

メタクリル酸 = 2,3 エポキシプロピルのラットを用いた  
吸入によるがん原性試験報告書

試験番号：0794

# TABLES

## TABLES

TABLE A      CONCENTRATIONS OF 2,3-EPOXYPROPYL METHACRYLATE  
IN THE INHALATION CHAMBER OF THE 2-YEAR INHALATION  
STUDY

TABLE B 1    SURVIVAL ANIMAL NUMBERS: MALE

TABLE B 2    SURVIVAL ANIMAL NUMBERS: FEMALE

TABLE C 1    CLINICAL OBSERVATION: MALE

TABLE C 2    CLINICAL OBSERVATION: FEMALE

TABLE D 1    BODY WEIGHT CHANGES AND SURVIVAL ANIMAL NUMBERS  
: MALE

TABLE D 2    BODY WEIGHT CHANGES AND SURVIVAL ANIMAL NUMBERS  
: FEMALE

TABLE D 3    BODY WEIGHT CHANGES: MALE

TABLE D 4    BODY WEIGHT CHANGES: FEMALE

TABLE E 1    FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS: MALE

TABLE E 2    FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS: FEMALE

TABLE E 3    FOOD CONSUMPTION CHANGES: MALE

TABLE E 4    FOOD CONSUMPTION CHANGES: FEMALE

TABLE F 1    HEMATOLOGY: MALE

TABLE F 2    HEMATOLOGY: FEMALE

TABLE G 1    BIOCHEMISTRY: MALE

TABLE G 2    BIOCHEMISTRY: FEMALE

## TABLES (CONTINUED)

TABLE H 1 URINALYSIS: MALE

TABLE H 2 URINALYSIS: FEMALE

TABLE I 1 GROSS FINDINGS: MALE

TABLE I 2 GROSS FINDINGS: FEMALE

TABLE J 1 ORGAN WEIGHT, ABSOLUTE: MALE

TABLE J 2 ORGAN WEIGHT, ABSOLUTE: FEMALE

TABLE K 1 ORGAN WEIGHT, RELATIVE: MALE

TABLE K 2 ORGAN WEIGHT, RELATIVE: FEMALE

TABLE L 1 HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS  
: MALE

TABLE L 2 HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS  
: FEMALE

TABLE M 1 NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF  
TUMORS-TIME RELATED: MALE

TABLE M 2 NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF  
TUMORS-TIME RELATED: FEMALE

TABLE N 1 HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS:  
MALE

TABLE N 2 HISTOPATHOLOGICAL FINDINGS: NEOPLASTIC LESIONS:  
FEMALE

TABLE O 1 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL  
ANALYSIS: MALE

TABLE O 2 NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL  
ANALYSIS: FEMALE

## TABLES (CONTINUED)

TABLE P 1 HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR:  
MALE

TABLE P 2 HISTOPATHOLOGICAL FINDINGS: METASTASIS OF TUMOR:  
FEMALE

TABLE Q 1 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC  
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER :  
F344/DuCr1Cr1j MALE RATS

TABLE Q 2 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC  
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER :  
F344/DuCr1Cr1j FEMALE RATS

TABLE R 1 CAUSE OF DEATH: MALE

TABLE R 2 CAUSE OF DEATH: FEMALE

TABLE A

CONCENTRATIONS OF 2,3-EPOXYPROPYL METHACRYLATE  
IN THE INHALATION CHAMBER  
OF THE 2-YEAR INHALATION STUDY

CONCENTRATIONS OF 2,3-EPOXYPROPYL METHACRYLATE IN THE  
INHALATION CHAMBER OF THE 2-YEAR INHALATION STUDY

Group Name	Concentration(ppm)
	Mean $\pm$ S.D.
Control	0.0 $\pm$ 0.0
3.2 ppm	3.2 $\pm$ 0.1
8 ppm	8.1 $\pm$ 0.1
20 ppm	20.1 $\pm$ 0.2

TABLE B1

SURVIVAL ANIMAL NUMBERS : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 1

Group	Name	Animals At start	Administration (Weeks)													
			0	1	2	3	4	5	6	7	8	9	10	11	12	13
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals			Survival rate(%)													

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 2

Group	Name	Animals At start	Administration (Weeks)													
			14	15	16	17	18	19	20	21	22	23	24	25	26	27
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals			Survival rate(%)													

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BAIS5

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1 104  
 SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 3

