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

 $(B1-1\sim B12-3)$

1 3 Week STUDY NO. 0087; 0088

- 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

- 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

- 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

- 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

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

SEX : MALE

PAGE: 1

Clinical sign	Group Name	Admini:	stration We	ek-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
	PROCESS AND ADDRESS AND ADDRES	1	1	1	1	1	1	1	1	1	1	1	1	1	1
UNCHBACK 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	ő	0	Ô	0	0	0	0	0	0	Ô	Ô	0	0
	640 ppm	0	Ö	0 .	0	0	0	0	0	0 -	0	Ô	Ô	0	0
	1600 ppm	0	Ö	Ö	0	0	Õ	0	0	0	0	0	0	0	Ŏ
	4000 ppm	0	1	1	0	0	0	0	0	0	0	Ö	Ö	Ö	0
ASTING	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
y.	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
ILOERECTION	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
DILED 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
BNORMAL 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

(HAN190)

APPENDIX B 1-2

CLINICAL OBSERVATION: SUMMARY, RAT: FEMALE

STUDY NO. : 0087 ANIMAL : RAT F344 REPORT TYPE : A1 13 CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

linical sign	Group Name	Adminis	stration W	eek-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
LOERECTION	Control	0	0	٥	٥	0	0	0	•	•	•	۰		٠	•
EOEREO110N	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	ū	0	0	•	0	0	0
	640 ppm	0	0	. 0	. 0	0	0	. 0	0	0	v	0	0	0	0
	1600 ppm	0	0	-	0	-	-	-	0	0	0	0	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
SS 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	Ò	0	0	0	0	0	0
	4000 ppm	0	0	0	0	0	0	0	0	1	1	1	1	2	2
DILED PERI GENITALIA	Control	0	0	0	0	. 0	0	0	0	0	0	0	0	0	0
	100 ppm	0	Ö	Ö	Ŏ	0	0	0	0	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	Ö	0	n	0	0	0	0	0
	640 ppm	Ô	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	Ö	6	10	10	10	10	10	10	10	10	10	10	10	10
CRYMATION	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	Ô	0	1	0
	250 ppm	0	0	0	Ö	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	Ö	0	0	0 .	0	0	0	0	0	0	0	0	0
	1600 ppm	0	Ö	0	0	Ö	0	Ŏ	ő	ő	0	0	. 0	0	0
	4000 ppm	0	0	0	Ö	0	1	1	0	. 0	0	0	1	2	1
М	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	۸	1	7
	250 ppm	0	0	0	0	0	0	0	0	0	0	0	0	7	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	-	0	·	-	-	-	U	•	U	0	ď
	1600 ppm	0	0		0	0	0	0	0	0	0	0	0	1	2
	4000 ppm	U	U	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	Admini	stration W	eek-day											
		0-0 1	1-7 1	2-7 1	3-7 1	4-7 1	5-7 1	6-7 1	7-7 1	8–7 1	9-7 1	10-7 1	11-7 1	12-7 1	13-' 1
EYE OPACITY	Control	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 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)

APPENDIX B 1-3

CLINICAL OBSERVATION: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

STUDY NO. : 0088

SEX : MALE

PAGE: 1

Clinical sign	Group Name	Admini	stration We	eek-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
	B-18-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	1	1	1 .	1	1	1	1	1	1	1	1	1	1	1
DEATH	C+1	۸	0	٥	^		0	0	^	0	0	0	0		0
DENTI	Control	0	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 640 ppm	0	0	0	. 0	0	0	0	. 0	0	0	0	. 0	0	0
	1600 ppm	Ů,	0	0	0	0	0	0	0	0	0	0	0	0	0
	1000 ppm	0	0	1	2	2	2	3	3	3	3	3	3	3	3
	4000 ppm	V	U	1	4	2	4	3	3	ა	3	3	ა	J	J
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
1	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
and I Ind	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	Ô	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	0	, 0	0	0	Ö	0	0	0	0
	4000 ppm	0	1	2	2	2	2	1	1	1	1	2	2	2	2

(HAN190)

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

SEX : MALE

 Δ

linical sign	Group Name	Admini:	stration W	eek-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
ATT ED	Control	0	0	0	^	٥	0	0	0		0	0	0	0	٥
DILED	Control 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	٥	0	٥	0
	640 ppm	0	0	0	. 0	0	0	0	0	0	0	0	0	٥.	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
	4000 PPIII	U	4	4	J	J	J	J	J	J	J	3	J	J	0
LOERECTION	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
SS 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
AUMA	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
ILED 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

(HAN190)

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

SEX : MALE

PAGE: 3

Clinical sign	Group Name	Admini	stration We	ek-day											
		0-0 - 1	1-7 1	2-7 1	3-7 1	4-7 1	5–7 1	6-7 1	7-7 1	8-7 1	9–7 1	10-7 1	11-7 1	12-7 1	13-7 1
ANEMIA	Control	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	Ö	0	0	0	0	0	0
	250 ppm	0	0	0	0	0	0	0	0	0	0	Ö	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)

APPENDIX B 1-4

CLINICAL OBSERVATION: SUMMARY, MOSUE: FEMALE

STUDY NO.: 0088

ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

Clinical sign	Group Name	Admini:	stration We	ek-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
OCOMOTOR 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
rremor	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	Ö	2	2	i	1	1	1	1	1	1	1	1	1

STUDY NO.: 0088

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

SEX : FEMALE

Clinical sign	Group Name	Admini	stration W	eek-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	Ö	0	0	Ö	0	0	0	. 0	Ŏ	0	0	0	Ŏ	0
	4000 ppm	0	0	1	Õ	0	0	0	2	. 0	0	0	0	0	0
	**************************************	•	•	•	v	•	•	v		Ü	U	•		·	•

STUDY NO. : 0088 ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13 CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : FEMALE

PAGE: 6

Clinical sign	Group Name	Admini:	stration We	ek-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
	4.4.	1	1	1	1	1	1	1	1	1	1	1	1	1	1
WODUMILLI WOO		•													
KOPHTHALMOS	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
YE 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
BNORMAL 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
UBNORMAL 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		0	1	0	0	0	0	0	0	0	0	0

(HAN190) BAIS 2

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

STUDY NO. : 0087

ANIMAL : RAT F344
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

Δ

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 1

oup Name	Administrati	on 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±	111	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**

(HAN260)

STUDY NO.: 0087 ANIMAL : RAT F344

UNIT : g

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

REPORT TYPE : A1 13 SEX : MALE

roup Name	Admini	stration	week-day											
	7-7		8-7		9–7		10-7		11-7		12-7		13-7	
			, , , , , , , , , , , , , , , , , , , ,			Andrew March Comment								
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±	10	287±	91	297±	21	307±	21	314±	22	322±	21
1000 PPIII	2001	10	2701	19	2011	21	287 1	21	307 I	21	214.1	22	322 1	21
4000 ppm	215±	17**	227±	19**	236±	18**	246±	19**	254±	18**	261±	18**	268±	18**
Significant differe	nce; *:P≦(0.05	**: P ≦ 0.0	01	***************************************		Test of D	unnett						

(HAN260)

BAIS 2

APPENDIX B 2-2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

STUDY NO.: 0087
ANIMAL: RAT F344

UNIT ; g
REPORT TYPE : A1 13

BODY WEIGHT CHANGES ALL ANIMALS (SUMMARY)

SEX : FEMALE

(HAN260)

PAGE: 3

roup Name		Admini:	stratio	n 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			3	118±	4		5	143±	6	149±	7		7	162±	
									О		1				
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 differer	nce;	* : P ≦ 0	.05	** : P ≦ 0.0	01			Test of Du	unnett		-			-	

STUDY NO. : 0087

ANIMAL : RAT F344

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

7

BODY WEIGHT CHANGES

(SUMMARY)

ALL ANIMALS

Group Name	Admini	stration	n week-day											
	7–7		8-7		9-7		10-7		11-7		12-7		13-7	
					i									
Control	171±	5	175±	6	179±	6	183±	6	186±	6	190土	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± 1	2	183±	12	186±	12	187±	12
640 ppm	167±	12	170±	12	173±	12	178± 1	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 ≦	0.05	** : P ≤ 0.0	01			Test of Dunr	nett						

