±	4	120±	15**	141±	17**	163±	15**	178±	14**	192±	15**	203±	18**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration week-day		7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	275±	16	290±	16	301±	15	311±	17	319±	17	328±	17	337±	18		
100 ppm	272±	18	285±	18	297±	19	306±	18	313±	18	321±	17	330±	16		
250 ppm	266±	15	277±	18	289±	19	296±	22	306±	22	314±	23	323±	24		
640 ppm	279±	10	292±	11	303±	12	313±	12	320±	13	330±	13	338±	13		
1600 ppm	266±	18	278±	19	287±	21	297±	21	307±	21	314±	22	322±	21		
4000 ppm	215±	17**	227±	19**	236±	18**	246±	19**	254±	18**	261±	18**	268±	18**		

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 2-2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
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	103±	3	120±	4	134±	5	143±	5	153±	4	160±	6	165±	5
100 ppm	103±	3	118±	4	133±	5	143±	6	149±	7	158±	7	162±	9
250 ppm	103±	3	119±	4	133±	5	145±	6	150±	6	158±	9	160±	9
640 ppm	103±	3	118±	4	132±	5	142±	6	150±	7	157±	8	160±	9
1600 ppm	103±	3	116±	4	130±	4	137±	5	145±	5*	153±	5	158±	7
4000 ppm	103±	3	100±	7**	117±	5**	127±	5**	135±	6**	138±	7**	144±	8**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0087
 ANIMAL : RAT F344
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration		week-day											
	7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	171±	5	175±	6	179±	6	183±	6	186±	6	190±	7	192±	6
100 ppm	168±	8	172±	9	174±	8	179±	9	180±	10	184±	10	186±	10
250 ppm	168±	11	171±	11	175±	11	180±	12	183±	12	186±	12	187±	12
640 ppm	167±	12	170±	12	173±	12	178±	13	179±	13	182±	12	183±	13
1600 ppm	164±	6	167±	8	172±	6	176±	7	180±	8	182±	7	183±	7
4000 ppm	148±	8**	150±	8**	154±	7**	156±	8**	159±	7**	162±	8**	164±	8**

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

Test of Dunnett

(HAN260)

BAIS 2

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE 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	19.3± 0.9	22.4± 1.9	24.0± 1.4	23.4± 1.4	25.1± 1.9	26.6± 2.0	27.7± 2.4
100 ppm	19.3± 0.9	22.6± 1.4	23.8± 0.7	23.5± 1.1	25.1± 0.6	26.1± 0.9	27.1± 1.0
250 ppm	19.3± 0.9	21.6± 1.4	23.9± 1.4	23.2± 0.9	25.2± 1.2	26.3± 1.5	27.5± 1.6
640 ppm	19.3± 0.9	22.2± 0.8	23.6± 0.9	23.1± 1.1	25.2± 1.1	26.4± 1.5	27.4± 1.7
1600 ppm	19.3± 1.0	21.0± 2.1	23.4± 1.2	23.0± 1.4	24.9± 1.2	25.7± 1.6	26.3± 1.8
4000 ppm	19.4± 1.2	15.2± 1.6**	15.0± 2.2**	15.9± 2.5**	16.7± 3.3**	16.8± 4.0**	17.9± 4.0**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE 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	28.5± 2.6	27.0± 2.6	27.8± 2.7	29.4± 2.6	30.2± 3.1	30.0± 3.0	30.0± 3.0
100 ppm	27.8± 1.0	27.0± 1.3	27.3± 1.2	29.2± 1.4	30.0± 1.6	30.3± 2.2	30.2± 1.7
250 ppm	28.2± 1.9	27.7± 2.4	27.8± 2.1	30.1± 2.2	30.9± 2.5	31.3± 3.1	31.6± 2.7
640 ppm	27.9± 2.0	27.1± 2.3	27.7± 2.2	29.5± 1.9	30.1± 2.1	30.5± 2.2	29.1± 2.3
1600 ppm	26.9± 1.8	26.2± 1.5	26.4± 1.8	28.4± 1.5	29.9± 1.9	30.0± 2.1	28.8± 1.9
4000 ppm	18.2± 4.1**	18.0± 4.0**	17.8± 4.2**	18.6± 4.9**	19.2± 5.3**	18.7± 5.6*	18.5± 5.7**

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 2-4

BODY WEIGHT CHANGES : SUMMARY, MOSUE: FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE 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	17.0± 0.8	17.5± 0.7	18.7± 0.9	18.8± 1.5	19.9± 1.2	20.2± 1.0	19.1± 1.3
100 ppm	17.4± 0.8	17.6± 1.0	19.0± 1.0	19.5± 1.0	20.7± 1.3	20.7± 1.4	20.1± 1.4
250 ppm	17.4± 0.7	17.7± 0.8	19.4± 1.3	20.1± 1.3	20.3± 1.1	20.8± 0.8	20.5± 1.1
640 ppm	17.4± 0.7	17.8± 0.7	19.1± 0.6	19.2± 0.4	20.1± 0.5	20.4± 0.7	19.1± 1.3
1600 ppm	17.4± 0.7	17.6± 0.9	18.3± 0.9	18.8± 0.7	19.8± 0.6	20.1± 0.4	19.2± 1.1
4000 ppm	17.4± 0.7	13.2± 1.2**	13.2± 2.4**	15.4± 2.9	16.7± 2.8	16.9± 2.8	16.9± 2.8

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(IIAN260)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE 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	21.1± 1.2	21.4± 0.9	21.6± 1.3	22.0± 1.6	22.0± 1.6	21.8± 1.1	21.4± 1.7
100 ppm	21.5± 1.4	22.0± 1.6	21.9± 0.9	23.7± 1.8	22.9± 1.4	23.5± 1.1*	23.4± 1.7
250 ppm	22.2± 1.6	21.7± 1.8	22.4± 0.7	22.9± 0.8	23.4± 1.7	23.2± 1.3	22.9± 1.4
640 ppm	21.4± 0.7	21.2± 0.7	21.8± 0.6	22.9± 1.2	22.1± 1.0	22.3± 0.7	21.5± 1.3
1600 ppm	20.7± 0.9	20.9± 0.9	20.1± 1.7	22.8± 0.9	21.6± 0.9	22.2± 1.4	20.4± 1.3
4000 ppm	17.3± 2.6**	17.8± 2.0**	17.6± 2.2**	18.1± 2.5*	18.1± 2.6**	17.8± 3.1	17.9± 2.9**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HAN260)

BAIS2

APPENDIX B 3-1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 1

Group Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	13.7± 0.5	14.6± 0.9	14.4± 0.8	14.5± 1.1	14.8± 1.4	14.5± 1.5	15.0± 1.4
100 ppm	13.1± 0.6	14.5± 1.1	14.3± 1.1	14.2± 1.3	14.5± 1.1	13.6± 1.5	14.4± 1.4
250 ppm	13.5± 0.7	14.5± 1.1	14.3± 1.2	14.0± 1.1	13.9± 1.5	13.0± 1.5	14.3± 1.8
640 ppm	13.2± 0.5	14.3± 0.6	14.3± 0.6	14.5± 0.8	14.8± 0.8	14.3± 0.8	15.2± 0.8
1600 ppm	11.8± 0.7**	13.7± 0.7	13.5± 0.9	13.6± 1.3	13.8± 1.4	13.6± 1.3	14.0± 1.7
4000 ppm	13.1± 6.3	10.5± 1.0**	12.4± 2.6	11.5± 1.6**	11.7± 0.8**	11.2± 1.2**	11.0± 1.2**

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

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	14.8± 1.1	15.1± 0.9	14.7± 1.2	14.4± 0.8	14.5± 0.9	14.2± 1.1
100 ppm	14.1± 1.2	14.3± 1.1	14.1± 1.0	13.9± 0.9	13.8± 0.9	13.7± 0.9
250 ppm	13.8± 1.7	14.1± 1.7	13.6± 1.7	14.1± 1.4	14.1± 1.6	13.7± 1.6
640 ppm	15.0± 1.1	14.9± 1.0	14.8± 0.9	14.7± 0.9	14.6± 1.1	14.5± 0.9
1600 ppm	13.8± 1.5	14.0± 1.5	13.8± 1.4	14.0± 1.1	13.7± 1.1	13.8± 1.1
4000 ppm	11.6± 1.3**	11.9± 1.2**	11.7± 1.0**	12.0± 0.9**	11.6± 1.0**	12.0± 0.9**

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration week-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	10.3± 0.4	10.8± 0.6	10.7± 0.8	10.5± 0.7	10.5± 0.6	10.0± 0.5	10.4± 0.5
100 ppm	10.2± 0.4	10.6± 0.5	10.9± 0.7	10.5± 0.8	10.4± 0.7	10.0± 0.9	10.2± 0.8
250 ppm	10.2± 0.5	10.8± 1.1	11.0± 0.9	10.4± 0.9	10.5± 1.3	9.8± 0.9	10.9± 1.1
640 ppm	10.0± 0.5	10.6± 0.6	10.7± 0.5	10.6± 0.7	10.6± 0.9	9.8± 0.8	10.6± 1.1
1600 ppm	9.2± 0.8**	10.1± 0.6	10.0± 0.6	10.4± 1.7	10.1± 0.8	10.0± 0.9	10.4± 0.8
4000 ppm	10.3± 4.1	9.6± 1.5**	9.5± 1.1**	8.9± 0.9**	9.0± 0.9**	8.9± 1.1	8.9± 0.9**

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

Test of Dunnett

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	10.1± 0.7	9.8± 0.7	9.8± 0.7	9.7± 0.4	10.0± 0.5	9.8± 0.5
100 ppm	9.9± 0.7	9.6± 0.5	9.7± 0.6	9.4± 0.7	9.7± 0.8	9.6± 0.5
250 ppm	10.0± 1.0	9.9± 0.9	9.8± 0.9	9.8± 1.0	9.7± 0.8	9.8± 1.0
640 ppm	10.0± 1.0	9.6± 0.8	9.9± 1.1	9.3± 0.7	9.6± 0.6	9.4± 0.8
1600 ppm	9.9± 1.1	9.7± 0.8	9.9± 1.0	9.8± 1.0	9.7± 0.9	9.7± 1.2
4000 ppm	8.7± 0.8**	9.5± 1.7	8.8± 0.8	8.7± 0.7*	8.7± 0.8**	8.4± 0.6**