Group Name	Animals At start	Administration (Weeks)													
		28	29	30	31	32	33	34	35	36	37	38	39	40	41
Control	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
3.2ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
8ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
20ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
Number of survival/ Number of effective animals Survival rate(%)															

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 4

Group	Name	Animals At start	Administration (Weeks)													
			42	43	44	45	46	47	48	49	50	51	52	53	54	55
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals			Survival rate(%)													

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 5

Group	Name	Animals At start	Administration (Weeks)													
			56	57	58	59	60	61	62	63	64	65	66	67	68	69
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	49/50	49/50	49/50	48/50	48/50	48/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	98.0	98.0	96.0	96.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	49/50	48/50	46/50	46/50	46/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	96.0	92.0	92.0
Number of survival/ Number of effective animals			Survival rate(%)													

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 6

Group Name	Animals At start	Administration (Weeks)													
		70	71	72	73	74	75	76	77	78	79	80	81	82	83
Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	49/50	48/50
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	96.0
3. 2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
8ppm	50	48/50	48/50	48/50	48/50	47/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50
		96.0	96.0	96.0	96.0	94.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0
20ppm	50	46/50	46/50	46/50	45/50	45/50	45/50	44/50	41/50	41/50	37/50	35/50	34/50	31/50	31/50
		92.0	92.0	92.0	90.0	90.0	90.0	88.0	82.0	82.0	74.0	70.0	68.0	62.0	62.0
Number of survival/ Number of effective animals Survival rate(%)															

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 7

Group	Name	Animals At start	Administration (Weeks)													
			84	85	86	87	88	89	90	91	92	93	94	95	96	97
	Control	50	48/50	48/50	48/50	48/50	48/50	47/50	47/50	47/50	46/50	46/50	46/50	45/50	45/50	45/50
			96.0	96.0	96.0	96.0	96.0	94.0	94.0	94.0	92.0	92.0	92.0	90.0	90.0	90.0
	3.2ppm	50	50/50	50/50	50/50	50/50	49/50	49/50	49/50	49/50	49/50	48/50	48/50	47/50	47/50	47/50
			100.0	100.0	100.0	100.0	98.0	98.0	98.0	98.0	98.0	96.0	96.0	94.0	94.0	94.0
	8ppm	50	46/50	46/50	46/50	46/50	46/50	46/50	45/50	45/50	45/50	45/50	44/50	44/50	44/50	44/50
			92.0	92.0	92.0	92.0	92.0	92.0	90.0	90.0	90.0	90.0	88.0	88.0	88.0	88.0
	20ppm	50	30/50	27/50	27/50	26/50	25/50	23/50	20/50	19/50	18/50	17/50	17/50	17/50	15/50	15/50
			60.0	54.0	54.0	52.0	50.0	46.0	40.0	38.0	36.0	34.0	34.0	34.0	30.0	30.0
Number of survival/ Number of effective animals			Survival rate(%)													

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 8

Group	Name	Animals At start	Administration (Weeks)						
			98	99	100	101	102	103	104
	Control	50	45/50	45/50	45/50	44/50	43/50	43/50	41/50
			90.0	90.0	90.0	88.0	86.0	86.0	82.0
	3.2ppm	50	47/50	47/50	47/50	46/50	45/50	45/50	44/50
			94.0	94.0	94.0	92.0	90.0	90.0	88.0
	8ppm	50	43/50	43/50	43/50	42/50	42/50	40/50	39/50
			86.0	86.0	86.0	84.0	84.0	80.0	78.0
	20ppm	50	14/50	14/50	14/50	12/50	10/50	9/50	9/50
			28.0	28.0	28.0	24.0	20.0	18.0	18.0
Number of survival/			Number of effective animals						
			Survival rate(%)						

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TABLE B2

SURVIVAL ANIMAL NUMBERS : FEMALE



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 9

Group	Name	Animals At start	Administration (Weeks)													
			0	1	2	3	4	5	6	7	8	9	10	11	12	13
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals			Survival rate(%)													

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BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 10

Group	Name	Animals At start	Administration (Weeks)													
			14	15	16	17	18	19	20	21	22	23	24	25	26	27
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	20ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals																
Survival rate(%)																

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STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 11

Group Name	Animals At start	Administration (Weeks)													
		28	29	30	31	32	33	34	35	36	37	38	39	40	41
Control	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
3.2ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
8ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
20ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
Number of survival/ Number of effective animals Survival rate(%)															