(HAN260)

BAIS 2

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

)

)

STUDY NO.: 0088

ANIMAL : MOUSE BDF1

UNIT : g

REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

(SUMMI)

Group Name Administration week-day_ 1-7 2-7 4-7 Control 19.3 ± 0.9 22.4± 1.9 24.0± 1.4 23.4 ± 1.4 25.1± 1.9 27.7 ± 2.4 26.6± 2.0 100 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** 16.8± 4.0** 17.9± 4.0** 15.9± 2.5** 16.7± 3.3**

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

(HAN260)

BAIS 2

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 2

roup 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 differe	nce; *:P≦0.05 ×	* : P ≤ 0.01		Test of Dunnett				

(HAN260)

APPENDIX B 2-4

BODY WEIGHT CHANGES: SUMMARY, MOSUE: FEMALE

STUDY NO.: 0088

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

0-0 17.0± 0.8	1-7	2-7	3-7	4-7	5–7	6–7
17.0+ 0.8						
1	17.5± 0.7	18.7± 0.9	18.8± 1.5	19.9± 1.2	20.2± 1.0	19.1± 1.3
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
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
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
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
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
	17.4 ± 0.7 17.4 ± 0.7 17.4 ± 0.7	$17.4 \pm$ 0.7 $17.7 \pm$ 0.8 $17.4 \pm$ 0.7 $17.8 \pm$ 0.7 $17.4 \pm$ 0.7 $17.6 \pm$ 0.9	17.4 ± 0.7 17.7 ± 0.8 19.4 ± 1.3 17.4 ± 0.7 17.8 ± 0.7 19.1 ± 0.6 17.4 ± 0.7 17.6 ± 0.9 18.3 ± 0.9	17.4 ± 0.7 17.7 ± 0.8 19.4 ± 1.3 20.1 ± 1.3 17.4 ± 0.7 17.8 ± 0.7 19.1 ± 0.6 19.2 ± 0.4 17.4 ± 0.7 17.6 ± 0.9 18.3 ± 0.9 18.8 ± 0.7	17.4 ± 0.7 17.7 ± 0.8 19.4 ± 1.3 20.1 ± 1.3 20.3 ± 1.1 17.4 ± 0.7 17.8 ± 0.7 19.1 ± 0.6 19.2 ± 0.4 20.1 ± 0.5 17.4 ± 0.7 17.6 ± 0.9 18.3 ± 0.9 18.8 ± 0.7 19.8 ± 0.6	$17.4\pm$ 0.7 $17.7\pm$ 0.8 $19.4\pm$ 1.3 $20.1\pm$ 1.3 $20.3\pm$ 1.1 $20.8\pm$ 0.8 $17.4\pm$ 0.7 $17.8\pm$ 0.7 $19.1\pm$ 0.6 $19.2\pm$ 0.4 $20.1\pm$ 0.5 $20.4\pm$ 0.7 $17.4\pm$ 0.7 $17.6\pm$ 0.9 $18.3\pm$ 0.9 $18.8\pm$ 0.7 $19.8\pm$ 0.6 $20.1\pm$ 0.4

(HAN260)

BAIS 2

STUDY NO.: 0088

ANIMAL : MOUSE BDF1
UNIT : g

REPORT TYPE : A1 13 SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

roup 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		
.600 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		
1000 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 differenc	e; *: P ≦ 0.05	** : P ≦ 0.01		Test of Dunnett					

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

Group Name Administration week-day(effective) 4-7(7) 1-7(7) 2-7(7) 3-7(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 14.3± 1.8 13.0 ± 1.5 640 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士 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)

BAIS 2

STUDY NO.: 0087 ANIMAL : RAT F344

UNIT : g

REPORT TYPE : A1 13 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 2

roup Name	Administration 8–7(7)	week-day(effective) 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 differ	rence; *: P ≤ 0.05 *	$*: P \leq 0.01$		Test of Dunnett			

(HAN260)

APPENDIX B 3-2

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE

STUDY NO.: 0087 ANIMAL : RAT F344

UNIT : g
REPORT TYPE : A1 13 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 3

oup Name		eek-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
O40 PPIII	10.01 0.0	10.01 0.0	10.71 0.5	10.01	10.01 0.0	0.01 0.0	10.01 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**
							•
		7-44-4-5-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4					
Significant differ	rence; *: P ≤ 0.05 *:	$*: P \leq 0.01$		Test of Dunnett			

(HAN260)

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STUDY NO. : 0087 ANIMAL : RAT F344

UNIT : g REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 4

Group Name		week-day(effective)				***************************************	
	8–7(7)	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	
1000 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 differ	ence; *: P ≤ 0.05 *	:*: P ≤ 0.01		Test of Dunnett			

(HAN260)

APPENDIX B 3-3

FOOD CONSUMPTION CHANGES: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

Δ

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 differer	nce; *:P≦0.05	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

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STUDY NO.: 0088

ANIMAL : MOUSE BDF1
UNIT : g
REPORT TYPE : A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 2

Group Name	Λdministration 8–7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	
			10 7(7)	11-7(1)	. 12-1(1)	. 15-7(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 differ	ence; *: P ≦ 0.05 *	* : P ≤ 0.01		Test of Dunnett			

(HAN260)

APPENDIX B 3-4

FOOD CONSUMPTION CHANGES: SUMMARY, MOSUE: FEMALE (13Week STUDY)

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STUDY NO.: 0088

ANIMAL : MOUSE BDF1

UNIT : g

REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

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 3.8± 0.3 3.7 ± 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)

BAIS 2

PAGE: 3

 Δ

STUDY NO. : 0088

ANIMAL : MOUSE BDF1
UNIT : g

REPORT TYPE : A1 13 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

Group Name	Administratio	n 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	
			1880-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1				
Significant difference ;	* : P ≤ 0.05	** : P ≤ 0.01	·	Test of Dunnett			

(HAN260)

BAIS 2

PAGE: 4

APPENDIX B 4-1

CHEMICAL INTAKE CHANGES: SUMMARY, RAT: MALE

STUDY NO.: 0087 ANIMAL: RAT F344

ALL ANIMALS

UNIT : mg/kg/day REPORT TYPE : A1 13

SEX : MALE

PAGE: 1

Administration (weeks)_	Name						
1	,	2	3	4	5	6	7
000± 0.000 0.00	ontrol C	0.000 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000	0.000± 0.000
073± 0.249 7.47) ppm 8	77± 0.266	6.709± 0.308	6.157± 0.333	5.910± 0.238	5.309± 0.279	5.277± 0.268
699± 0.667 18.88) ppm 20	84± 0.813	16.956± 0.726	15.563± 0.799	14.548± 0.838	13.023± 0.749	13.405± 0.973
932± 1.861 47.54) ppm 51	47± 1.580	43.183± 1.140	40.155± 1.575	38.206± 1.768	34.927± 1.701	34.841± 2.061
579± 4.798 118.87) ppm 120	71± 2.716	106.431± 4.135	98.387± 5.141	92.887± 5.260	86.983± 3.393	84.086± 5.461
540±255.946 287.63	0 ppm 455	330± 20.952	310.478±104.143	258.334± 27.503	243.762± 10.086	221.221± 7.676	203.399± 7.936
540±255.946 287.63	0 ppm 458	330± 20.952	310.478±104.143	258.334± 27.503	243.762± 10.086	221.221± 7.676	203.399±

CHEMICAL INTAKE CHENGES (SUMMARY)

(HAN300) BAIS 2

ANIMAL : RAT F344

UNIT : mg/kg/day REPORT TYPE : A1 13

SEX : MALE

CHEMICAL INTAKE CHENGES (SUMMARY)

ALL ANIMALS

PAGE: 2

Group Name	Adminis	stration	(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	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)

APPENDIX B 4-2

CHEMICAL INTAKE CHANGES: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344

UNIT : mg/kg/day REPORT TYPE : A1 13

SEX: FEMALE

7

CHEMICAL INTAKE CHENGES (SUMMARY)

ALL ANIMALS

Group Name Administration (weeks) 1 2 3 5 6 Control 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