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-3

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	4.1± 0.5	3.7± 0.2	3.2± 0.2	3.7± 0.3	4.1± 0.3	3.9± 0.3	3.9± 0.3
100 ppm	4.1± 0.5	3.5± 0.2	3.2± 0.3	3.8± 0.2	3.9± 0.3	3.9± 0.4	3.9± 0.3
250 ppm	3.9± 0.4	3.7± 0.2	3.3± 0.2	3.9± 0.3	4.0± 0.3	4.1± 0.3	4.2± 0.3
640 ppm	4.0± 0.5	3.5± 0.3	3.3± 0.4	3.9± 0.3	3.9± 0.5	3.8± 0.4	4.0± 0.5
1600 ppm	4.1± 0.8	3.8± 0.4	3.5± 0.6	4.0± 0.3	4.0± 0.5	3.9± 0.4	4.1± 0.4
4000 ppm	2.7± 1.0*	3.4± 1.8	3.7± 1.6	4.1± 2.3	4.0± 1.5	3.5± 1.2	3.4± 1.0

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

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	3.3± 0.3	3.3± 0.4	4.2± 0.2	3.9± 0.4	3.5± 0.3	3.7± 0.3
100 ppm	3.4± 0.3	3.3± 0.4	4.2± 0.2	4.0± 0.4	3.7± 0.4	3.8± 0.4
250 ppm	3.7± 0.4	3.4± 0.2	4.5± 0.3	4.3± 0.4	4.1± 0.7	4.3± 0.5
640 ppm	3.5± 0.4	3.3± 0.3	4.3± 0.4	4.0± 0.5	3.9± 0.4	3.4± 0.4
1600 ppm	3.6± 0.3	3.2± 0.4	4.5± 0.4	4.4± 0.4	3.9± 0.3*	3.4± 0.4
4000 ppm	3.1± 0.8	3.4± 0.8	3.7± 1.1	3.8± 1.3	3.3± 1.0	3.4± 1.1

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 3-4

FOOD CONSUMPTION CHANGES : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE 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(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	3.2± 0.3	3.3± 0.2	3.3± 0.3	3.6± 0.3	3.8± 0.2	3.2± 0.3	4.0± 0.4
100 ppm	3.3± 0.4	3.4± 0.2	3.5± 0.3	3.7± 0.3	4.0± 0.3	3.4± 0.3	4.1± 0.3
250 ppm	3.2± 0.3	3.6± 0.4	3.6± 0.4	3.6± 0.2	3.9± 0.4	3.5± 0.3	4.6± 0.7
640 ppm	3.2± 0.2	3.3± 0.3	3.4± 0.4	3.6± 0.3	3.9± 0.5	3.1± 0.3	4.1± 0.5
1600 ppm	3.5± 0.5	3.3± 0.4	3.4± 0.2	3.7± 0.3	3.8± 0.3	3.2± 0.4	3.8± 0.3
4000 ppm	3.1± 0.7	4.3± 1.3	4.9± 1.3**	4.8± 1.6	5.0± 1.9	4.1± 1.5	4.3± 1.7

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

Test of Dunnett

(HAN260)

BAIS2

STUDY NO. : 0088
 ANIMAL : MOUSE 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	3.6± 0.3	3.4± 0.3	3.8± 0.3	3.8± 0.4	3.5± 0.3	3.4± 0.5
100 ppm	3.9± 0.3	3.4± 0.7	4.3± 0.6	3.9± 0.6	3.9± 0.4	4.0± 0.7
250 ppm	3.6± 0.5	3.7± 0.4	4.3± 0.4	4.2± 0.5	4.0± 0.5	3.8± 0.3
640 ppm	3.6± 0.2	3.5± 0.4	4.4± 0.5	3.7± 0.4	4.0± 0.2	3.9± 0.5
1600 ppm	3.4± 0.3	3.0± 0.4	4.3± 0.5	3.6± 0.5	3.8± 0.4	3.5± 0.4
4000 ppm	4.0± 1.3	3.6± 0.6	4.2± 0.9	4.6± 1.2	3.9± 1.0	4.1± 1.0

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

Test of Dunnett

(HAN260)

BAIS2

APPENDIX B 4-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
 ANIMAL : RAT F344
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	8.073± 0.249	7.477± 0.266	6.709± 0.308	6.157± 0.333	5.910± 0.238	5.309± 0.279	5.277± 0.268
250 ppm	20.699± 0.667	18.884± 0.813	16.956± 0.726	15.563± 0.799	14.548± 0.838	13.023± 0.749	13.405± 0.973
640 ppm	51.932± 1.861	47.547± 1.580	43.183± 1.140	40.155± 1.575	38.206± 1.768	34.927± 1.701	34.841± 2.061
1600 ppm	120.579± 4.798	118.871± 2.716	106.431± 4.135	98.387± 5.141	92.887± 5.260	86.983± 3.393	84.086± 5.461
4000 ppm	455.540±255.946	287.630± 20.952	310.478±104.143	258.334± 27.503	243.762± 10.086	221.221± 7.676	203.399± 7.936

(HAN300)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : mg/kg/d a y
REPORT TYPE : A1 13
SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)		9	10	11	12	13
	8						
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	4.955± 0.182		4.812± 0.164	4.620± 0.203	4.445± 0.173	4.290± 0.176	4.150± 0.189
250 ppm	12.436± 0.810		12.174± 0.793	11.456± 0.673	11.478± 0.433	11.156± 0.538	10.572± 0.533
640 ppm	32.788± 1.950		31.528± 1.693	30.170± 1.589	29.336± 1.435	28.406± 1.512	27.422± 1.259
1600 ppm	79.447± 3.967		77.809± 3.649	74.421± 3.382	73.134± 2.323	69.719± 2.336	68.505± 2.797
4000 ppm	204.173± 8.104		200.724± 7.386	191.044± 5.809	188.483± 4.852	178.174± 6.022	179.738± 6.319

(HAN300)

BAIS 2

APPENDIX B 4-2

CHEMICAL INTAKE CHANGES: SUMMARY,RAT: FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
UNIT : mg/kg/d a y
REPORT TYPE : A1 13
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	8.620± 0.352	7.957± 0.231	7.602± 0.243	6.989± 0.321	6.582± 0.364	6.160± 0.307	6.054± 0.256
250 ppm	21.429± 0.527	20.347± 1.527	19.024± 0.884	17.297± 0.868	16.662± 1.307	15.275± 0.827	16.133± 0.827
640 ppm	54.002± 1.705	51.182± 2.356	48.231± 1.455	45.260± 1.985	43.140± 2.694	39.251± 2.031	40.663± 2.083
1600 ppm	126.618± 10.115	125.064± 6.193	117.143± 4.853	114.584± 15.299	105.698± 5.723	100.765± 5.910	100.746± 6.249
4000 ppm	416.517±175.660	329.955± 49.909	299.805± 37.157	264.613± 14.158	258.947± 16.899	248.080± 20.311	240.928± 16.310

(HAN300)

BAIS 2

STUDY NO. : 0087
 ANIMAL : RAT F344
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	5.765± 0.281	5.515± 0.187	5.426± 0.195	5.191± 0.224	5.249± 0.236	5.176± 0.136
250 ppm	14.558± 0.719	14.065± 0.571	13.519± 0.697	13.386± 0.737	13.015± 0.688	13.096± 0.846
640 ppm	37.543± 1.968	35.602± 1.739	35.698± 2.298	33.379± 2.004	33.689± 2.106	32.787± 1.501
1600 ppm	94.010± 7.508	90.122± 7.012	90.184± 6.631	87.216± 6.574	85.130± 5.630	84.831± 7.898
4000 ppm	232.460± 12.267	247.627± 45.120	225.913± 16.284	218.866± 13.815	215.073± 14.675	206.223± 10.485

(HAN300)

BAIS2

APPENDIX B 4-3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE (13Week STUDY)

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)						
	1	2	3	4	5	6	7
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	18.256± 1.363	14.656± 0.912	13.600± 0.946	15.006± 0.974	14.738± 0.923	14.478± 1.210	13.850± 1.000
250 ppm	44.758± 3.426	39.260± 2.443	35.829± 3.348	38.315± 3.250	37.924± 2.886	37.207± 2.788	36.758± 2.162
640 ppm	115.113± 11.013	95.449± 8.666	92.444± 9.966	98.306± 9.221	93.368± 9.488	89.256± 7.871	91.212± 10.070
1600 ppm	310.116± 50.844	262.846± 31.506	244.127± 38.936	258.174± 18.669	246.121± 22.034	235.677± 18.624	241.301± 16.562
4000 ppm	710.009±282.609	929.712±516.691	932.224±450.709	1031.002±723.414	1010.758±592.117	799.895±213.844	768.331±214.456

(HAN300)

BAIS 2

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	12.465± 0.776	11.905± 1.451	14.478± 0.690	13.456± 1.197	12.149± 0.958	12.742± 1.457
250 ppm	33.143± 2.418	30.217± 2.628	37.669± 2.622	34.433± 2.875	32.375± 3.558	34.354± 3.200
640 ppm	82.537± 8.598	76.033± 6.706	94.381± 8.155	84.697± 10.061	82.715± 8.048	74.703± 6.876
1600 ppm	220.782± 21.462	192.870± 18.708	254.882± 28.452	236.368± 18.481	209.788± 11.388	190.072± 20.035
4000 ppm	705.892±210.244	761.993±149.064	806.720±227.351	812.440±210.104	703.370± 88.532	747.947±239.952

(HAN300)

BAIS2

APPENDIX B 4-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

(13Week STUDY)

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 UNIT : mg/kg/d a y
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)		2	3	4	5	6	7
	1							
Control	0.000± 0.000		0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	18.813± 1.205		18.163± 1.484	18.188± 2.076	17.999± 1.565	19.262± 1.318	17.023± 1.584	19.256± 2.050
250 ppm	44.512± 4.103		46.492± 3.465	45.202± 4.318	44.465± 2.550	46.747± 4.258	43.248± 2.886	51.624± 5.902
640 ppm	113.492± 5.517		110.698± 9.597	114.570± 12.467	114.447± 9.791	120.714± 13.877	102.407± 5.943	121.766± 12.059
1600 ppm	319.968± 39.669		291.510± 42.214	290.057± 23.855	300.105± 21.429	301.721± 17.774	266.345± 21.212	292.364± 22.566
4000 ppm	950.637±201.380		1353.183±542.560	1352.162±544.142	1224.029±642.397	1274.230±747.114	1066.991±644.380	1062.990±638.025