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BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 12

Group Name	Animals At start	Administration (Weeks)													
		42	43	44	45	46	47	48	49	50	51	52	53	54	55
Control	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
3.2ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
8ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	49/50 98.0	49/50 98.0	49/50 98.0	49/50 98.0	49/50 98.0
20ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0
Number of survival/ Number of effective animals Survival rate(%)															

(HAN360)

BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 13

Group	Name	Animals At start	Administration (Weeks)													
			56	57	58	59	60	61	62	63	64	65	66	67	68	69
	Control	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	3.2ppm	50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50	50/50
			100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
	8ppm	50	49/50	49/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50
			98.0	98.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0
	20ppm	50	50/50	49/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50	48/50
			100.0	98.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0
Number of survival/ Number of effective animals			Survival rate(%)													

(HAN360)

BA1S5

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1 104  
 SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 14

Group Name	Animals At start	Administration (Weeks)													
		70	71	72	73	74	75	76	77	78	79	80	81	82	83
Control	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	48/50 96.0	48/50 96.0	48/50 96.0	48/50 96.0	48/50 96.0	47/50 94.0	47/50 94.0	46/50 92.0
3.2ppm	50	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	50/50 100.0	49/50 98.0	49/50 98.0	49/50 98.0	49/50 98.0
8ppm	50	48/50 96.0	48/50 96.0	48/50 96.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	46/50 92.0	46/50 92.0	46/50 92.0	46/50 92.0	45/50 90.0
20ppm	50	48/50 96.0	48/50 96.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	47/50 94.0	46/50 92.0	46/50 92.0	46/50 92.0	45/50 90.0	44/50 88.0	43/50 86.0
Number of survival/ Number of effective animals Survival rate(%)															

(HAN360)

BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 15

Group	Name	Animals At start	Administration (Weeks)													
			84	85	86	87	88	89	90	91	92	93	94	95	96	97
	Control	50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	46/50	45/50	44/50	44/50	44/50
			92.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0	92.0	90.0	88.0	88.0	88.0
	3.2ppm	50	49/50	49/50	49/50	49/50	49/50	49/50	48/50	48/50	48/50	47/50	46/50	45/50	43/50	43/50
			98.0	98.0	98.0	98.0	98.0	98.0	96.0	96.0	96.0	94.0	92.0	90.0	86.0	86.0
	8ppm	50	45/50	44/50	44/50	43/50	43/50	43/50	42/50	41/50	41/50	40/50	40/50	40/50	39/50	39/50
			90.0	88.0	88.0	86.0	86.0	86.0	84.0	82.0	82.0	80.0	80.0	80.0	78.0	78.0
	20ppm	50	43/50	43/50	42/50	41/50	41/50	39/50	38/50	38/50	37/50	37/50	37/50	37/50	37/50	37/50
			86.0	86.0	84.0	82.0	82.0	78.0	76.0	76.0	74.0	74.0	74.0	74.0	74.0	74.0
Number of survival/ Number of effective animals Survival rate(%)																

(HAN360)

BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104  
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 16

Group Name	Animals At start	Administration (Weeks)						
		98	99	100	101	102	103	104
Control	50	42/50	42/50	42/50	41/50	41/50	41/50	39/50
		84.0	84.0	84.0	82.0	82.0	82.0	78.0
3.2ppm	50	43/50	43/50	42/50	42/50	42/50	42/50	39/50
		86.0	86.0	84.0	84.0	84.0	84.0	78.0
8ppm	50	38/50	36/50	36/50	36/50	36/50	36/50	35/50
		76.0	72.0	72.0	72.0	72.0	72.0	70.0
20ppm	50	37/50	35/50	34/50	31/50	30/50	30/50	29/50
		74.0	70.0	68.0	62.0	60.0	60.0	58.0
Number of survival/ Number of effective animals Survival rate(%)								

(HAN360)

BA1S5



TABLE C1

CLINICAL OBSERVATION : MALE

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 1

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 2

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 3

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 4

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 5

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 6

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 7

[illegible]