PAGE: 3

ANIMAL: RAT F344
UNIT: mg/kg/day
REPORT TYPE: A1 13
SEX: FEMALE

CHEMICAL INTAKE CHENGES (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)

APPENDIX B 4-3

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: MALE

ANIMAL : MOUSE BDF1

UNIT : mg/kg/day

REPORT TYPE : A1 13

SEX : MALE

CHEMICAL INTAKE CHENGES (SUMMARY)

ALL ANIMALS

PAGE: 1

roup 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)

ANIMAL : MOUSE BDF1

UNIT : mg/kg/day REPORT TYPE : A1 13

CHEMICAL INTAKE CHENGES (SUMMARY)

ALL ANIMALS

SEX : MALE

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	00 140-1 0 410	20 217 - 2 222	97 CCO-L 9 C99	24 422 - 0 075	00 075-1 0 550	24 254 1 2 200	
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)

APPENDIX B 4-4

CHEMICAL INTAKE CHANGES: SUMMARY, MOUSE: FEMALE

CHEMICAL INTAKE CHENGES (SUMMARY) ALL ANIMALS

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

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	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)

CHEMICAL INTAKE CHENGES (SUMMARY)

ANIMAL : MOUSE BDF1

ALL ANIMALS

UNIT : mg/kg/day REPORT TYPE : A1 13

SEX : FEMALE

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)

APPENDIX B 5-1

HEMATOLOGY: SUMMARY, RAT: MALE

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 BI	LOOD CELL µl	HEMOGLOBIN g / dl		HEMATOCRIT %		MCV fℓ		MCH Pg		g∕dl g∕dl		PLATELET 1 Ο³ / 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**

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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 O³∕μશ		Differentia N-BAND	L 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
Significar	nt difference;	*: P ≤ 0.0	05	**: P ≤ 0,	01			Γ	est of	Dunnett							

(JCL71A)

APPENDIX B 5-2

HEMATOLOGY: SUMMARY, RAT: FEMALE

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 BI	LOOD CELL µl	HEMOGL g∕dl	OBIN	HEMATO %	CRIT	MCV fℓ		MCH Pg		MCHC g∕dl		PLATELI 1 O³/μ	
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**

(HCL070)

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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 1 O³∕µl	!	Differentia N-BAND	al 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

(JCL71A)

APPENDIX B 5-3

HEMATOLOGY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

SEX : MALE

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

PAGE: 1 Group Name NO. of RED BLOOD CELL HEMOGLOBIN HEMATOCRIT MCV MCH PLATELET MCHC Animals 1 06/μl g/dl % fℓ g/dl 1 03/με рg Control 10 11.64± 0.40 $16.5 \pm$ 0.4 51.2± 1.4 $44.0 \pm$ 0.5 $14.2 \pm$ 32.3 ± 0.3 $1585 \pm$ 0.3 140 100 ppm 10 11.54± 0.38 $16.3 \pm$ 0.4 $50.6 \pm$ 1.6 43.8± 32.2 ± 0.3 0.4 $14.1 \pm$ 0.1 $1671 \pm$ 112 250 ppm 11.07 ± 0.34 $15.8 \pm$ 0.5* 48.8± 1.4* $44.0 \pm$ 0.4 $14.3 \pm$ 0.1 32.5 ± 0.4 1584± 143 640 ppm 10 11.18± 0.24 $15.9 \pm$ 0.4 $49.5 \pm$ 1.3 44.2± 0.5 $14.3 \pm$ 0.2 $32.2 \pm$ 0.4 1619± 77 1600 ppm 10 10.73± 0.36** $15.7 \pm$ 0.5** $48.0 \pm$ 1.5** $44.7 \pm$ 0.5 $14.6 \pm$ 0.2** 1686± $32.7\pm$ 0.4 131 4000 ppm 9.86± 1.52** 14.0± 1.9** 42.7± 6.0** 43.4± 1.1 $14.3 \pm$ 0.6 32.8± 0.6* $1683 \pm$ 155 Significant difference; $*: P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HCL070)

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

SEX : MALE

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

PAGE: 1

iroup Name	NO. of Animals	WBC 1 O³∕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	
Significan	t difference;	*: P ≤ 0.0)5	**: P ≤ 0.0	1		-]	Cest of I	Dunnett								
(JCL71A)																		BAIS

APPENDIX B 5-4

HEMATOLOGY: SUMMARY, MOSUE: FEMALE

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (13)

PAGE: 2

roup Name	NO. of Animals	RED BI 1 O ⁶ /I	LOOD CELL ul	g∕al	OBIN	HEMATO %	OCRIT	MCV f ℓ		MCH Pg		MCHC g∕dl		PLATEL 1 O³∕µ	
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

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 O³∕μl	Differer N-BAN	ntial WBC ND	(%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER		
Control	10	1.28± 0.	74 0±	1	14士	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	
Significan	t difference ;	*: P ≤ 0.05	** : P ≦	0.01			,	Test of	Dunnett								BAIS

APPENDIX B 6-1

BIOCHEMISTRY: SUMMARY, RAT: MALE

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

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

PAGE: 1

Group Name	NO. of Animals	TOTAL P	ROTEIN	aLBUMIN g∕dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg∕dl		T-CHOLES	STEROL	TRIGLYC mg/dl	ERIDE
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

(HCL074)

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1

SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

PAGE: 2

Group Name	NO. of Animals	PHOSPHOI mg/dl	LIPID	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

(HCL074) BAIS 2

7.

STUDY NO.: 0087 ANIMAL : RAT F344

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

SEX : MALE

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

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

(HCL074)

BAIS 2

PAGE: 3

APPENDIX B 6-2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

STUDY NO. : 0087 ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	TOTAL P g∕dl	ROTEIN	ALBUMIN g∕dl		۸/	G RATIO			T-BILIF	RUBIN	GLUCOSE mg/dl		T-CHOLES	TEROL	TRIGLYCE mg/dl	CRIDE
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		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**
Significan	t difference ;	*: P ≦ (0.05	**: P ≤ 0.0)1			HEW	Tes	st of Du	nnett						

PAGE: 4

(HCL074) BAIS 2 STUDY NO.: 0087
ANIMAL: RAT F344

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

REPORT TYPE : A1
SEX : FEMALE

Group Name	NO. of Animals	PHOSPHOI mg/dl	LIPID	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士	7

PAGE: 5

(HCL074) BAIS 2

STUDY NO. : 0087 ANIMAL : RAT F344 BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

REPORT TYPE : A1 SEX : FEMALE

Group Name	NO. of Animals	UREA NI mg∕dl	TROGEN	CREATIN mg∕dl	INE	SODIUM mEq∕ℓ		POTASSI mEq/4		CHLORIDE mEq∕ℓ		CALCIUM mg∕dl		INORGAN mg/dl	IC PHOSPHORUS
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土	1	10.0±	0.2	4.8±	1.3
Significan	t difference ;	*: P ≦ ().05	**: P ≤ 0.0)1			Test of Dur	nett						RAIS

(HCL074)

BAIS 2

APPENDIX B 6-3

BIOCHEMISTRY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

SEX : MALE

PAGE: 1

Group Name	NO. of Animals	TOTAL P	ROTEIN	ALBUMIN g∕dl		A/G RAT	10	T-BILII mg/dl		GLUCOSE mg∕dl		T−CHOLE mg∕dl	STEROL	TRIGLYCE mg/dl	ERIDE
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*

(HCL074)

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

SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

PAGE : 2

Group Name	NO. of Animals	GOT IU∕ℓ		GPT IU∕ℓ		LDH IU/	e	ALP IU/é		CPK IU/4	?	UREA N 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士	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

(HCL074)

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

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

roup Name	NO. of Animals	POTASSI mEq/		CHLORIDE mEq∕ℓ		CALCIUM mg∕dl		INORGANI mg∕dl	C PHOSPHORUS		
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		
.600 ppm	10	4.6±	0.3	121±	3	8.6±	0.4	6.5±	1.3		
1000 ppm	7	5.2±	0.4	120±	4	8.2±	0.5	7.1±	1.2		
Significan	t difference;	* : P ≦ (0.05	**: P ≤ 0.01				Test of Dunr	nett	 	
HCL074)			· · · · · · · · · · · · · · · · · · ·							 	BAIS