(HAN300)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
UNIT : mg/kg/day
REPORT TYPE : A1 13
SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)					
	8	9	10	11	12	13
Control	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
100 ppm	17.824± 1.735	15.533± 2.871	17.995± 1.490	17.113± 2.306	16.485± 1.506	17.035± 2.316
250 ppm	40.815± 3.921	41.634± 3.949	46.538± 4.245	44.805± 3.854	42.886± 5.219	40.934± 3.416
640 ppm	107.336± 5.040	102.403± 9.708	121.671± 9.534	107.934± 7.566	114.157± 4.516	114.273± 11.950
1600 ppm	260.399± 23.689	240.052± 12.729	303.841± 35.831	265.463± 33.581	272.335± 20.601	276.252± 26.707
4000 ppm	942.928±417.964	846.098±217.816	967.693±353.669	1057.547±461.020	881.919±222.145	946.228±334.418

(HAN300)

BAIS 2

APPENDIX B 5-1

HEMATOLOGY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	10	10.06±	0.20	17.1±	0.5	48.8±	1.0	48.4±	0.3	17.0±	0.3	35.1±	0.6	886±	32
100 ppm	10	10.05±	0.19	17.2±	0.3	48.8±	1.0	48.6±	0.4	17.2±	0.2	35.3±	0.5	881±	45
250 ppm	10	10.07±	0.25	17.2±	0.3	49.0±	1.4	48.6±	0.4	17.1±	0.3	35.1±	0.6	872±	48
640 ppm	10	9.96±	0.28	16.8±	0.4	47.8±	1.6	47.9±	0.8	16.9±	0.2	35.2±	0.7	863±	41
1600 ppm	10	9.76±	0.29*	16.6±	0.4*	47.3±	1.3	48.4±	0.4	17.0±	0.3	35.1±	0.5	925±	67
4000 ppm	10	9.03±	0.23**	15.8±	0.4**	45.8±	1.2**	50.7±	0.8**	17.6±	0.3**	34.6±	0.5	988±	60**

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	WBC 1 0 ³ /μℓ		Differential N-BAND		WBC (%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER		
Control	10	5.47±	1.20	0±	0	18±	4	1±	1	0±	0	3±	2	78±	6	0±	0
100 ppm	10	5.25±	1.03	0±	0	20±	8	1±	1	0±	0	3±	2	75±	9	1±	1
250 ppm	10	5.49±	1.18	0±	0	20±	4	1±	1	0±	0	3±	2	76±	4	1±	1
640 ppm	10	5.68±	1.44	0±	0	22±	6	1±	1	0±	0	4±	2	72±	6	1±	1
1600 ppm	10	5.39±	1.47	0±	0	18±	6	0±	1	0±	0	3±	1	78±	6	0±	1
4000 ppm	10	5.84±	1.47	0±	0	16±	5	1±	1	0±	0	2±	1	80±	5	1±	1

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX B 5-2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μℓ		HEMOGLOBIN g/dℓ		HEMATOCRIT %		MCV fℓ		MCH p g		MCHC g/dℓ		PLATELET 10 ⁹ /μℓ	
Control	10	9.03±	0.28	16.8±	0.5	46.6±	1.5	51.5±	0.3	18.6±	0.2	36.1±	0.5	910±	46
100 ppm	10	9.07±	0.22	16.8±	0.4	46.7±	0.9	51.4±	0.4	18.5±	0.2	36.0±	0.4	932±	61
250 ppm	10	9.05±	0.23	16.7±	0.4	46.3±	1.0	51.1±	0.4	18.5±	0.2	36.0±	0.4	957±	58
640 ppm	10	8.96±	0.15	16.5±	0.2	46.0±	0.9	51.3±	0.3	18.4±	0.3	35.8±	0.6	980±	58*
1600 ppm	10	8.61±	0.35**	15.9±	0.5**	44.4±	1.9*	51.6±	0.3	18.5±	0.2	35.9±	0.5	975±	48*
4000 ppm	10	8.19±	0.38**	15.4±	0.6**	43.5±	2.2**	53.0±	0.4**	18.8±	0.3	35.4±	0.6*	1093±	49**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	3.87±	0.70	0±	0	17±	6	1±	1	0±	0	3±	1	78±	7	0±	0
100 ppm	10	3.47±	0.84	0±	0	16±	4	1±	1	0±	0	2±	1	81±	4	0±	1
250 ppm	10	3.15±	0.58	0±	0	17±	6	1±	1	0±	0	3±	1	79±	6	0±	0
640 ppm	10	3.16±	1.02	0±	0	18±	6	1±	1	0±	0	3±	1	78±	6	1±	1
1600 ppm	10	3.67±	1.21	0±	0	15±	5	0±	1	0±	0	2±	1	82±	4	0±	0
4000 ppm	10	3.72±	0.87	0±	0	18±	5	1±	1	0±	0	3±	1	78±	5	0±	0

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX B 5-3

HEMATOLOGY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl	HEMOGLOBIN g/dl	HEMATOCRIT %	MCV fl	MCH pg	MCHC g/dl	PLATELET 10 ³ /μl
Control	10	11.64± 0.40	16.5± 0.4	51.2± 1.4	44.0± 0.5	14.2± 0.3	32.3± 0.3	1585± 140
100 ppm	10	11.54± 0.38	16.3± 0.4	50.6± 1.6	43.8± 0.4	14.1± 0.1	32.2± 0.3	1671± 112
250 ppm	8	11.07± 0.34	15.8± 0.5*	48.8± 1.4*	44.0± 0.4	14.3± 0.1	32.5± 0.4	1584± 143
640 ppm	10	11.18± 0.24	15.9± 0.4	49.5± 1.3	44.2± 0.5	14.3± 0.2	32.2± 0.4	1619± 77
1600 ppm	10	10.73± 0.36**	15.7± 0.5**	48.0± 1.5**	44.7± 0.5	14.6± 0.2**	32.7± 0.4	1686± 131
4000 ppm	7	9.86± 1.52**	14.0± 1.9**	42.7± 6.0**	43.4± 1.1	14.3± 0.6	32.8± 0.6*	1683± 155

Significant difference ; * : P ≤ 0.05

** : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 2

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HEMATOLOGY(2) (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	1.56±	0.77	0±	1	14±	4	0±	1	0±	0	1±	1	84±	3	0±	0
100 ppm	10	1.96±	1.31	1±	1	16±	4	1±	1	0±	0	2±	2	80±	5	0±	0
250 ppm	8	1.33±	0.70	1±	1	15±	4	1±	1	0±	0	2±	1	82±	5	0±	0
640 ppm	10	1.55±	0.89	1±	1	16±	6	1±	0	0±	0	2±	2	80±	5	0±	0
1600 ppm	10	1.38±	0.98	1±	1	15±	6	1±	1	0±	0	2±	1	82±	7	0±	0
4000 ppm	7	0.84±	0.24	1±	1	45±	22**	0±	0	0±	0	1±	2	53±	23**	0±	1

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

Test of Dunnett

(JCL71A)

BAIS2

APPENDIX B 5-4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

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	11.67± 0.23	16.7± 0.2	51.3± 0.7	43.9± 0.5	14.3± 0.3	32.5± 0.3	1441± 126
100 ppm	10	11.55± 0.33	16.6± 0.4	50.9± 1.5	44.0± 0.6	14.4± 0.1	32.6± 0.4	1509± 91
250 ppm	10	11.35± 0.45	16.5± 0.4	50.6± 2.0	44.6± 0.7	14.6± 0.3	32.6± 0.6	1484± 54
640 ppm	10	11.59± 0.32	16.8± 0.5	51.6± 1.6	44.5± 0.3	14.5± 0.2	32.5± 0.3	1589± 101*
1600 ppm	10	10.97± 0.46**	16.0± 0.5	48.8± 1.9**	44.4± 0.7	14.6± 0.3*	32.9± 0.6	1650± 198**
4000 ppm	8	10.20± 0.57**	14.1± 0.7**	43.5± 2.2**	42.6± 1.1	13.8± 0.4**	32.4± 0.5	1561± 80

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	WBC 1 O ³ /μℓ		Differential N-BAND		WBC	(%) N-SEG	EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	1.28±	0.74	0±	1	14±	6	1±	1	0±	0	2±	1	82±	8	0±	0
100 ppm	10	1.98±	1.46	1±	0	15±	7	2±	1	0±	0	1±	1	81±	7	0±	1
250 ppm	10	1.87±	0.83	0±	0	15±	5	1±	1	0±	0	2±	2	81±	5	0±	0
640 ppm	10	1.97±	1.18	1±	1	17±	6	1±	1	0±	0	2±	1	81±	6	0±	0
1600 ppm	10	1.57±	0.98	0±	1	20±	11	1±	1	0±	0	2±	1	77±	11	0±	0
4000 ppm	8	0.86±	0.58	0±	1	27±	18	1±	1	0±	0	3±	2	70±	18	0±	0

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

Test of Dunnett

(JCL71A)

BAIS 2

APPENDIX B 6-1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.9±	0.2	3.9±	0.1	1.3±	0.1	0.16±	0.02	185±	11	54±	4	89±	27
100 ppm	10	6.8±	0.1	3.8±	0.1	1.3±	0.1	0.15±	0.02	187±	10	55±	4	95±	27
250 ppm	10	6.8±	0.3	3.9±	0.1	1.4±	0.1	0.16±	0.02	189±	13	58±	4	104±	18
640 ppm	10	6.9±	0.2	3.9±	0.1	1.3±	0.1	0.16±	0.01	191±	9	56±	3	111±	28
1600 ppm	10	6.8±	0.2	3.9±	0.1	1.4±	0.1	0.16±	0.02	187±	13	60±	5*	109±	24
4000 ppm	10	6.5±	0.2**	3.8±	0.1	1.4±	0.0**	0.18±	0.02	180±	13	67±	5**	98±	22

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
Control	10	105±	7	64±	10	21±	3	122±	42	283±	17	1±	0	69±	6
100 ppm	10	107±	11	78±	22	24±	5	137±	35	289±	17	1±	0	68±	7
250 ppm	10	114±	8	73±	22	22±	5	139±	52	283±	31	1±	0	70±	12
640 ppm	10	112±	8	80±	22	23±	5	145±	45	271±	18	1±	0	68±	7
1600 ppm	10	116±	9*	67±	16	19±	3	124±	32	254±	23*	1±	0	63±	5
4000 ppm	10	127±	10**	56±	9	12±	2**	104±	24	235±	20**	1±	0	61±	8