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 8

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
DEATH	Control	3	3	3	4	4	6
	3.2ppm	1	1	2	3	3	3
	8ppm	6	6	6	6	8	8
	20ppm	9	9	10	12	13	13
MORIBUND SACRIFICE	Control	2	2	3	3	3	3
	3.2ppm	2	2	2	2	2	3
	8ppm	1	1	2	2	2	3
	20ppm	27	27	28	28	28	28
LOCOMOTOR MOVEMENT DEGR	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	1	1	0	0	0	0
	20ppm	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	1	1	1	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
WASTING	Control	0	0	0	0	1	1
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
SOILED	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	1	2	1	1
	20ppm	0	0	0	0	0	0
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0
	3.2ppm	1	1	1	1	1	1
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	1
EXOPHTHALMOS	Control	0	0	0	0	0	0
	3.2ppm	1	1	1	1	0	0
	8ppm	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 9

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 10

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 11

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 12

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 13

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 14

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 15

[illegible]



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 16

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
CATARACT	Control	5	5	5	5	5	6
	3.2ppm	5	5	5	5	5	5
	8ppm	6	6	5	5	5	6
	20ppm	0	0	0	0	0	0
CORNEAL OPACITY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
EXTERNAL MASS	Control	6	6	5	4	4	4
	3.2ppm	10	10	10	10	11	10
	8ppm	10	10	11	14	14	14
	20ppm	8	8	7	6	5	5
INTERNAL MASS	Control	0	0	0	0	1	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. NOSE	Control	0	0	0	0	0	1
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. EYE	Control	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0
M. PERI-MOUTH	Control	1	1	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	2	2	1	1	1	1
M. ORAL CAVITY	Control	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 17

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 18

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 19

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 20

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 21

[illegible]

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 22

Clinical sign	Group Name	Administration Week-day				74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		71-7	72-7	73-7												
M. EAR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0		0	0	0	0	0	1	1	1	1	1	1
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	1	1	1		2	2	2	2	3	3	3	3	3	3	3
	8ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0		0	0	0	0	0	1	1	1	1	1	1
	3. 2ppm	1	1	1		1	2	2	2	2	2	2	2	2	2	2
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	1
	20ppm	1	1	1		1	1	1	1	1	1	1	1	1	1	1
M. ANTERIOR. DORSUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	1	1	1		1	1	2	2	2	2	2	3	3	3	3
	8ppm	1	1	1		1	1	1	1	1	1	1	2	2	2	3
	20ppm	2	2	2		2	2	2	2	0	2	2	2	2	3	3
M. POSTERIOR DORSUM	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	3	3	3		3	3	2	2	1	1	1	2	2	2	2
M. HINDLIMB	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0		0	0	0	0	0	0	0	1	0	0	0
	3. 2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	1	0	0	0	0	0	1

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 23

Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
M. EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0	0	0	1	1	1	1	1	1
M. PERI EAR	Control	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	1	1	1	1	1	1	1	0	0	0	0	1	1	1
	3.2ppm	3	3	3	2	2	2	2	2	2	2	2	2	2	3
	8ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	20ppm	0	0	0	0	0	0	0	1	1	1	1	1	1	1
M. ABDOMEN	Control	1	1	1	1	1	1	1	1	1	1	1	2	2	2
	3.2ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	8ppm	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	20ppm	1	1	1	1	1	0	0	2	2	2	2	2	2	1
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	3	3	4	3	4	4	4	4	3	3	3	3	3	3
	8ppm	3	3	3	3	3	3	3	3	3	4	4	4	4	4
	20ppm	2	2	1	1	1	0	1	2	2	2	2	2	2	3
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	8ppm	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	20ppm	2	2	2	3	3	2	2	1	1	1	1	1	1	1
M. HIND LIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
ANEMIA	Control	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	1	0	0	0	0	0	0	0	0	0	1	0	0	0



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 24

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
M. EAR	Control	0	0	0	0	0	0
	3. 2ppm	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1
	20ppm	1	1	1	1	1	1
M. PERI EAR	Control	1	1	1	0	0	0
	3. 2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. BREAST	Control	1	2	1	1	2	2
	3. 2ppm	4	5	5	5	6	6
	8ppm	2	2	2	2	2	2
	20ppm	1	1	1	1	0	0
M. ABDOMEN	Control	2	2	2	2	1	1
	3. 2ppm	2	2	2	2	2	2
	8ppm	2	2	2	3	3	3
	20ppm	1	1	2	1	1	1
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0
	3. 2ppm	3	2	2	2	2	1
	8ppm	4	4	4	6	6	6
	20ppm	3	3	3	2	2	3
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0
	3. 2ppm	1	1	2	2	2	2
	8ppm	0	0	2	2	2	2
	20ppm	2	2	1	1	1	1
M. HINDLIMB	Control	0	0	0	0	0	0
	3. 2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	1	1	1	1	0	0
M. GENITALIA	Control	0	0	0	0	0	0
	3. 2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	1	1	1	1	1	1
ANEMIA	Control	1	2	2	0	0	1
	3. 2ppm	0	0	0	0	0	0
	8ppm	0	0	3	2	1	2
	20ppm	0	0	2	1	0	0