APPENDIX B 6-4

BIOCHEMISTRY: SUMMARY, MOSUE: FEMALE

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

SEX : FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

PAGE: 4

Group Name	NO. of Animals	TOTAL PR g/dl	OTEIN	g∕dl g∕dl		A/G RATI	0	T-BILII mg/dl		GLUCOSE mg/dl		T-CHOLES	TEROL	TRIGLYCE mg/dl	ERIDE
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士	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士	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
Significan	t difference;	*: P ≤ 0.	05	**: P ≤ 0.01	l · .		***	Test of Du	nnett						

(HCL074)

^

STUDY NO.: 0088

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX: FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (13)

Group Name NO. of GPT GOT LDH ALP CPK UREA NITROGEN SODIUM Animals IU/e IU∕ℓ IU∕ℓ IU/l IU∕ℓ mg/dl mEq∕ℓ Control 10 43± 6 $12\pm$ 2 $292 \pm$ 50 $238 \pm$ 32 $34\pm$ 8 21.6± 3.0 $150 \pm$ 4 100 ppm 10 44± 9 $12\pm$ 4 $243 \pm$ 74 $250 \pm$ 39 $28\pm$ 7 $21.0\pm$ 2.5 $151 \pm$ 6 43± 250 ppm 10 5 $11\pm$ 1 296± 67 $265 \pm$ 26 $32\pm$ 5 $20.8 \pm$ 1.9 $150 \pm$ 4 640 ppm 10 47± 6 10± 2 $290 \pm$ 81 279± 22* $49\pm$ 29 20.9± 3.0 151± 4 1600 ppm 10 $55\pm$ 15 11± 2 406± 120* $291 \pm$ 36** $63 \pm$ 39 $23.5 \pm$ 2.7 $151 \pm$ 4 4000 ppm 8 $74\pm$ 16** $14\pm$ 4 449± 3 121** $304 \pm$ 39** \pm 08 18** 25.8± 5.3* $150 \pm$

Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ 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	POTASSI mEq/		CHLORIDE mEq∕ℓ		CALCIUM mg∕dl		INORGAN mg/dl	NIC PHOSPHORUS	
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*	
Significan	t difference;	*: P ≦ (0.05	** : P ≤ 0.01				Test of Dur	nnett	
(HCL074)										BA

APPENDIX B 7-1

URINALYSIS: SUMMARY, RAT: MALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 013-7

SEX : MALE

REPORT TYPE : A1

Group Name	NO. of	рH							Protei	in				G	uco	se				Ket	one	bodyBilirubir	1				
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5 CHI	- ±		2+ 3	3+ 4+	CHI				2+	3+ 4+	CHI			2+ 3+ CHI		+	2+	3+ CHI	

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	0	
100 ppm	10	0	0	0	0	0	9	1	0 0	7	3	0 0)	10	0	0	0	0 ()	9	1	0 0	10	0 0	0	0	
250 ppm	10	0	0	0	0	1	6	3	0 0	7	3	0 0) .	10	0 (0	0	0 ()	. 9	1	0 0	10	0 0	0	0	
640 ppm	10	. 0	0	0	0	0	8	2	0 0	10	0	0 0) *	1	0	0	0	0 ()	9	1	0 0	. 10	0 0	0	0	
1600 ppm	10	0	0	0	0	0	8	2	0 0	7	3	0 0)	1	0 (0	0	0 ()	9	1	0 0	1	0 0	0	0	
4000 ppm	10	0	0	1	0	0	9	0	0 0	7	3	0 0)	1	0 0	0	0	0 ()	9	1	0 0	1	0 0	0	0	

Significen	t difference	; *	; P ≦	≦ 0.05	5	** :	P ≦	0.01					Tes	t of	CHI	SQU	ARE										
JCL101)	**************************************							·	·····																		В

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 013-7

SEX : MALE

REPORT TYPE : A1

PAGE: 2 Group Name NO. of Occult blood Urabilinagen Animals $- \pm + 2 + 3 + CHI$ \pm + 2+ 3+ 4+ CHI 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 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 Significent difference ; $*: P \le 0.05$ $**: P \le 0.01$ Test of CHI SQUARE

(JCL101)

APPENDIX B 7-2

URINALYSIS : SUMMARY, RAT : FEMALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE : 013-7

SEX: FEMALE

REPORT TYPE : A1

PAGE: 3

Group Name	NO. of	pH_								Pro	teir)	-			GL	ucos	:e				Кe	tone	e bac	yBili	rubin					
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI				+ 3+	4+	CHI				2+ 3+	+ 4+	CHI				3+ C			F 2+	3+	CHI	
Control	10	0	0	0	0	2	8	0		0	٥	7	9 N	0		10	٥	٥	0 (0 0		1.0	. ^	0	0		10	^ ^			
				-	V	4	_									10	V	U		, ,		10	v	U	U		10	0 (0		
100 ppm	10	0	1	0	0	0	9	0		0	2	8	0 0	0		10	0	0	0 (0 0		5	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	Ó	0	0 (0 0		10	0	0	0		10	0 (0		
Significer	nt difference	; *	: P ≦	≦ 0.08	5	** :	P ≦	0.01							Test	of C	HIS	SQUA	RE												
(JCL 101)																															 D

(JCL101)

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 013-7

SEX : FEMALE	REPORT	TYPE : A1					PAGE: 4
Group Name	NO. of Animals	0ccult bload — ± + 2+ 3+ CHI	Vrobilinogen ± + 2+ 3+ 4+ CHI				
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				
Cianificant	- diff		. D = 0.01	m	 	-	
	difference	; *:P≦0.05 **	: P ≦ 0.01	Test of CHI SQUARE			
(JCL101)							BAIS 2

APPENDIX B 7-3

URINALYSIS: SUMMARY, MOSUE: MALE

URINALYSIS

ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-7

SEX : MALE

REPORT TYPE : A1

PAGE: 1

Animals 5.0 6.0 6.5 7.0 7.5 8.0 8.5 CHI	10 0 1 0 3 5 1 0 1 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0
Control 10 0 1 0 3 5 1 0 1 0 1 0 1 0 1 0 0 1 0 0 1 0 0 0 0	10 0 1 0 3 5 1 0 0 1 0 0 1 0 0 1 0 0 0 1 0 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 8 2 0 0 10 0 0 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 0 0 0 10 0 0 0 0 0 0	10
250 ppm 10 0 0 1 2 6 1 0 0 0 4 6 0 0 10 0 0 0 0 5 5 0 0 10 0 0 0	10 0 0 1 2 6 1 0 0 0 0 0 1 2 0 0 1 0 0 0 0 0 0 0 0 0
	10 0 1 3 0 4 2 0 0 0 5 5 0 0 10 0 0 0 0 0 0 0 10 0 0 10 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 0 0 10 0 0 0	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
1600 ppm 10 0 0 3 2 3 2 0 0 0 5 5 0 0 10 0 0 0 0 6 4 0 0 10 0 0 0 0	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
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	

(JCL104X)

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE : 013-7

SEX : MALE

REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinosen ± + 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 **	
Significent	difference	* : $P \le 0.05$ ** : $P \le 0.01$ Test of CHI SQUARE	
(JCL104X)			 BAIS

APPENDIX B 7-4

URINALYSIS: SUMMARY, MOSUE: FEMALE

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-7

URINALYSIS

Group Name NO. of Animals Control 10	pH	7.0 7.5 8.0 8.5 CF	Protein I — ± + 2+ 3+ 4+ CHI	Glucose - ± + 2+ 3+ 4+ CHI		Occult blood — ± + 2+ 3+ CHI
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

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-7

SEX : FEMALE

REPORT TYPE : A1

Group Name	NO. of Animals	Urabilinagen ± + 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	**				
			·				
Significer	nt difference	; *: P ≤ 0.05	** : P ≤ 0.01		Test of CHI SQUARE		
(JCL104X)	7.						BAIS 2

APPENDIX B 8-1

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1
SEX : MALI : MALE GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

PAGE: 1

0rgan	Findings	Group Name NO. of Animals	Control 10 (%)	100 ppm 10 (%)	250 ppm 10 (%)	640 ppm 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)
ather	yellow		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