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	16.8±	1.2	0.5±	0.1	142±	1	3.8±	0.4	105±	2	10.5±	0.3	5.6±	0.8
100 ppm	10	17.4±	1.0	0.5±	0.0	142±	1	3.7±	0.2	106±	2	10.3±	0.2	5.0±	0.9
250 ppm	10	17.4±	1.4	0.5±	0.1	142±	1	3.8±	0.4	105±	2	10.4±	0.3	5.2±	0.9
640 ppm	10	17.3±	1.0	0.5±	0.1	141±	1	3.8±	0.2	105±	2	10.4±	0.1	5.1±	0.8
1600 ppm	10	17.8±	0.7	0.5±	0.0	142±	1	3.9±	0.3	105±	2	10.4±	0.3	5.3±	0.9
4000 ppm	10	18.1±	1.2	0.5±	0.0	141±	1	4.1±	0.3	105±	1	10.3±	0.2	5.4±	0.7

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 6-2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.6±	0.2	3.8±	0.1	1.4±	0.1	0.18±	0.02	148±	7	68±	6	44±	8
100 ppm	10	6.5±	0.2	3.7±	0.1	1.4±	0.1	0.18±	0.02	142±	11	67±	4	39±	4
250 ppm	10	6.5±	0.2	3.8±	0.1	1.4±	0.1	0.17±	0.01	150±	11	69±	5	43±	12
640 ppm	10	6.5±	0.2	3.8±	0.1	1.4±	0.1	0.18±	0.02	148±	5	72±	5	38±	6
1600 ppm	10	6.5±	0.2	3.8±	0.1	1.4±	0.1	0.18±	0.01	141±	9	73±	6	41±	8
4000 ppm	10	6.3±	0.2*	3.7±	0.1	1.4±	0.1	0.18±	0.01	132±	13**	73±	5	33±	5**

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

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	135±	11	59±	13	19±	6	96±	18	199±	28	1±	0	63±	6
100 ppm	10	132±	11	58±	6	18±	4	102±	60	198±	28	1±	0	64±	13
250 ppm	10	136±	11	58±	5	17±	2	93±	18	186±	15	1±	0	63±	9
640 ppm	10	139±	9	62±	8	18±	3	108±	32	182±	31	1±	0	63±	10
1600 ppm	10	143±	12	58±	5	15±	2	86±	19	185±	29	1±	0	60±	8
4000 ppm	10	138±	10	58±	7	12±	2**	94±	22	182±	24	1±	0	56±	7

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	16.7±	1.3	0.5±	0.1	141±	1	3.7±	0.2	107±	1	10.1±	0.2	4.4±	1.3
100 ppm	10	16.6±	1.5	0.5±	0.1	141±	1	3.7±	0.2	108±	2	10.0±	0.2	4.5±	0.9
250 ppm	10	16.8±	1.3	0.5±	0.1	141±	1	3.7±	0.2	107±	1	10.0±	0.2	4.3±	1.4
640 ppm	10	17.1±	1.5	0.5±	0.0	141±	1	3.6±	0.1	107±	2	10.0±	0.2	4.2±	1.4
1600 ppm	10	17.2±	2.1	0.5±	0.0	141±	1	3.8±	0.2	107±	2	10.1±	0.2	4.5±	1.2
4000 ppm	10	19.0±	1.9*	0.5±	0.1	141±	2	3.9±	0.2	107±	1	10.0±	0.2	4.8±	1.3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 6-3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	5.1±	0.2	2.8±	0.1	1.2±	0.1	0.53±	0.12	215±	48	73±	5	60±	9
100 ppm	10	5.0±	0.2	2.8±	0.1	1.2±	0.0	0.48±	0.10	224±	45	73±	7	62±	14
250 ppm	8	5.0±	0.2	2.7±	0.2	1.2±	0.1	0.57±	0.18	217±	26	70±	4	62±	12
640 ppm	10	5.0±	0.2	2.8±	0.1	1.3±	0.1	0.55±	0.06	201±	53	72±	6	62±	13
1600 ppm	10	5.0±	0.1	2.8±	0.1	1.3±	0.1	0.57±	0.14	178±	42	75±	4	59±	10
4000 ppm	7	4.5±	0.8	2.6±	0.4	1.5±	0.2**	0.61±	0.13	150±	55*	75±	11	44±	10*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dl		SODIUM mEq / ℓ	
Control	10	38±	5	10±	2	288±	122	192±	16	36±	14	27.2±	4.4	150±	2
100 ppm	10	35±	4	9±	2	245±	29	196±	13	33±	12	27.1±	4.3	151±	2
250 ppm	8	39±	4	9±	1	368±	129	195±	10	42±	16	27.2±	2.9	151±	5
640 ppm	10	41±	5	9±	2	300±	83	192±	18	46±	20	27.0±	3.9	152±	4
1600 ppm	10	44±	7	11±	2	284±	117	203±	9	53±	22	28.8±	4.1	150±	3
4000 ppm	7	90±	86	23±	23	381±	203	281±	51**	92±	60*	35.1±	9.0**	151±	2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 3

Group Name	NO. of Animals	POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
Control	10	4.9±	0.5	120±	3	8.5±	0.3	7.0±	1.6
100 ppm	10	4.7±	0.3	121±	2	8.4±	0.3	6.3±	0.8
250 ppm	8	4.9±	0.3	122±	4	8.4±	0.3	6.8±	1.6
640 ppm	10	5.0±	0.6	122±	4	8.1±	1.0	7.0±	1.4
1600 ppm	10	4.6±	0.3	121±	3	8.6±	0.4	6.5±	1.3
4000 ppm	7	5.2±	0.4	120±	4	8.2±	0.5	7.1±	1.2

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 6-4

BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g /dl		ALBUMIN g /dl		A/G RATIO		T-BILIRUBIN mg /dl		GLUCOSE mg /dl		T-CHOLESTEROL mg /dl		TRIGLYCERIDE mg /dl	
Control	10	5.0±	0.2	3.0±	0.1	1.5±	0.1	0.55±	0.10	165±	29	63±	6	57±	4
100 ppm	10	5.0±	0.3	3.0±	0.2	1.5±	0.1	0.54±	0.12	175±	25	67±	6	54±	11
250 ppm	10	4.9±	0.2	2.9±	0.1	1.5±	0.1	0.55±	0.08	170±	31	63±	4	52±	9
640 ppm	10	5.1±	0.2	3.0±	0.2	1.5±	0.1	0.56±	0.13	172±	28	69±	7	54±	11
1600 ppm	10	4.9±	0.3	3.0±	0.1	1.5±	0.1	0.60±	0.13	157±	34	70±	12	53±	6
4000 ppm	8	4.8±	0.4	2.9±	0.2	1.6±	0.2	0.60±	0.10	130±	30	68±	12	50±	8

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 5

Group Name	NO. of Animals	GOT I U / ℓ		GPT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		CPK I U / ℓ		UREA NITROGEN mg / dl		SODIUM mEq / ℓ	
Control	10	43±	6	12±	2	292±	50	238±	32	34±	8	21.6±	3.0	150±	4
100 ppm	10	44±	9	12±	4	243±	74	250±	39	28±	7	21.0±	2.5	151±	6
250 ppm	10	43±	5	11±	1	296±	67	265±	26	32±	5	20.8±	1.9	150±	4
640 ppm	10	47±	6	10±	2	290±	81	279±	22*	49±	29	20.9±	3.0	151±	4
1600 ppm	10	55±	15	11±	2	406±	120*	291±	36**	63±	39	23.5±	2.7	151±	4
4000 ppm	8	74±	16**	14±	4	449±	121**	304±	39**	80±	18**	25.8±	5.3*	150±	3

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
SURVIVAL ANIMALS (13)

PAGE : 6

Group Name	NO. of Animals	POTASSIUM mEq / ℓ		CHLORIDE mEq / ℓ		CALCIUM mg / dl		INORGANIC PHOSPHORUS mg / dl	
Control	10	4.9±	0.4	121±	3	8.4±	0.3	6.2±	1.1
100 ppm	10	5.0±	0.5	122±	6	8.6±	0.3	5.2±	1.1
250 ppm	10	4.9±	0.4	122±	4	8.3±	0.3	5.5±	1.1
640 ppm	10	5.0±	0.3	121±	4	8.3±	0.4	6.3±	1.1
1600 ppm	10	4.9±	0.3	121±	3	8.1±	0.3	6.4±	0.8
4000 ppm	8	5.5±	0.4*	118±	2	8.1±	0.3	7.5±	1.0*

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 2

APPENDIX B 7-1

URINALYSIS : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087

ANIMAL : RAT F344

SAMPLING DATE : 013-7

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body				Bilirubin				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	+	2+	3+	-	+		2+	3+	
Control	10	0	0	0	0	1	7	2		0	0	6	4	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	
100 ppm	10	0	0	0	0	0	9	1		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
250 ppm	10	0	0	0	0	1	6	3		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
640 ppm	10	0	0	0	0	0	8	2		0	0	10	0	0	0	*	10	0	0	0	0	0		9	1	0	0		10	0	0	0	
1600 ppm	10	0	0	0	0	0	8	2		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
4000 ppm	10	0	0	1	0	0	9	0		0	0	7	3	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0		10	0	0	0	0	
100. ppm	10	10	0	0	0	0		10	0	0	0	0	
250 ppm	10	10	0	0	0	0		10	0	0	0	0	
640 ppm	10	10	0	0	0	0		10	0	0	0	0	
1600 ppm	10	10	0	0	0	0		10	0	0	0	0	
4000 ppm	10	10	0	0	0	0		0	10	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 7-2

URINALYSIS : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
 ANIMAL : RAT F344
 SAMPLING DATE : 013-7
 SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body				Bilirubin				CHI			
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	+	2+	3+	-	+		2+	3+	
Control	10	0	0	0	0	2	8	0		0	0	7	3	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
100 ppm	10	0	1	0	0	0	9	0		0	2	8	0	0	0		10	0	0	0	0	0		9	1	0	0		10	0	0	0	
250 ppm	10	0	0	0	0	2	7	1		0	1	7	2	0	0		10	0	0	0	0	0		10	0	0	0		10	0	0	0	
640 ppm	10	0	1	0	1	0	5	3		0	4	6	0	0	0	*	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
1600 ppm	10	0	0	0	0	0	9	1		0	5	5	0	0	0	*	10	0	0	0	0	0		10	0	0	0		10	0	0	0	
4000 ppm	10	0	0	0	0	8	2	0	**	0	8	2	0	0	0	**	10	0	0	0	0	0		10	0	0	0		10	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