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 25

Clinical sign	Group Name	Administration Week-day													
		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	14-7
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 26

Clinical sign	Group Name	Administration Week-day													
		15-7	16-7	17-7	18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : MALE

PAGE : 27

Clinical sign	Group Name	Administration Week-day			32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
		29-7	30-7	31-7											
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 28

Clinical sign	Group Name	Administration Week-day			46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
		43-7	44-7	45-7											
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 29

Clinical sign	Group Name	Administration Week-day			57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
		57-7	58-7	59-7														
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	1	2	2	2	2	1	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 30

Clinical sign	Group Name	Administration Week-day				74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		71-7	72-7	73-7												
ULCER	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	1
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0		0	0	0	0	0	0	0	1	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	1	1		1	1	2	0	3	2	2	4	1	2	3
RESPIRATORY SOUND ABNOR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	2	2	0	1	0	0	0
NOISY	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		1	1	1	0	0	0	2	2	1	1	2

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 31

Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
ULCER	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EROSION	Control	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	1	1	1	1	1	1	1	2	2	2	2	2
	3.2ppm	0	0	0	0	0	0	0	1	1	2	1	1	1	1
	8ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	20ppm	0	1	2	3	2	1	0	2	1	2	2	1	1	3
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	1	2	2	1	1	0	1	1	1	1	0	0	0



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 32

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
ULCER	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	1	1	0	0	0	0
	20ppm	0	0	0	0	0	0
EROSION	Control	1	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
HEMORRHAGE	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
PROLAPSE OF PENIS	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	1
IRREGULAR BREATHING	Control	2	2	2	1	1	1
	3.2ppm	1	0	1	1	1	1
	8ppm	1	1	0	0	1	0
	20ppm	3	4	3	1	1	1
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0
	3.2ppm	1	1	1	1	1	0
	8ppm	0	0	0	0	0	0
	20ppm	2	2	0	0	0	0

TABLE C2

CLINICAL OBSERVATION : FEMALE

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 33

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 34

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 35

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 36

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 37

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 38

Clinical sign	Group Name	Administration				Week-day									
		71-7	72-7	73-7		74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7
DEATH	Control	0	0	0		0	0	2	2	2	2	2	2	3	3
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	2	2	2		2	2	2	2	2	3	3	3	4	4
	20ppm	1	2	2		2	2	2	2	2	2	2	2	2	2
MORIBUND SACRIFICE	Control	0	0	0		0	0	0	0	0	0	1	1	1	1
	3.2ppm	0	0	0		0	0	0	0	0	1	1	1	1	1
	8ppm	0	0	1		1	1	1	1	1	1	1	1	1	1
	20ppm	1	1	1		1	1	1	1	2	2	2	3	4	5
LOCOMOTOR MOVEMENT DECR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0		0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	1	0	0		0	0	0	0	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0		0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	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
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
SOILED	Control	0	0	0		0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
FROG BELLY	Control	0	0	0		0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	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
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	1	0	0	0	1	1	0



CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 39

[illegible]

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 40

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
DEATH	Control	5	5	5	5	5	6
	3.2ppm	1	2	2	2	2	3
	8ppm	6	6	6	6	6	7
	20ppm	6	7	7	7	7	8
MORIBUND SACRIFICE	Control	3	3	4	4	4	5
	3.2ppm	6	6	6	6	6	8
	8ppm	8	8	8	8	8	8
	20ppm	9	9	12	13	13	13
LOCOMOTOR MOVEMENT DECR	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	1	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
ATAXIC GAIT	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
PARALYTIC GAIT	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
WASTING	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	1	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
SOILED	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
FROG BELLY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	1
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0
	3.2ppm	0	1	1	1	1	1
	8ppm	0	0	1	0	0	0
	20ppm	0	0	0	0	1	2

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 41

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 42

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 43

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 44

[illegible]

REPORT TYPE : A1 104

ALL ANIMALS

PAGE : 45

[illegible]