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STUDY NO. : 0087

ANIMAL : RAT F344 REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

SEX : MALE

0rgan	Findings	Group Name 1600 ppm NO. of Animals 10 (%)	4000 ppm 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

APPENDIX B 8-2

GROSS FINDINGS: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS

Λ

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1

SEX : FEMALE

GROSS FINDINGS (SUMMARY)

SACRIFICED ANIMALS (13W)

0rgan	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)
vary	cyst		0 (0)	0 (0)	1 (10)	0 (0)
erus	dilated lumen		2 (20)	1 (10)	2 (20)	5 (50)
ther	yellow .		0 (0)	0 (0)	1 (10)	1 (10)

(HPT080)

BAIS 2

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1
SEX : FEMA : FEMALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

PAGE: 4

Organ	Findings	Group Name 1600 ppm NO. of Animals 10 (%)	4000 ppm 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)	
(UDMO O O)				
(HPT080)				BAIS

APPENDIX B 8-3

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

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1 : MALE SEX

gan	Findings	Group Name NO. of Animals	Control 0 (%)	100 ppm 0 (%)	250 ppm 0 (%)	640 ppm 0 (%)
ng	red		- ' (-)	- (-)	- (-)	- (-)
leen	atrophic		- (-)	- (-)	- (-)	- (-)
restomach	ulcer		- (-)	- (-)	- (-)	- (-)
all intes	fluid:black		- (-)	- (-)	- (-)	- (-)
ll bladd	dilated		- (-)	- (-)	- (-)	- (-)
				, ,	()	

(HPT080)

BAIS 2

Δ

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE

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

Group Name 1600 ppm 4000 ppm NO. of Animals 0 (%) 3 (%) Organ___ Findings_ - (-) lung red 1 (33) - (-) spleen 1 (33) atrophic ulcer - (-) forestomach 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)

Δ

STUDY NO. : 0088 ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE

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

100 ppm 0 (%) Control 250 ppm 640 ppm Group Name 0 (%) 0 (%) 0rgan__ Findings_ NO. of Animals 0 (%) - (-) - (· -) - (-) - (-) lung red - (-) - (-) - (-) - (-) forestomach ulcer (HPT080) BAIS 2

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : FEMALE

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

Organ	Findings	Group Name NO. of Animals	1600 ppm 0 (%)	4000 ppm 2 (%)	
lung	red		- (-)	1 (50)	
forestomach	ulcer		- (-)	1 (50)	
(HPT080)					BAIS 2

APPENDIX B 8-5

GROSS FINDINGS: SUMMARY, MOSUE: MALE: SACRIFICED ANIMALS

ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY)

SACRIFICED ANIMALS (13W)

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

(HPT080)

BAIS 2

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

0rgan	Findings	Group Name 1600 ppm NO. of Animals 10 (%)	4000 ppm 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)				BAIS 2

APPENDIX B 8-6

GROSS FINDINGS: SUMMARY, MOSUE: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0088 ANIMAL : MOUSE BDF1

REPORT TYPE : A1 : FEMALE SEX

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

PAGE: 3

)rgan	Findings	Group Name NO. of Animals	Control 10 (%)	100 ppm 10 (%)	250 ppm 10 (%)	640 ppm 10 (%)
hymus	atrophic		0 (0)	0 (0)	0 (0)	0 (0)
leen	black		0 (0)	0 (0)	0 (0)	0 (0)
	black zone		1 (10)	1 (10)	1 (10)	0 (0)
Jer .	dark		0 (0)	0 (0)	0 (0)	0 (0)
vroid	dark		0 (0)	0 (0)	0 (0)	0 (0)
e	absence		0 (0)	0 (0)	1 (10)	0 (0)
her	yellow		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (13W)

REPORT TYPE : A1 SEX : FEMALE

PAGE: 4

pleen blac	ck zone	0 ((100)	8	(13) (100) (0)		
pleen blac	ck zone	10 ((100)	8	(100)		
		0 ((0)	0	(0)		
iver dark							
	<	0 ((0)	8	(100)		
nyroid dark	•	0 ((0)	6	(75)		
ye abse	ence	0 ((0)	0	(0)		
ther yell	Low	0 ((0)	5	(63)		

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

315±	19 0.249±	0.043 0	0.046±							
306±				0.005	2.843±	0.112	0.946±	0.071	1.012±	0.055
	17 0.241±	0.032	0.049±	0.003	2.820±	0.110	0.919±	0.036	0.992±	0.046
300±	21 0.253±	0.031 0	0.049±	0.005	2.818±	0.155	0.901±	0.061	0.986±	0.061
315±	13 0.247±	0.033	0.048±	0.003	2.873±	0.091	0.961±	0.055	1.046±	0.044
300±	19 0.224±	0.028	0.048±	0.003	2.818±	0.102	0.911±	0.053	0.997±	0.061
250±	17** 0.193±	0.025**	0.043±	0.004	2.772±	0.103	0.793±	0.060**	0.881±	0.045**
	315± 300± 250±	315 ± 13 0.247± 300 ± 19 0.224± $250\pm 17**$ 0.193±	$315\pm$ 13 $0.247\pm$ 0.033 $300\pm$ 19 $0.224\pm$ 0.028 $250\pm$ 17** $0.193\pm$ 0.025**	$315\pm$ 13 $0.247\pm$ 0.033 $0.048\pm$ $300\pm$ 19 $0.224\pm$ 0.028 $0.048\pm$ $250\pm$ $17**$ $0.193\pm$ $0.025**$ $0.043\pm$	315± 13	$315\pm$ 13 $0.247\pm$ 0.033 $0.048\pm$ 0.003 $2.873\pm$ $300\pm$ 19 $0.224\pm$ 0.028 $0.048\pm$ 0.003 $2.818\pm$ $250\pm$ $17**$ $0.193\pm$ $0.025**$ $0.043\pm$ 0.004 $2.772\pm$	315± 13	315± 13	315± 13	315± 13

(HCL040)

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	KID	NEYS	SPL	EEN	LIV	ER	BRA		
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**	

(HCL040)

APPENDIX B 9-2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: FEMALE

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

UNIT: g

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

PAGE: 3

NO. of Animals	Body (weight	THYMU	JS	ADRE	VALS	OVAR	IES	HEART		LUNGS	S	
10	179±	6	0.196±	0.017	0.054±	0.003	0.085±	0.012	0.611±	0.016	0.742±	0.044	
10	174±	10	0.195±	0.023	0.052±	0.005	0.088±	0.011	0.622±	0.040	0.732±	0.036	
10	175±	12	0.194±	0.012	0.056±	0.007	0.088±	0.013	0.626±	0.043	0.748±	0.040	
10	170±	12	0.200±	0.022	0.054±	0.005	0.088±	0.008	0.615±	0.044	0.744±	0.047	ė.
10	171±	8	0.196±	0.017	0.054±	0.004	0.089±	0.012	0.623±	0.040	0.741±	0.037	
10	152±	8**	0.163±	0.024**	0.050±	0.005	0.089±	0.015	0.565±	0.029*	0.720±	0.052	
	10 10 10 10 10 10	10 179± 10 174± 10 175± 10 170± 10 171±	10 179± 6 10 174± 10 10 175± 12 10 170± 12 10 171± 8	Animals 10	Animals 10	Animals 10 179± 6 0.196± 0.017 0.054± 10 174± 10 0.195± 0.023 0.052± 10 175± 12 0.194± 0.012 0.056± 10 170± 12 0.200± 0.022 0.054± 10 171± 8 0.196± 0.017 0.054±	Animals 10 179± 6 0.196± 0.017 0.054± 0.003 10 174± 10 0.195± 0.023 0.052± 0.005 10 175± 12 0.194± 0.012 0.056± 0.007 10 170± 12 0.200± 0.022 0.054± 0.005 10 171± 8 0.196± 0.017 0.054± 0.004	10	10	10	10	10	10

(HCL040)