STUDY NO. : 0087
ANIMAL : RAT F344
SAMPLING DATE : 013-7
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0		10	0	0	0	0	
100 ppm	10	10	0	0	0	0		10	0	0	0	0	
250 ppm	10	10	0	0	0	0		10	0	0	0	0	
640 ppm	10	10	0	0	0	0		10	0	0	0	0	
1600 ppm	10	10	0	0	0	0		10	0	0	0	0	
4000 ppm	10	10	0	0	0	0		7	3	0	0	0	

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

Test of CHI SQUARE

(JCL101)

BAIS2

APPENDIX B 7-3

URINALYSIS : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-7
 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+	-	±		+	2+	3+
Control	10	0	1	0	3	5	1	0		1	0	6	3	0	0		10	0	0	0	0	0		5	5	0	0		10	0	0	0	0	
100 ppm	10	0	1	1	3	4	1	0		0	0	8	2	0	0		10	0	0	0	0	0		8	2	0	0		10	0	0	0	0	
250 ppm	10	0	0	1	2	6	1	0		0	0	4	6	0	0		10	0	0	0	0	0		5	5	0	0		10	0	0	0	0	
640 ppm	10	0	1	3	0	4	2	0		0	0	5	5	0	0		10	0	0	0	0	0		4	6	0	0		10	0	0	0	0	
1600 ppm	10	0	0	3	2	3	2	0		0	0	5	5	0	0		10	0	0	0	0	0		6	4	0	0		10	0	0	0	0	
4000 ppm	7	0	1	3	2	1	0	0		0	0	3	4	0	0		7	0	0	0	0	0		3	4	0	0		7	0	0	0	0	

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

Test of CHI SQUARE

(JCL104X)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urabilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0
100 ppm	10	10 0 0 0 0
250 ppm	10	10 0 0 0 0
640 ppm	10	10 0 0 0 0
1600 ppm	10	10 0 0 0 0
4000 ppm	7	2 5 0 0 0 **

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

Test of CHI SQUARE

(JCL104X)

BAIS2

APPENDIX B 7-4

URINALYSIS : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 SAMPLING DATE : 013-7
 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+	-	±	+		2+	3+
Control	10	0	3	4	2	0	1	0		0	0	8	2	0	0		10	0	0	0	0	0		4	6	0	0		10	0	0	0	0	
100 ppm	10	0	1	2	5	2	0	0		0	2	8	0	0	0		10	0	0	0	0	0		6	4	0	0		10	0	0	0	0	
250 ppm	10	0	1	6	1	1	1	0		0	2	8	0	0	0		10	0	0	0	0	0		5	5	0	0		10	0	0	0	0	
640 ppm	10	0	2	2	4	2	0	0		0	1	7	2	0	0		10	0	0	0	0	0		4	6	0	0		10	0	0	0	0	
1600 ppm	10	0	0	3	4	2	1	0		0	0	9	1	0	0		10	0	0	0	0	0		7	3	0	0		10	0	0	0	0	
4000 ppm	8	0	1	2	2	1	2	0		0	2	6	0	0	0		8	0	0	0	0	0		3	5	0	0		8	0	0	0	0	

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

Test of CHI SQUARE

(JCL104X)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7
SEX : FEMALE

URINALYSIS

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urabilinogen ± + 2+ 3+ 4+ CHI
Control	10	10 0 0 0 0
100 ppm	10	10 0 0 0 0
250 ppm	10	10 0 0 0 0
640 ppm	10	9 1 0 0 0
1600 ppm	10	2 8 0 0 0 **
4000 ppm	8	0 6 2 0 0 **

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

Test of CHI SQUARE

(JCL104X)

BAIS2

APPENDIX B 8-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name	Control	100 ppm	250 ppm	640 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
Lung	white zone		0 (0)	0 (0)	0 (0)	0 (0)
Liver	enlarged		0 (0)	0 (0)	0 (0)	0 (0)
	herniation		0 (0)	0 (0)	1 (10)	1 (10)
semin ves	adhesion		0 (0)	0 (0)	1 (10)	0 (0)
other	yellow		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

Organ	Findings	Group Name	1600 ppm	4000 ppm
		NO. of Animals	10 (%)	10 (%)
lung	white zone		0 (0)	1 (10)
liver	enlarged		1 (10)	0 (0)
	herniation		0 (0)	2 (20)
semin ves	adhesion		0 (0)	0 (0)
other	yellow		7 (70)	9 (90)

(HPT080)

BAIS 2

APPENDIX B 8-2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	100 ppm 10 (%)	250 ppm 10 (%)	640 ppm 10 (%)
forestomach	ulcer		0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		0 (0)	0 (0)	0 (0)	1 (10)
ovary	cyst		0 (0)	0 (0)	1 (10)	0 (0)
uterus	dilated lumen		2 (20)	1 (10)	2 (20)	5 (50)
other	yellow		0 (0)	0 (0)	1 (10)	1 (10)

(HPT080)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

Organ_____	Findings_____	Group Name	1600 ppm	4000 ppm
		NO. of Animals	10 (%)	10 (%)
forestomach	ulcer		0 (0)	1 (10)
liver	herniation		0 (0)	1 (10)
ovary	cyst		1 (10)	1 (10)
uterus	dilated lumen		3 (30)	0 (0)
other	yellow		9 (90)	10 (100)

(HPT080)

BAIS2

APPENDIX B 8-3

GROSS FINDINGS : SUMMARY, MOUSE: MALE :DEAD AND MORIBUND ANIMALS
(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name	Control	100 ppm	250 ppm	640 ppm
		NO. of Animals	0 (%)	0 (%)	0 (%)	0 (%)
lung	red		- (-)	- (-)	- (-)	- (-)
spleen	atrophic		- (-)	- (-)	- (-)	- (-)
forestomach	ulcer		- (-)	- (-)	- (-)	- (-)
small intes	fluid:black		- (-)	- (-)	- (-)	- (-)
gall bladd	dilated		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 2

Organ	Findings	Group Name	1600 ppm	4000 ppm
		NO. of Animals	0 (%)	3 (%)
lung	red		- (-)	1 (33)
spleen	atrophic		- (-)	1 (33)
forestomach	ulcer		- (-)	1 (33)
small intes	fluid:black		- (-)	1 (33)
gall bladd	dilated		- (-)	1 (33)

(HPT080)

BAIS 2

APPENDIX B 8-4

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

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	100 ppm 0 (%)	250 ppm 0 (%)	640 ppm 0 (%)
lung	red		- (-)	- (-)	- (-)	- (-)
forestomach	ulcer		- (-)	- (-)	- (-)	- (-)

(HPT080)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 4

Organ	Findings	Group Name	1600 ppm	4000 ppm
		NO. of Animals	0 (%)	2 (%)
lung	red		- (-)	1 (50)
forestomach	ulcer		- (-)	1 (50)

(HPT080)

BATS2

APPENDIX B 8-5

GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control	100 ppm	250 ppm	640 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black		0 (0)	0 (0)	0 (0)	0 (0)
	black zone		2 (20)	3 (30)	1 (10)	2 (20)
	nodule		1 (10)	0 (0)	0 (0)	0 (0)
liver	dark		0 (0)	0 (0)	0 (0)	0 (0)
thyroid	dark		0 (0)	0 (0)	0 (0)	0 (0)
other	yellow		0 (0)	0 (0)	0 (0)	1 (10)

(HPT080)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 2

Organ	Findings	Group Name	1600 ppm	4000 ppm
		NO. of Animals	10 (%)	7 (%)
thymus	atrophic		0 (0)	2 (29)
spleen	black		5 (50)	7 (100)
	black zone		0 (0)	0 (0)
	nodule		0 (0)	0 (0)
liver	dark		1 (10)	7 (100)
thyroid	dark		0 (0)	3 (43)
other	yellow		9 (90)	7 (100)

(HPT080)

BAIS2

APPENDIX B 8-6

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	100 ppm 10 (%)	250 ppm 10 (%)	640 ppm 10 (%)
thymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
spleen	black		0 (0)	0 (0)	0 (0)	0 (0)
	black zone		1 (10)	1 (10)	1 (10)	0 (0)
liver	dark		0 (0)	0 (0)	0 (0)	0 (0)
thyroid	dark		0 (0)	0 (0)	0 (0)	0 (0)
eye	absence		0 (0)	0 (0)	1 (10)	0 (0)
other	yellow		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE : 4

Organ	Findings	Group Name	1600 ppm	4000 ppm
		NO. of Animals	10 (%)	8 (%)
thymus	atrophic		0 (0)	1 (13)
spleen	black		10 (100)	8 (100)
	black zone		0 (0)	0 (0)
liver	dark		0 (0)	8 (100)
thyroid	dark		0 (0)	6 (75)
eye	absence		0 (0)	0 (0)
other	yellow		0 (0)	5 (63)

(HPT080)

BAIS2

APPENDIX B 9-1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	315± 19	0.249± 0.043	0.046± 0.005	2.843± 0.112	0.946± 0.071	1.012± 0.055
100 ppm	10	306± 17	0.241± 0.032	0.049± 0.003	2.820± 0.110	0.919± 0.036	0.992± 0.046
250 ppm	10	300± 21	0.253± 0.031	0.049± 0.005	2.818± 0.155	0.901± 0.061	0.986± 0.061
640 ppm	10	315± 13	0.247± 0.033	0.048± 0.003	2.873± 0.091	0.961± 0.055	1.046± 0.044
1600 ppm	10	300± 19	0.224± 0.028	0.048± 0.003	2.818± 0.102	0.911± 0.053	0.997± 0.061
4000 ppm	10	250± 17**	0.193± 0.025**	0.043± 0.004	2.772± 0.103	0.793± 0.060**	0.881± 0.045**

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.934±	0.098	0.540±	0.034	7.889±	0.600	1.917±	0.027
100 ppm	10	1.925±	0.055	0.537±	0.035	7.643±	0.600	1.884±	0.044
250 ppm	10	1.927±	0.161	0.540±	0.029	7.668±	0.757	1.906±	0.034
640 ppm	10	2.021±	0.095	0.587±	0.051	8.201±	0.399	1.903±	0.037
1600 ppm	10	1.986±	0.124	0.579±	0.055	8.162±	0.742	1.876±	0.039
4000 ppm	10	1.788±	0.149*	0.644±	0.050**	7.324±	0.703	1.845±	0.055**