### CLINICAL OBSERVATION (SUMMARY)

ALL ANIMALS

SEX : FEMALE

PAGE : 46

[illegible]



CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 47

Clinical sign	Group Name	Administration Week-day													
		85-7	86-7	87-7	88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
EXOPHTHALMOS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CATARACT	Control	5	5	5	5	5	5	6	6	6	6	6	6	6	6
	3.2ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	8ppm	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	20ppm	1	1	1	1	1	1	1	1	1	1	1	1	1	1
CORNEAL OPACITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	1	1	1	1
ANTERIOR CHAMBER OPACITY	Control	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EXTERNAL MASS	Control	2	2	2	2	2	2	2	2	2	2	3	4	4	3
	3.2ppm	5	7	7	7	8	7	7	8	7	9	9	9	9	11
	8ppm	4	4	5	6	7	6	7	7	7	8	9	10	14	14
	20ppm	7	7	7	7	7	6	6	5	6	6	6	7	7	7
INTERNAL MASS	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	8ppm	0	0	0	0	0	0	0	1	0	0	1	0	0	0
	20ppm	0	1	1	1	0	0	0	0	0	0	0	0	0	0
M. PERI-MOUTH	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	1	1	1	1	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ORAL CAVITY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 48

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
EXOPHTHALMOS	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
CATARACT	Control	6	6	6	6	6	5
	3.2ppm	2	2	2	2	2	2
	8ppm	2	2	2	2	2	2
	20ppm	1	1	1	1	1	1
CORNEAL OPACITY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
ANTERIOR CHAMBER OPACITY	Control	1	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
EXTERNAL MASS	Control	4	4	6	6	6	6
	3.2ppm	11	10	12	13	13	15
	8ppm	13	13	15	14	16	15
	20ppm	7	6	6	8	13	15
INTERNAL MASS	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	1	1	1
	20ppm	0	0	1	0	0	0
M. PERI-MOUTH	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0
M. ORAL CAVITY	Control	0	0	0	0	0	0
	3.2ppm	0	0	1	1	1	1
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. PERI EAR	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1
	20ppm	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 49

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 50

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 51

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 52

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
M. NECK	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. BREAST	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ABDOMEN	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. ANTERIOR. DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M. GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANEMIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CRUSTA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 53

[illegible]

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

PAGE : 54

[illegible]



REPORT TYPE : A1 104

ALL ANIMALS

PAGE : 55

[illegible]

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
 ALL ANIMALS

SEX : FEMALE

PAGE : 56

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
M. NECK	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	2	2	2	2	2	1
M. BREAST	Control	3	3	3	3	3	3
	3.2ppm	8	7	8	9	9	10
	8ppm	8	8	8	9	10	9
	20ppm	3	2	2	4	9	12
M. ABDOMEN	Control	1	1	2	2	2	2
	3.2ppm	2	2	2	2	2	3
	8ppm	3	3	5	4	5	4
	20ppm	1	1	1	1	1	1
M. ANTERIOR DORSUM	Control	1	1	1	1	1	1
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. POSTERIOR DORSUM	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. HINDLIMB	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
M. GENITALIA	Control	0	0	1	1	1	1
	3.2ppm	1	1	1	2	2	2
	8ppm	1	1	1	1	1	1
	20ppm	1	1	1	1	1	2
ANEMIA	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	2	2	1	1
	20ppm	0	1	1	0	0	0
CRUSTA	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 57

Clinical sign	Group Name	Administration Week-day													
		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	14-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 58

Clinical sign	Group Name	Administration Week-day			18-7	19-7	20-7	21-7	22-7	23-7	24-7	25-7	26-7	27-7	28-7
		15-7	16-7	17-7											
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 59

Clinical sign	Group Name	Administration Week-day		29-7	30-7	31-7	32-7	33-7	34-7	35-7	36-7	37-7	38-7	39-7	40-7	41-7	42-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BA1S5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 60

Clinical sign	Group Name	Administration Week-day													
		43-7	44-7	45-7	46-7	47-7	48-7	49-7	50-7	51-7	52-7	53-7	54-7	55-7	56-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 61

Clinical sign	Group Name	Administration Week-day													
		57-7	58-7	59-7	60-7	61-7	62-7	63-7	64-7	65-7	66-7	67-7	68-7	69-7	70-7
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 62