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

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

SEX : FEMALE UNIT: g

Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals 1.202± 0.033 0.370 ± 0.027 4.093± 0.130 1.739± 0.017 Control 10 10 1.221 ± 0.075 0.374± 0.026 4.068± 0.289 1.747 ± 0.051 100 ppm 1.750 ± 0.034 0.378± 0.028 4.126± 0.337 250 ppm 10 1.237 ± 0.080 0.414± 0.076 640 ppm 10 1.231 ± 0.065 4.114± 0.456 1.757 ± 0.042 0.406± 0.027* 4.317± 0.230 1.749± 0.047 10 1.254 ± 0.071 1600 ppm 0.454± 0.030** 4.085 ± 0.271 1.726 ± 0.043 4000 ppm 10 1.186± 0.038 Significant difference; $*:P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett BAIS 2

PAGE: 4

(HCL040)

APPENDIX B 9-3

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOSUE: MALE

STUDY NO. : 0088
ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : MALE UNIT: g

Δ

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*
Significa	nt difference;	*: P ≤ 0.05 **:	P ≤ 0.01	Test	of Dunnett		

(HCL040)

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STUDY NO.: 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

SEX : MALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY)

SURVIVAL ANIMALS (13)

Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals Control 0.376± 0.029 10 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 0.280± 0.068** 0.066± 0.036 0.727± 0.209 0.404± 0.037 Significant difference; $*:P \leq 0.05$ ** : P ≤ 0.01 Test of Dunnett

(HCL040)

BAIS 2

APPENDIX B 9-4

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOSUE: FEMALE

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

SEX : FEMALE
UNIT: g

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

PAGE: 3

roup 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**

(HCL040)

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

REPORT TYPE: SEX: FEMALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (13)

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN		
Contral	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**		
Significar	nt difference;	* : P ≤ 0.05 *	* : P ≤ 0.01	. T	est of Dunnett		***************************************
(HCL040)						,	В.

APPENDIX B 10-1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

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

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

Group Name	NO. of Animals	Body weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
						WARRAN AND A CONTRACTOR OF THE		
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**	
Significa	nt difference;	*: P ≤ 0.05 **	: P ≤ 0.01	Tes	t of Dunnett			
(HCL042)								E

STUDY NO.: 0087

ANIMAL : RAT F344
REPORT TYPE : A1

SEX : MALE UNIT: %

Δ

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

PAGE: 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
		WAX-WALLER WAY-PARTY CO. 1				
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**	

(HCL042)

APPENDIX B 10-2

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: FEMALE

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**	
Significar	nt difference;	*: P ≤ 0.05 **	: P ≤ 0.01	Tes	st of Dunnett			
(HCL042)								BA

STUDY NO.: 0087 ANIMAL : RAT F344

REPORT TYPE : A1 SEX : FEMALE UNIT: %

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

roup Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
		0.070 0.000	0.000 0.011	0.000 0.000	0.070 0.000	
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**	

APPENDIX B 10-3

ORGAN WEIGHT, RELATIVE: SUMMARY, MOSUE: MALE

STUDY NO. : 0088

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : MALE UNIT: %

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

PAGE: 1

iroup 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	
1000 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**	
Significar	nt difference;	* : P ≤ 0.05 **	: P ≤ 0.01	Tes	st of Dunnett			
HCL042)								BA

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE UNIT: %

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

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士 0.508**	
Significar	nt difference ;	*: P ≤ 0.05 **:	P ≤ 0.01	Tes	af Dunnett	
(HCL042)						BAIS 2

APPENDIX B 10-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

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STUDY NO. : 0088
ANIMAL : MOUSE BDF1

REPORT TYPE : A1

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

SEX : FEMALE UNIT: %

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	

(HCL042)

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*	

(HCL042)

APPENDIX B 11-1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: SACRIFICED ANIMALS

STUDY NO. : 0087 ANIMAL

: RAT F344

REPORT TYPE : A1

SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

		Group Name Control No. of Animals 10 <1> <2> <3> <4>	100 ppm 10 <1> <2> <3> <4>	250 ppm 10 <1> <2> <3> <4>	640 ppm 10 <1> <2> <3> <4>
gan	Findings	(%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)	(%) (%) (%) (%)
Respiratory s	ystem]				
ina	bronchiolar-alveolar cell hyperplasia	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (10) (10) (10)	0 0 0 0 0 (0) (0)
lematopoietic	: system]				
pleen	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)
	deposit of hemosiderin	0 10 0 0 0 (0) (100) (0) (0)	0 10 0 0 (0) (100) (0) (0)	1 9 0 0 (10) (90) (0) (0)	0 10 0 0 (0) (100) (0) (0)
	extramedullary hematopoiesis	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)
Circulatory s	system]				
eart	granulation	2 0 0 0 0 (20) (0) (0) (0)	1 0 0 0 0 (10) (10) (10)	2 0 0 0 0 (20) (20) (0) (0)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Digestive sy	stem]				
alivary 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
	easinophilic 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)
stomach	erasian: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)
	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

(HPT150)

BAIS2

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1 SEX : MALE

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

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

(HPT150)

STUDY NO. : 0087 ANIMAL : RAT F344

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 3

SACRIFICED ANIMALS (13W)

Group Name Control 100 ppm 250 ppm 640 ppm No. of Animals 10 10 10 10 〈2〉 〈3〉 〈4〉 <1> <2> <3> <4> <2> <3> <1> <1> <4> <1> <2> <3> <4> (%) (%) (%) Findings (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) [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) epidermal cyst (0) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) (10) (0) (0) (0) pancreas atrophy (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) [Urinary system] kidney basophilic change 1 0 0 0 2 0 0 0 3 0 0 1 0 0 0 (20) (0) (0) (0) (10) (0) (0) (0) (10) (0) (0) (0) (30) (0) (0) (0) easinophilic body 0 6 4 2 8 0 7 3 ** (0)(60)(40)(0) (0)(20)(80)(0) (0) (10) (80) (10) (0) (0) (70) (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) thyroid ultimibranchial body remanet 0 0 0 0 1 0 0 0 0 0 0 0 1 0 (0) (0) (0) (0) (10) (0) (0) (0) (0)(0)(0)(0) (10) (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

: MALE

SEX

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

Group Name 1600 ppm 4000 ppm No. of Animals 10 10 <1> <2> <3> <4> <1> <2> <3> <4> Findings (%) (%) (%) (%) (%) (%) (%) (%) [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) 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) easinaphilic bady 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)

<1>:Slight

0 0 0 0

(0)(0)(0)(0)

<2>:Moderate

<3>:Marked

<4>:Severe

1 0 0 0

(10) (0) (0) (0)

(HPT150)

thyroid

ultimibranchial body remanet

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

BAIS2

APPENDIX B 11-2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: FEMALE: SACRIFICED ANIMALS

STUDY NO. : 0087 ANIMAL : RAT F344 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

REPORT TYPE : A1 SEX : FEMALE

0rgan	Findings	Group Name Control No. of Animals 10 <1> <2> <3> <4> (%) (%) (%) (%)	100 ppm 10 <1> <2> <3> <4> (%) (%) (%) (%)	250 ppm 10 <1> <2> <3> <4> (%) (%) (%) (%)	640 ppm 10 <1> <2> <3> <4> (%) (%) (%) (%)
	_				
[Respiratory s	system]				
nasal cavit	inflammation:respiratory epithelium	4 0 0 0 0 (40) (0) (0) (0)	1 0 0 0 0 (10) (10) (10)	2 0 0 0 0 (20) (0) (0)	4 0 0 0 (40) (40) (0) (0)
lung	accumulation of foamy cells	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (10) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0
[Hematopoietic	c system]				
bone marrow	granulation	2 2 0 0 (20) (20) (0) (0)	1 0 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 2 0 0 (10) (20) (0) (0)	1 2 0 0 (10) (20) (0) (0)
	erythropolesis:increased	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 0 (0) (0)	1 0 0 0 0 (10) (10) (10)
spleen	cangestian	0 0 0 0 0 (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 10 0 0 (0) (100) (0) (0)	0 10 0 0 (0) (0) (0)	0 10 0 0 (0) (100) (0) (0)	0 10 0 0 (0) (100) (0) (0)
	extramedullary hematopoiesis	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (100) (100)	10 0 0 0 (100) (0) (0) (0)	10 0 0 0 (100) (0) (0) (0)
[Digestive sy	stem]				
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)
	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)
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)