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 9-2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	179± 6	0.196± 0.017	0.054± 0.003	0.085± 0.012	0.611± 0.016	0.742± 0.044
100 ppm	10	174± 10	0.195± 0.023	0.052± 0.005	0.088± 0.011	0.622± 0.040	0.732± 0.036
250 ppm	10	175± 12	0.194± 0.012	0.056± 0.007	0.088± 0.013	0.626± 0.043	0.748± 0.040
640 ppm	10	170± 12	0.200± 0.022	0.054± 0.005	0.088± 0.008	0.615± 0.044	0.744± 0.047
1600 ppm	10	171± 8	0.196± 0.017	0.054± 0.004	0.089± 0.012	0.623± 0.040	0.741± 0.037
4000 ppm	10	152± 8**	0.163± 0.024**	0.050± 0.005	0.089± 0.015	0.565± 0.029*	0.720± 0.052

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.202±	0.033	0.370±	0.027	4.093±	0.130	1.739±	0.017
100 ppm	10	1.221±	0.075	0.374±	0.026	4.068±	0.289	1.747±	0.051
250 ppm	10	1.237±	0.080	0.378±	0.028	4.126±	0.337	1.750±	0.034
640 ppm	10	1.231±	0.065	0.414±	0.076	4.114±	0.456	1.757±	0.042
1600 ppm	10	1.254±	0.071	0.406±	0.027*	4.317±	0.230	1.749±	0.047
4000 ppm	10	1.186±	0.038	0.454±	0.030**	4.085±	0.271	1.726±	0.043

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 9-3

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 1

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	28.1± 3.2	0.037± 0.011	0.009± 0.001	0.203± 0.015	0.128± 0.009	0.143± 0.008
100 ppm	10	28.5± 1.8	0.041± 0.003	0.008± 0.001	0.201± 0.020	0.130± 0.004	0.145± 0.009
250 ppm	10	29.5± 2.8	0.038± 0.007	0.008± 0.001	0.202± 0.015	0.136± 0.009	0.149± 0.006
640 ppm	10	27.7± 1.8	0.034± 0.004	0.007± 0.001**	0.204± 0.025	0.128± 0.005	0.145± 0.004
1600 ppm	10	26.7± 2.1	0.033± 0.005	0.008± 0.001	0.208± 0.029	0.133± 0.010	0.143± 0.009
4000 ppm	7	17.3± 4.9**	0.020± 0.013*	0.007± 0.000**	0.164± 0.048	0.110± 0.025	0.119± 0.017*

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

Test of Dunnett

(HCL040)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.376±	0.029	0.043±	0.004	0.953±	0.083	0.439±	0.010
100 ppm	10	0.384±	0.023	0.043±	0.006	0.961±	0.063	0.442±	0.012
250 ppm	10	0.394±	0.029	0.045±	0.007	1.011±	0.085	0.442±	0.008
640 ppm	10	0.369±	0.017	0.043±	0.005	0.956±	0.061	0.435±	0.008
1600 ppm	10	0.369±	0.028	0.054±	0.011	0.968±	0.051	0.445±	0.014
4000 ppm	7	0.280±	0.068**	0.066±	0.036	0.727±	0.209	0.404±	0.037

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

Test of Dunnett

(HCL040)

BAIS2

APPENDIX B 9-4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 3

Group Name	NO. of Animals	Body weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	20.1± 1.6	0.038± 0.010	0.011± 0.002	0.019± 0.003	0.105± 0.008	0.136± 0.008
100 ppm	10	21.5± 1.4	0.044± 0.008	0.011± 0.001	0.018± 0.003	0.108± 0.007	0.137± 0.008
250 ppm	10	21.3± 1.5	0.043± 0.004	0.011± 0.002	0.019± 0.003	0.111± 0.008	0.140± 0.007
640 ppm	10	20.1± 1.1	0.040± 0.005	0.011± 0.001	0.021± 0.004	0.109± 0.008	0.138± 0.007
1600 ppm	10	19.1± 0.7	0.035± 0.006	0.011± 0.001	0.019± 0.002	0.106± 0.006	0.137± 0.007
4000 ppm	8	16.2± 2.2**	0.032± 0.011	0.009± 0.001	0.016± 0.005	0.115± 0.018	0.118± 0.010**

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

Test of Dunnett

(HCL040)

BAIS2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	0.255±	0.020	0.049±	0.009	0.802±	0.062	0.450±	0.011
100 ppm	10	0.267±	0.014	0.051±	0.007	0.831±	0.078	0.451±	0.011
250 ppm	10	0.283±	0.019*	0.059±	0.021	0.844±	0.040	0.455±	0.015
640 ppm	10	0.270±	0.018	0.052±	0.011	0.788±	0.062	0.450±	0.010
1600 ppm	10	0.259±	0.012	0.062±	0.013	0.768±	0.053	0.445±	0.012
4000 ppm	8	0.241±	0.032	0.119±	0.038**	0.772±	0.114	0.425±	0.020**

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

Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 10-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	315± 19	0.079± 0.011	0.015± 0.001	0.905± 0.054	0.301± 0.014	0.322± 0.020
100 ppm	10	306± 17	0.079± 0.007	0.016± 0.001	0.925± 0.050	0.301± 0.012	0.325± 0.014
250 ppm	10	300± 21	0.084± 0.010	0.016± 0.001*	0.940± 0.043	0.301± 0.016	0.329± 0.013
640 ppm	10	315± 13	0.078± 0.008	0.015± 0.001	0.913± 0.041	0.305± 0.013	0.332± 0.014
1600 ppm	10	300± 19	0.075± 0.008	0.016± 0.001	0.943± 0.045	0.305± 0.010	0.333± 0.014
4000 ppm	10	250± 17**	0.077± 0.010	0.017± 0.001**	1.111± 0.059**	0.317± 0.015	0.352± 0.014**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.615± 0.031	0.172± 0.011	2.505± 0.093	0.611± 0.038
100 ppm	10	0.631± 0.026	0.176± 0.005	2.501± 0.103	0.618± 0.029
250 ppm	10	0.642± 0.020	0.180± 0.006	2.550± 0.090	0.637± 0.036
640 ppm	10	0.642± 0.026	0.186± 0.014	2.604± 0.089	0.605± 0.022
1600 ppm	10	0.664± 0.030**	0.193± 0.011**	2.722± 0.117**	0.628± 0.037
4000 ppm	10	0.714± 0.021**	0.257± 0.012**	2.921± 0.090**	0.739± 0.035**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 10-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	179± 6	0.110± 0.010	0.030± 0.002	0.048± 0.007	0.341± 0.009	0.414± 0.022
100 ppm	10	174± 10	0.112± 0.012	0.030± 0.002	0.051± 0.006	0.358± 0.011*	0.422± 0.021
250 ppm	10	175± 12	0.111± 0.009	0.032± 0.003	0.050± 0.006	0.358± 0.011*	0.429± 0.025
640 ppm	10	170± 12	0.118± 0.012	0.031± 0.003	0.052± 0.004	0.361± 0.015*	0.438± 0.021
1600 ppm	10	171± 8	0.115± 0.009	0.032± 0.002	0.052± 0.007	0.364± 0.017**	0.434± 0.018
4000 ppm	10	152± 8**	0.107± 0.013	0.033± 0.004	0.059± 0.009**	0.372± 0.021**	0.474± 0.031**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.672± 0.028	0.206± 0.011	2.286± 0.062	0.972± 0.036
100 ppm	10	0.704± 0.026	0.215± 0.011	2.343± 0.058	1.009± 0.044
250 ppm	10	0.708± 0.036	0.217± 0.012	2.360± 0.091	1.004± 0.050
640 ppm	10	0.724± 0.033**	0.243± 0.042**	2.414± 0.192	1.035± 0.067*
1600 ppm	10	0.733± 0.023**	0.238± 0.011**	2.525± 0.093**	1.024± 0.040
4000 ppm	10	0.781± 0.041**	0.298± 0.012**	2.685± 0.070**	1.137± 0.055**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 10-3

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 1

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	28.1± 3.2	0.131± 0.030	0.032± 0.006	0.731± 0.094	0.459± 0.035	0.512± 0.035
100 ppm	10	28.5± 1.8	0.143± 0.016	0.029± 0.004	0.707± 0.064	0.458± 0.019	0.512± 0.038
250 ppm	10	29.5± 2.8	0.128± 0.017	0.028± 0.005	0.688± 0.071	0.464± 0.032	0.508± 0.049
640 ppm	10	27.7± 1.8	0.121± 0.014	0.026± 0.004	0.737± 0.087	0.464± 0.030	0.524± 0.045
1600 ppm	10	26.7± 2.1	0.125± 0.014	0.031± 0.004	0.778± 0.076	0.500± 0.026*	0.537± 0.027
4000 ppm	7	17.3± 4.9**	0.107± 0.049	0.042± 0.014	0.951± 0.082**	0.649± 0.047**	0.719± 0.120**

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.347± 0.095	0.155± 0.024	3.406± 0.173	1.580± 0.160
100 ppm	10	1.349± 0.042	0.151± 0.024	3.376± 0.145	1.558± 0.135
250 ppm	10	1.344± 0.108	0.155± 0.028	3.440± 0.261	1.511± 0.158
640 ppm	10	1.336± 0.069	0.154± 0.015	3.457± 0.226	1.577± 0.098
1600 ppm	10	1.387± 0.069	0.201± 0.037*	3.640± 0.194	1.674± 0.110
4000 ppm	7	1.639± 0.080**	0.353± 0.125**	4.210± 0.279**	2.466± 0.508**

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 10-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 3

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	20.1± 1.6	0.185± 0.039	0.054± 0.006	0.094± 0.016	0.522± 0.022	0.677± 0.029
100 ppm	10	21.5± 1.4	0.202± 0.031	0.051± 0.007	0.083± 0.017	0.506± 0.029	0.641± 0.047
250 ppm	10	21.3± 1.5	0.203± 0.024	0.054± 0.010	0.091± 0.014	0.522± 0.041	0.660± 0.059
640 ppm	10	20.1± 1.1	0.197± 0.020	0.054± 0.004	0.106± 0.021	0.543± 0.018	0.688± 0.032
1600 ppm	10	19.1± 0.7	0.181± 0.026	0.058± 0.008	0.101± 0.010	0.559± 0.039	0.720± 0.049
4000 ppm	8	16.2± 2.2**	0.193± 0.059	0.059± 0.011	0.099± 0.020	0.712± 0.052**	0.734± 0.072