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

: FEMALE

SEX

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

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

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

SEX : FEMALE

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

0rgan	Findings	Group Name Control No. of Animals 10	100 ppm 10 <1> <2> <3> <4> (%) (%) (%) (%)	250 ppm -10 <1> <2> <3> <4> (%) (%) (%) (%)	640 ppm 10 <1> <2> <3> <4> (%) (%) (%) (%)
	-				
[Digestive syst	tem]				
Liver	herniation	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 0 0 0 0 (20) (0) (0)	0 0 0 0 0 0 (0)	1 0 0 0 0 (10) (10) (10)	1 0 0 0 0 (10) (10) (10) (10)
[Urinary system	m]				
kidney	mineralization:cortico-medullary junction	9 0 0 0 0 (90) (90) (90)	9 0 0 0 0	6 0 0 0 (60) (0) (0) (0)	7 0 0 0 (70) (0) (0) (0)
	eosinophilic droplet;proximal tubule	0 0 0 0 0 (0) (0)	7 3 0 0 ** (70) (30) (0) (0)	3 7 0 0 ** (30) (70) (0) (0)	1 7 2 0 ** (10) (70) (20) (0)
[Endocrine sys	etem]				
pituitary	Rathke pouch	0 0 0 0 0 (0) (0)	(0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(0) (0) (0) (0)
thyroid	ultimibranchial body remanet	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
[Special sense	ə organs/appandage]				
Harder gl	inflammation	3 0 0 0 0 (30) (0) (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	2 1 0 0 (20) (10) (0) (0)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

ANIMAL : RAT F344
REPORT TYPE : A1
SEX : FEMALE

(HPT150)

4000 ppm Group Name 1600 ppm No. of Animals 10 10 <1> <2> <3> <4> <1> <2> <3> <4> (%) (%) (%) (%) (%) (%) (%) (%) Findings_ [Digestive system] liver herniation 0 0 0 0 1 0 0 0 (10) (0) (0) (0) (0) (0) (0) (0) pancreas atrophy (0) (0) (0) (0) (10) (0) (0) (0) [Urinary system] 8 0 0 0 kidney mineralization:cortico-medullary junction 6 0 0 0 (80) (0) (0) (0) (60) (0) (0) (0) eosinophilic droplet; proximal tubule 0 4 6 0 ** 0 0 10 0 ** (0)(40)(60)(0) (0) (0) (100) (0) [Endocrine system] pituitary Rathke pouch (0)(0)(0)(0) (0)(0)(0)(0) 1 0 0 0 ultimibranchial body remanet thyraid (10) (0) (0) (0) (20) (0) (0) (0) [Special sense organs/appandage] 2 0 0 0 3 0 0 0 Harder gl inflammation (20) (0) (0) (0) (30) (0) (0) (0) <1>;Slight <2>:Moderate <3>:Marked <4>:Severe Significant difference; *: $P \le 0.05$ **: $P \le 0.01$ Test of Chi Square

BAIS2

APPENDIX B 11-3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOSUE: MALE: DEAD AND MORIBUNDANIMALS

(13Week STUDY)

STUDY NO. : 0088 ANIMAL

7

: MOUSE BDF1

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 13W)

Group Name Control 100 ppm 250 ppm 640 ppm No. of Animals 0 0 0 0 <1> (2> 〈3〉 〈4〉 <1> <2> <3> <4> <2> <3> (4) <1> <2> <3> <4> (1) Findings_ (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) (%) [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 (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-)

(HPT150)

<1>:Slight

<2>: Moderate

<3>:Marked

<4>:Severe

BAIS2

Λ.

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE

(HPT150)

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 〈2〉 〈3〉 〈4〉 <1> <2> <3> <4> <1> 0rgan____ Findings_ (%) (%) (%) (%) (%) (%) (%) [Hematopoietic system] thymus atrophy 0 1 1 0 (-) (-) (-) (-) (0) (33) (33) (0) spleen atrophy 0 3 0 0 (-) (-) (-) (-) (0)(100)(0)(0) [Circulatory system] heart thrombus (-) (-) (-) (-) (0)(67)(0)(0) [Digestive system] tongue erosion (-) (-) (-) (-) (33) (0) (0) (0) salivary gl swelling;acinar cell (-) (-) (-) (-) (0) (33) (0) (0) eosinophilic granule:decreased 0 0 2 0 (-) (-) (-) (-) (0)(0)(67)(0). hyperplasia:forestomach stomach 1 1 0 0 (-) (-) (-) (-) (33) (33) (0) (0) <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

BAIS2

APPENDIX B 11-4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOSUE: FEMALE: DEAD AND MORIBUND ANIMALS

(13Week STUDY))

 Δ

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 3

DEAD AND MORIBUND ANIMALS (0- 13W)

Group Name Control 100 ppm 250 ppm 640 ppm No. of Animals 0 0 (1) <2> <3> <4> <1> <2> <3> <4> <2> <3> <1> <2> <3> <4> <1> <4> (%) (%) (%) (%) (%) Findings_ (%) (%) (%) (%) (%) (%) (%) (%) [Respiratory system] nasal cavit inflammation (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) [Hematopoietic system] thymus atrophy (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) spleen atrophy (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) [Digestive system] stomach hyperplasia: forestomach (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) <1>:Slight <2>: Moderate <3>:Marked <4>:Severe (HPT150) BAIS2

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

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

0rgan:	Findings	Group Name 1600 ppm No. of Animals 0 <1> <2> <3> <4>	4000 ppm 2 <1> <2> <3> <4> (%) (%) (%) (%)	
[Respiratory s	system]			
nasal cavit	inflammation	(-) (-) (-) (-)	0 1 0 0 (0) (50) (0) (0)	
[Hematopoietio	c system]			
thymus	atrophy	(-) (-) (-)	0 1 0 0 (0) (50) (0) (0)	
spleen	atrophy	(-) (-) (-) (-)	1 1 0 0 (50) (50) (0) (0)	
[Digestive sys	stem]			
stomach	hyperplasia:forestomach	(-) (-) (-) (-)	2 0 0 0 (100) (0) (0) (0)	
<1>	:Slight <2>:Moderate <3>	:Marked <4>:Severe		
(HPT150)				· B

APPENDIX B 11-5

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOSUE: MALE: SACRIFICED ANIMALS

(13Week STUDY))

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (13W)

		Group Name Control	100 ppm	250 ppm	640 ppm
rgan	Findings	No. of Animals 10 <pre></pre>	(1) (2) (3) (4) (%) (%) (%) (%)	10 <1> <2> <3> <4> (%) (%) (%) (%)	10 <1> <2> <3> <4> (%) (%) (%) (%)
Hematopoieti	c system]				
pleen	deposit of hemosiderin	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	7 0 0 0 * (70) (0) (0) (0)	10 0 0 0 *** (100) (0) (0) (0)
	deposit of melanin	2 0 0 0 (20) (0) (0)	3 0 0 0 (30) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 0 (10) (10) (10)
	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)
Digestive sy	stem]				
alivary 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)
	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)
tomach	erosion:forestomach	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)	1 0 0 0 (10) (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)	1 0 0 0 (10) (0) (0) (0)
i∪er	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)
	granulation	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 0 (10) (10) (10) (10)	2 0 0 0 0 (20) (0) (0)
Urinary sys	tem]				
<idney< td=""><td>basophilic change</td><td>1 0 0 0 (10) (0) (0) (0)</td><td>0 0 0 0 0 (0) (0)</td><td>0 0 0 0 0 (0) (0) (0)</td><td>0 0 0 0 0 (0) (0)</td></idney<>	basophilic change	1 0 0 0 (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)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

PAGE: 2 Group Name 1600 ppm 4000 ppm No. of Animals 10 <1> <2> <3> <4> <1> <2> <3> <4> Findings (%) (%) (%) (%) (%) (%) (%) (%) [Hematopoietic system] spleen deposit of hemosiderin 0 7 0 0 ** (0) (100) (0) (0) (0)(100)(0)(0) deposit of melanin (10) (0) (0) (0) (0)(0)(0)(0) extramedullary hematopoiesis 9 1 0 0 ** 1 6 0 0 ** (90) (10) (0) (0) (14) (86) (0) (0) [Digestive system] salivary gl swelling:acinar cell (0) (0) (0) (0) (0)(29)(0)(0) eosinophilic granule:decreased 0 0 0 0 (0)(0)(0)(0) (0)(14)(14)(0) stomach erosion:forestomach 1 0 0 0 (0)(0)(0)(0) (14) (0) (0) (0) hyperplasia: forestomach 0 0 0 0 4 2 0 0 ** (0)(0)(0)(0) (57) (29) (0) (0) liver deposit of pigment (0)(0)(0)(0) (86) (0) (0) (0) granulation 1 0 0 0 0 0 0 (10) (0) (0) (0) (0)(0)(0)(0) [Urinary system] kidney basophilic change (0) (0) (0) (0) (0)(0)(0)(0) Significant difference : * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

 Δ

STUDY NO. : 0088

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)
SACRIFICED ANIMALS (13W)

		Graup No. of	· Animals	Contro		440		1	ppm			10				10		
Organ	Findings		<1> (%)	<2> (%)	<3> (%)	<4> (%)	<1> (%)			<4> (%)	<1> (%)	<2> (%)	<3> (%)	<4> (%)		<2> (%)	<3> (%)	<4> (%)
[Urinary sy:	steml					-												
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)
Endocrine :	system]																	
hyroid:	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)
Significant	difference; $*:P \leq 0.05$ **:P	≦ 0.01 Test o	of Chi Squar	e	<1	>:Slight		<2>:Moo	derate		<3>:Marked		<4>: Se	evere	 	***		
(HPT150)															 			В

: MOUSE BDF1 ANIMAL

REPORT TYPE : A1 SEX : MALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (13W)

Group Name 1600 ppm 4000 ppm No. of Animals 10 <1> <2> <3> <4> <1> <2> <3> <4> 0rgan____ Findings_ (%) (%) (%) (%) (%) (%) (%) [Urinary system] kidney deposit of hemosiderin 0 0 0 0 3 3 0 0 ** (0) (0) (0) (0) (43) (43) (0) (0) [Endocrine system] thyroid deposit of pigment 0 0 0 ** 3 4 0 0 ** (43) (57) (0) (0) (80) (0) (0) (0) Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ 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))

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE

(HPT150)

7

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 5

BAIS2

SACRIFICED ANIMALS (13W)

Group Name 250 ppm 640 ppm Control 100 ppm No. of Animals 10 10 10 10 <2> <3> 〈2〉 〈3〉 〈2〉 〈3〉 ⟨2⟩ ⟨3⟩ ⟨4⟩ (1) (4) <1> (4) <1> (4) <1> (%) (%) (%) (%) (%) (%) (%) (%) 0rgan__ Findings_ (%) (%) (%) (%) (%) [Hematopoietic system] deposit of hemosiderin 0 ** spleen 0 0 0 10 0 0 10 10 (80) (0) (0) (0) (100) (0) (0) (0) (100) (0) (0) (0) (0)(100)(0)(0) deposit of melanin (10) (0) (0) (0) (10) (0) (0) (0) (0)(0)(0)(0) (0)(0)(0)(0) extramedullary hematopoiesis 10 10 9 1 0 9 1 (90) (10) (0) (0) (90) (10) (0) (0) (100) (0) (0) (0) (100) (0) (0) (0) [Digestive system] 0 0 stomach erosion:forestomach (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 liver deposit of pigment 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) 5 4 0 0 granulation 5 4 (40) (10) (0) (0) (50) (0) (0) (0) (50) (10) (0) (0) (40) (0) (0) (0) [Urinary system] kidney 0 deposit of hemosiderin (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) (0)(0)(0)(0) [Endocrine system] 0 0 0 0 thyroid deposit of pigment (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

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (13W)

PAGE: 6 Group Name 1600 ppm 4000 ppm No. of Animals 10 <1> <2> <3> <4> <1> <2> <3> <4> (%) (%) (%) (%) Findings_ (%) (%) (%) (%) [Hematopoietic system] spleen deposit of hemosiderin 0 10 0 0 ** 0 1 7 0 ** (0) (100) (0) (0) (0)(13)(88)(0) deposit of melanin (0) (0) (0) (0) (0) (0) (0) (0) extramedullary hematopoiesis 0 2 6 0 ** (60) (40) (0) (0) (0)(25)(75)(0) [Digestive system] stomach erosion:forestomach 1 0 0 0 (0)(0)(0)(0) (13) (0) (0) (0) hyperplasia: forestomach (0)(0)(0)(0) (75) (25) (0) (0) Liver deposit of pigment 0 0 0 0 4 4 0 0 ** (0) (0) (0) (0) (50) (50) (0) (0) granulation 2 0 0 0 2 0 0 0 (20) (0) (0) (0) (25) (0) (0) (0) [Urinary system] kidney deposit of hemosiderin 3 5 (0)(0)(0)(0) (38) (63) (0) (0) [Endocrine system] thyroid deposit of pigment 0 0 ** 2 6 (100) (0) (0) (0) (25) (75) (0) (0) Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ Test of Chi Square <1>:Slight <2>:Moderate <3>:Marked <4>:Severe

(HPT150)

APPENDIX B 12-1

IDENTITY AND PURITY OF CDNB PERFORMED AT THE JAPAN BIOASSAY LABORATORY (13Week STUDY)

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

Lot no.TLM5643

1. Physical properties

<u>Determines</u>

Literature Values

Appearance:

Yellow solid

Yellow solid

Melting point:

2.Spectral data

51°C

51°C

(ENCYCLOPAEDIA

Published by Kyooritsu

CO..LTD.)

-

Mass spectrometry

Instrument

Hitachi M-80B

Ionization

EI(Electron Impact)

Range of Measurement

0~500

Results

Molecule Weight

Theory

202(Calculated without isotope)

Determined

202

Infrared

Instrument

: Hitachi 270-30

Cell

: KBr

Slit

: Medium

Results	<pre>Determines : Wave Number (CM⁻¹)</pre>	<u>Literature Values</u>
	485 525 555 620 670 705 750 760 850	480 520 550 610 665 700 740 755
	860 915 930 1060 1115 1150 1170 1260 1360 1475 1560 1600	855 905 920 1050 1100 1140 1160 1250 1350 1460 1540 1595
Ultraviolet	1620 1720 1980 3130	1710 1980 3100 (WAKO PURE CHEMICAL INDUSTRIES, LTD)
Instrument	: Shimazdu UV-240	
Cell	: 10mm cell	

Slit : 2

Results : Wavelength (nm)

205 235~260

B.Gas Chromatography

Instrument

: HEWLETT PACKARD 5890A

Column

: METHYL SILICONE, 50m, 0.2ϕ

Column Temperature

: 180°C

Flow Rate

: 1ml/min

Detector

: Flame Ionization Detector(FID)

Injection Volume

 $: 1 \mu 1$

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 Litrature values. Ultraviolet spectra was indecated 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 $5\,^{\circ}\text{C}$.

	Previous determined of test (07/20/87)	After determined of test (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)	
	485 525 555 620 670	485 525 555 620 670
•	705 750 760 850 860	705 750 760 850 860
	915 930 1060 1115 1150	915 930 1060 1115 1150
	1170 1260 1360 1475	1170 1260 1360 1475

Previous determined of test (07/20/87) After determined of test (11/16/87)

Ultraviolet

Instrument : Shimazdu UV-240

Cell : 10mm cell

Slit : 2

Results : Wavelength

(nm)

205 235~260 235~260 235~260

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 : $1\mu 1$

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	

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

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.

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)

	Cond	centration of DNCB	in feed for Taget	Concentration(ppm	1)
Date Mixed	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)					
	Con	centration of DNCB	in feed for Taget	Concentration(ppm	1)
Date Mixed	100 (a)	250.1(a)	640 (a)	1600 (a)	4000 (a)
08/26/87(b) 09/02/87	95.1 66.5(66.5)	236.7 148.3(59.3)	619.6 403.9(63.1)	1565.6 1098.3(68.6)	3933.6 2999.0(75.0)

⁽a) Determined as a percent of taget

⁽b) Formulated