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

Test of Dunnett

(HCL042)

BAIS 2

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.271± 0.045	0.241± 0.027	3.997± 0.213	2.248± 0.160
100 ppm	10	1.249± 0.093	0.239± 0.036	3.868± 0.208	2.109± 0.153
250 ppm	10	1.335± 0.119	0.278± 0.097	3.974± 0.240	2.146± 0.158
640 ppm	10	1.348± 0.032	0.258± 0.043	3.931± 0.213	2.247± 0.128
1600 ppm	10	1.360± 0.073	0.326± 0.061*	4.027± 0.177	2.338± 0.102
4000 ppm	8	1.491± 0.072**	0.717± 0.192**	4.763± 0.179**	2.664± 0.347*

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

Test of Dunnett

(HCL042)

BAIS 2

APPENDIX B 11-1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	Control				100 ppm				250 ppm				640 ppm			
		No. of Animals	10				10				10				10			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]																		
lung	bronchiolar-alveolar cell hyperplasia		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)	
[Hematopoietic system]																		
spleen	congestion		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)	
	deposit of hemosiderin		0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	1 (10)	9 (90)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	
	extramedullary hematopoiesis		10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	
[Circulatory system]																		
heart	granulation		2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
[Digestive system]																		
salivary gl	swelling:acinar cell		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 granule:decreased		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)	
stomach	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)	
	hyperplasia: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)	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
lung	bronchiolar-alveolar cell hyperplasia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]													
spleen	congestion	10 (100)	0 (0)	0 (0)	0 ** (0)	0 (0)	10 (100)	0 (0)	0 ** (0)	0 (0)	10 (100)	0 (0)	0 ** (0)
	deposit of hemosiderin	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)
	extramedullary hematopoiesis	9 (90)	1 (10)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 ** (0)	0 (0)	10 (100)	0 (0)	0 ** (0)
[Circulatory system]													
heart	granulation	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
[Digestive system]													
salivary gl	swelling:acinar cell	0 (0)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
	eosinophilic granule:decreased	0 (0)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 ** (0)
stomach	erosion:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0 ** (0)	0 (0)	5 (50)	0 (0)	0 ** (0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name No. of Animals	Control 10				100 ppm 10				250 ppm 10				640 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
Liver	herniation		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)
	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
pancreas	atrophy		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)
[Urinary system]																		
kidney	basophilic change		1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)
	eosinophilic body		0 (0)	6 (60)	4 (40)	0 (0)	0 (0)	2 (20)	8 (80)	0 (0)	0 (0)	1 (10)	8 (80)	1 (10)	0 (0)	0 (0)	7 (70)	3 ** (30)
[Endocrine system]																		
pituitary	Rathke pouch		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)
	ultimibranhial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]													
liver	herniation	0	0	0	0	1	0	0	0				
		(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)				
	epidermal cyst	0	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
pancreas	atrophy	1	0	0	0	0	0	0	0				
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
[Urinary system]													
kidney	basophilic change	2	0	0	0	0	0	0	0				
		(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
	eosinophilic body	0	0	5	5 **	0	0	2	8 **				
		(0)	(0)	(50)	(50)	(0)	(0)	(20)	(80)				
[Endocrine system]													
pituitary	Rathke pouch	1	0	0	0	0	0	0	0				
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
thyroid	ultimibranhial body remanet	1	0	0	0	0	0	0	0				
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BAIS2

APPENDIX B 11-2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE : SACRIFICED ANIMALS

(13Week STUDY)

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name No. of Animals	Control 10				100 ppm 10				250 ppm 10				640 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Respiratory system]																		
nasal cavit	inflammation:respiratory epithelium		4 (40)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	4 (40)	0 (0)	0 (0)	0 (0)
lung	accumulation of foamy cells		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]																		
bone marrow	granulation		2 (20)	2 (20)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	2 (20)	0 (0)	0 (0)	1 (10)	2 (20)	0 (0)	0 (0)
	erythropoiesis:increased		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
spleen	congestion		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)
	deposit of hemosiderin		0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)
	extramedullary hematopoiesis		10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)
[Digestive system]																		
salivary gl	swelling:acinar cell		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 granule:decreased		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)
stomach	hyperplasia: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)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0087
 ANIMAL : RAT F344
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	inflammation:respiratory epithelium	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
lung	accumulation of foamy cells	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Hematopoietic system]													
bone marrow	granulation	2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	erythropoiesis:increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
spleen	congestion	8 (80)	0 (0)	0 (0)	0 ** (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)
	deposit of hemosiderin	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	10 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis	10 (100)	0 (0)	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)
[Digestive system]													
salivary gl	swelling:acinar cell	0 (0)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)	0 * (0)	0 (0)	0 (0)	0 (0)
	eosinophilic granule:decreased	0 (0)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)
stomach	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	5 (50)	5 (50)	0 (0)	0 (0)	0 ** (0)	0 (0)	0 (0)	0 (0)

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 7

Organ	Findings	Group Name No. of Animals	Control 10				100 ppm 10				250 ppm 10				640 ppm 10			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Digestive system]																		
Liver	herniation		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)	
pancreas	atrophy		2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	
[Urinary system]																		
kidney	mineralization:cortico-medullary junction		9 (90)	0 (0)	0 (0)	0 (0)	9 (90)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)	7 (70)	0 (0)	0 (0)	0 (0)	
	eosinophilic droplet;proximal tubule		0 (0)	0 (0)	0 (0)	0 (0)	7 (70)	3 (30)	0 (0)	0 ** (0)	3 (30)	7 (70)	0 (0)	0 ** (0)	1 (10)	7 (70)	2 (20)	0 ** (0)
[Endocrine system]																		
pituitary	Rathke pouch		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
thyroid	ultimibranhial body remanet		0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
[Special sense organs/appandage]																		
Harder gl	inflammation		3 (30)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	1 (10)	0 (0)	0 (0)	
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe																		
(HPT150)																		

(HPT150)

BAIS2

STUDY NO. : 0087
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 8

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 10			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]													
Liver	herniation	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
pancreas	atrophy	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Urinary system]													
kidney	mineralization:cortico-medullary junction	8 (80)	0 (0)	0 (0)	0 (0)	6 (60)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	eosinophilic droplet:proximal tubule	0 (0)	4 (40)	6 (60)	0 ** (0)	0 (0)	0 (0)	10 (100)	0 ** (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Endocrine system]													
pituitary	Rathke pouch	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
thyroid	ultimibranchial body remanet	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
[Special sense organs/appandage]													
Harder gl	inflammation	2 (20)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX B 11-3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : DEAD AND MORIBUNDANIMALS

(13Week STUDY)

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 1

Organ	Findings	Group Name No. of Animals	Control 0				100 ppm 0				250 ppm 0				640 ppm 0			
			<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]																		
thymus	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
spleen	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
[Circulatory system]																		
heart	thrombus		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
[Digestive system]																		
tongue	erosion		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
salivary gl	swelling:acinar cell		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
	eosinophilic granule:decreased		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
stomach	hyperplasia:forestomach		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)

<1>:Slight

<2>:Moderate

<3>:Marked

<4>:Severe

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 2

		Group Name	1600 ppm				4000 ppm			
		No. of Animals	0				3			
Organ_____	Findings_____		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
<hr/>										
[Hematopoietic system]										
thymus	atrophy		- (-)	- (-)	- (-)	- (-)	0 (0)	1 (33)	1 (33)	0 (0)
spleen	atrophy		- (-)	- (-)	- (-)	- (-)	0 (0)	3 (100)	0 (0)	0 (0)
[Circulatory system]										
heart	thrombus		- (-)	- (-)	- (-)	- (-)	0 (0)	2 (67)	0 (0)	0 (0)
[Digestive system]										
tongue	erosion		- (-)	- (-)	- (-)	- (-)	1 (33)	0 (0)	0 (0)	0 (0)
salivary gl	swelling:acinar cell		- (-)	- (-)	- (-)	- (-)	0 (0)	1 (33)	0 (0)	0 (0)
	eosinophilic granule:decreased		- (-)	- (-)	- (-)	- (-)	0 (0)	0 (0)	2 (67)	0 (0)
stomach	hyperplasia:forestomach		- (-)	- (-)	- (-)	- (-)	1 (33)	1 (33)	0 (0)	0 (0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX B 11-4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

(13Week STUDY))

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 3

Organ	Findings	Group Name	Control				100 ppm				250 ppm				640 ppm			
		No. of Animals	0				0				0				0			
		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	
[Respiratory system]																		
nasal cavit	inflammation		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
[Hematopoietic system]																		
thymus	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
spleen	atrophy		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	
[Digestive system]																		
stomach	hyperplasia:forestomach		- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	

(HPT150)

BAIS2

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)
 DEAD AND MORIBUND ANIMALS (0- 13W)

PAGE : 4

Organ	Findings	Group Name No. of Animals				1600 ppm 0				4000 ppm 2			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]													
nasal cavit	inflammation	-	-	-	-	0	1	0	0	0	1	0	0
		(-)	(-)	(-)	(-)	(0)	(50)	(0)	(0)	(0)	(50)	(0)	(0)
[Hematopoietic system]													
thymus	atrophy	-	-	-	-	0	1	0	0	0	1	0	0
		(-)	(-)	(-)	(-)	(0)	(50)	(0)	(0)	(0)	(50)	(0)	(0)
spleen	atrophy	-	-	-	-	1	1	0	0	1	1	0	0
		(-)	(-)	(-)	(-)	(50)	(50)	(0)	(0)	(50)	(50)	(0)	(0)
[Digestive system]													
stomach	hyperplasia:forestomach	-	-	-	-	2	0	0	0	2	0	0	0
		(-)	(-)	(-)	(-)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)

<1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

BA1S2

APPENDIX B 11-5

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : MALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	Control				100 ppm				250 ppm				640 ppm			
		No. of Animals	10				10				10				10			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen	deposit of hemosiderin		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	7 (70)	0 (0)	0 (0)	0 * (0)	10 (100)	0 (0)	0 (0)	0 ** (0)
	deposit of melanin		2 (20)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
	extramedullary hematopoiesis		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)
[Digestive system]																		
salivary gl	swelling:acinar cell		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 granule:decreased		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)
stomach	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)	1 (10)	0 (0)	0 (0)	0 (0)
	hyperplasia: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)	1 (10)	0 (0)	0 (0)	0 (0)
liver	deposit of pigment		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		1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)
[Urinary system]																		
kidney	basophilic change		1 (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)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

		Group Name No. of Animals				1600 ppm 10				4000 ppm 7			
Organ	Findings	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)
[Hematopoietic system]													
spleen	deposit of hemosiderin	0 (0)	10 (100)	0 (0)	0 ** (0)	0 (0)	7 (100)	0 (0)	0 ** (0)				
	deposit of melanin	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	extramedullary hematopoiesis	9 (90)	1 (10)	0 (0)	0 ** (0)	1 (14)	6 (86)	0 (0)	0 ** (0)				
[Digestive system]													
salivary gl	swelling:acinar cell	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (29)	0 (0)	0 (0)				
	eosinophilic granule:decreased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	1 (14)	0 (0)				
stomach	erosion:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	0 (0)	0 (0)				
	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	4 (57)	2 (29)	0 (0)	0 ** (0)				
liver	deposit of pigment	0 (0)	0 (0)	0 (0)	0 (0)	6 (86)	0 (0)	0 (0)	0 ** (0)				
	granulation	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
[Urinary system]													
kidney	basophilic change	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

PAGE : 3

Organ	Findings	Group Name	Control				100 ppm				250 ppm				640 ppm			
		No. of Animals	10				10				10				10			
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																		
kidney	deposit of hemosiderin		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)
[Endocrine system]																		
thyroid	deposit of pigment		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)
Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe																		
(HPT150)																		

BAIS2

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 7			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]													
kidney	deposit of hemosiderin	0	0	0	0	3	3	0	0 **	(43)	(43)	(0)	(0)
		(0)	(0)	(0)	(0)	(43)	(43)	(0)	(0)				
[Endocrine system]													
thyroid	deposit of pigment	8	0	0	0 **	3	4	0	0 **	(43)	(57)	(0)	(0)
		(80)	(0)	(0)	(0)	(43)	(57)	(0)	(0)				
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square													
		<1>:Slight		<2>:Moderate		<3>:Marked		<4>:Severe					

(HPT150)

BAIS2

APPENDIX B 11-6

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOSUE : FEMALE : SACRIFICED ANIMALS

(13Week STUDY))

STUDY NO. : 0088
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name	Control				100 ppm				250 ppm				640 ppm			
		No. of Animals	10	10	10	10	10	10	10	10	10	10	10	10	10	10		
			<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen	deposit of hemosiderin		8	0	0	0	10	0	0	0	10	0	0	0	0	10	0	0 **
			(80)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(0)	(0)	(100)	(0)
	deposit of melanin		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)
	extramedullary hematopoiesis		10	0	0	0	10	0	0	0	9	1	0	0	9	1	0	0
			(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(90)	(10)	(0)	(0)	(90)	(10)	(0)	(0)
[Digestive system]																		
stomach	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	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
liver	deposit of pigment		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		5	0	0	0	5	1	0	0	4	1	0	0	4	0	0	0
			(50)	(0)	(0)	(0)	(50)	(10)	(0)	(0)	(40)	(10)	(0)	(0)	(40)	(0)	(0)	(0)
[Urinary system]																		
kidney	deposit of hemosiderin		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)
[Endocrine system]																		
thyroid	deposit of pigment		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)

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

STUDY NO. : 0088
 ANIMAL : MOUSE BDF1
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 6

Organ	Findings	Group Name No. of Animals				1600 ppm 10				4000 ppm 8			
		<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>	<1>	<2>	<3>	<4>
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]													
spleen	deposit of hemosiderin	0 (0)	10 (100)	0 (0)	0 ** (0)	0 (0)	1 (13)	7 (88)	0 ** (0)				
	deposit of melanin	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)				
	extramedullary hematopoiesis	6 (60)	4 (40)	0 (0)	0 (0)	0 (0)	2 (25)	6 (75)	0 ** (0)				
[Digestive system]													
stomach	erosion:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)				
	hyperplasia:forestomach	0 (0)	0 (0)	0 (0)	0 (0)	6 (75)	2 (25)	0 (0)	0 ** (0)				
liver	deposit of pigment	0 (0)	0 (0)	0 (0)	0 (0)	4 (50)	4 (50)	0 (0)	0 ** (0)				
	granulation	2 (20)	0 (0)	0 (0)	0 (0)	2 (25)	0 (0)	0 (0)	0 (0)				
[Urinary system]													
kidney	deposit of hemosiderin	0 (0)	0 (0)	0 (0)	0 (0)	3 (38)	5 (63)	0 (0)	0 ** (0)				
[Endocrine system]													
thyroid	deposit of pigment	10 (100)	0 (0)	0 (0)	0 ** (0)	2 (25)	6 (75)	0 (0)	0 ** (0)				

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

APPENDIX B 12-1

IDENTITY AND PURITY OF CDNB

PERFORMED AT THE JAPAN BIOASSAY LABORATORY

(13Week STUDY)

IDENTITY AND PURITY OF CDNB PERFORMED AT THE JAPAN BIOASSAY LABORATORY
(THIRTEEN-WEEK STUDIES)

Lot no.TLM5643

1.Physical properties	<u>Determines</u>	<u>Literature Values</u>
Appearance:	Yellow solid	Yellow solid
Melting point:	51°C	51°C (ENCYCLOPAEDIA Published by Kyooritsu CO..LTD.)
2.Spectral data		
Mass spectrometry		
Instrument	Hitachi M-80B	
Ionization	EI(Electron Impact)	
Range of Measurement	0~500	
Results	<u>Molecule Weight</u>	
Theory	202(Calculated without isotope)	
Determined	202	
Infrared		
Instrument	: Hitachi 270-30	
Cell	: KBr	
Slit	: Medium	

Results	<u>Determines</u>	<u>Literature Values</u>
	: Wave Number (CM ⁻¹)	
	485	480
	525	520
	555	550
	620	610
	670	665
	705	700
	750	740
	760	755
	850	840
	860	855
	915	905
	930	920
	1060	1050
	1115	1100
	1150	1140
	1170	1160
	1260	1250
	1360	1350
	1475	1460
	1560	1540
	1600	1595
	1620	
	1720	1710
	1980	1980
	3130	3100
		(WAKO PURE CHEMICAL INDUSTRIES,LTD)

Ultraviolet

Instrument : Shimadzu UV-240

Cell : 10mm cell

Slit : 2

Results : Wavelength
(nm)

205

235~260

B. Gas Chromatography

Instrument : HEWLETT PACKARD 5890A
Column : METHYL SILICONE, 50m, 0.2 ϕ
Column Temperature : 180°C
Flow Rate : 1ml/min
Detector : Flame Ionization Detector(FID)
Injection Volume : 1 μ l
Results : Only one major peak

Peak No.	Retention Time(min)	Retention Time Relative to Major Peak	Area (percent of Major peak)
1	5.39	1.00	100

C. Conclusions: The results of the Mass spectra agreed with the theoretical values. Boiling point agreed with the Literature values. Impurity was not detected in test substance by Gas chromatography. The infrared spectra agreed with the Literature values. Ultraviolet spectra was indicated of absorption of aromatic hydrocarbone (235nm~260nm).

APPENDIX B 12-2

STABILITY OF CDNB AT THE JAPAN BIOASSAY LABORATORY

(13Week STUDY)

STABILITY OF CDNB AT THE JAPAN BIOASSAY LABORATORY(THIRTEEN WEEK STUDIES)

Lot no.TLM5643

1.Sample storage: CDNB were stored for about two weeks at 5°C.

	<u>Previous determined of test</u> (07/20/87)	<u>After determined of test</u> (11/16/87)
--	--	---

2.Physical properties

Appearance:	Yellow solid	Yellow solid
Melting point:	51°C	51°C

3.Spectral data

Infrared

Instrument : Hitachi 270-30

Cell : KBr

Slit : Medium

Results : Wave Number
(CM⁻¹)

485	485
525	525
555	555
620	620
670	670
705	705
750	750
760	760
850	850
860	860
915	915
930	930
1060	1060
1115	1115
1150	1150
1170	1170
1260	1260
1360	1360
1475	1475
1560	1560
1600	1600
1620	1620
1720	1720
1980	1980
3130	3130

	<u>Previous determined of test</u> (07/20/87)	<u>After determined of test</u> (11/16/87)
Ultraviolet		
Instrument	: Shimadzu UV-240	
Cell	: 10mm cell	
Slit	: 2	
Results	: Wavelength (nm)	
	205	205
	235~260	235~260

4. Gas Chromatography

Instrument : HEWLETT PACKARD 5890A

Column : METHYL SILICONE, 50m, 0.2 ϕ

Column Temperature : 180°C

Flow Rate : 1ml/min

Detector : Flame Ionization Detector(FID)

Injection Volume : 1 μ l

Results : Only one major peak

Date	Retention Time(min)	Retention Time Relative to Major Peak	Area (percent of Major peak)
07/20/87	5.39	1.00	100
11/16/87	5.395	1.00	100

D. Conclusions: The results of the Infrared and Ultraviolet spectra agreed with the previous determine of test Values. Boiling point agreed with the previous determine of test Values. Impurity was not detected in test substance by Gas chromatography.

Consequently, CDNB was stable as the chemical when stored for about thirteen weeks at temperatures to 5°C.

APPENDIX B 12-3

RESULTS OF ANALYSIS AND STABILITY OF FORMULATED FIETS IN THE THIRTEEN - WEEK STUDIES OF CDNB

RESULTS OF ANALYSIS OF FORMULATED DIETS IN THE THIRTEEN-WEEK STUDIES OF CDNB
(Rat)(Mouse)

Date Mixed	Concentration of DNCB in feed for Taget Concentration(ppm)				
	100 (a)	250.1(a)	640 (a)	1600 (a)	4000 (a)
08/26/87	95.1(95.1)	236.7(94.7)	619.6(97.9)	1565.6(97.8)	3933.6(98.3)

(Rat)(Mouse)

Date Mixed	Concentration of DNCB in feed for Taget Concentration(ppm)				
	100 (a)	250.1(a)	640 (a)	1600 (a)	4000 (a)
08/26/87(b)	95.1	236.7	619.6	1565.6	3933.6
09/02/87	66.5(66.5)	148.3(59.3)	403.9(63.1)	1098.3(68.6)	2999.0(75.0)

(a) Determined as a percent of taget

(b) Formulated