Clinical sign	Group Name	Administration Week-day				74-7	75-7	76-7	77-7	78-7	79-7	80-7	81-7	82-7	83-7	84-7
		71-7	72-7	73-7												
HEMORRHAGE	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	1	0	0	0	0	0
IRREGULAR BREATHING	Control	0	1	0		0	0	0	0	0	0	1	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	1	0		0	0	0	0	1	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
RESPIRATORY SOUND ABNOR	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0		0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS5



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 63

Clinical sign	Group Name	Administration Week-day			88-7	89-7	90-7	91-7	92-7	93-7	94-7	95-7	96-7	97-7	98-7
		85-7	86-7	87-7											
HEMORRHAGE	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	1	1	0	0	1
	8ppm	0	1	1	1	2	1	0	1	0	0	1	0	1	1
	20ppm	1	0	0	1	0	0	0	0	0	0	0	0	1	2
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOISY	Control	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	8ppm	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1 104

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 64

Clinical sign	Group Name	Administration Week-day					
		99-7	100-7	101-7	102-7	103-7	104-7
HEMORRHAGE	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0
IRREGULAR BREATHING	Control	0	1	0	0	0	0
	3.2ppm	1	1	1	1	1	0
	8ppm	0	0	0	0	0	0
	20ppm	3	3	1	0	0	1
RESPIRATORY SOUND ABNOR	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	1	1	0	0	0	0
NOISY	Control	0	0	0	0	0	0
	3.2ppm	0	0	0	0	0	0
	8ppm	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0

(HAN190)

BAIS 5

TABLE D1

BODY WEIGHT CHANGES AND SURVIVAL ANIMAL  
NUMBERS : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 1

Week on Study	Control		3.2ppm			8ppm			20ppm		
	Av. Wt.	No. of Surviv. <50>	Av. Wt.	% of cont. <50>	No. of Surviv.	Av. Wt.	% of cont. <50>	No. of Surviv.	Av. Wt.	% of cont. <50>	No. of Surviv.
0	120 (50)	50/50	120 (50)	100	50/50	120 (50)	100	50/50	120 (50)	100	50/50
1	151 (50)	50/50	150 (50)	99	50/50	151 (50)	100	50/50	141 (50)	93	50/50
2	182 (50)	50/50	182 (50)	100	50/50	181 (50)	99	50/50	167 (50)	92	50/50
3	206 (50)	50/50	206 (50)	100	50/50	205 (50)	100	50/50	187 (50)	91	50/50
4	227 (50)	50/50	227 (50)	100	50/50	226 (50)	100	50/50	205 (50)	90	50/50
5	242 (50)	50/50	243 (50)	100	50/50	242 (50)	100	50/50	222 (50)	92	50/50
6	255 (50)	50/50	257 (50)	101	50/50	255 (50)	100	50/50	235 (50)	92	50/50
7	269 (50)	50/50	270 (50)	100	50/50	268 (50)	100	50/50	250 (50)	93	50/50
8	282 (50)	50/50	283 (50)	100	50/50	281 (50)	100	50/50	259 (50)	92	50/50
9	292 (50)	50/50	292 (50)	100	50/50	292 (50)	100	50/50	267 (50)	91	50/50
10	299 (50)	50/50	300 (50)	100	50/50	300 (50)	100	50/50	275 (50)	92	50/50
11	304 (50)	50/50	305 (50)	100	50/50	306 (50)	101	50/50	279 (50)	92	50/50
12	312 (50)	50/50	314 (50)	101	50/50	314 (50)	101	50/50	285 (50)	91	50/50
13	318 (50)	50/50	320 (50)	101	50/50	320 (50)	101	50/50	292 (50)	92	50/50
14	323 (50)	50/50	325 (50)	101	50/50	326 (50)	101	50/50	297 (50)	92	50/50
18	338 (50)	50/50	341 (50)	101	50/50	343 (50)	101	50/50	312 (50)	92	50/50
22	352 (50)	50/50	352 (50)	100	50/50	357 (50)	101	50/50	326 (50)	93	50/50
26	364 (50)	50/50	362 (50)	99	50/50	367 (50)	101	50/50	333 (50)	91	50/50
30	375 (50)	50/50	373 (50)	99	50/50	377 (50)	101	50/50	344 (50)	92	50/50
34	386 (50)	50/50	382 (50)	99	50/50	386 (50)	100	50/50	353 (50)	91	50/50
38	393 (50)	50/50	386 (50)	98	50/50	392 (50)	100	50/50	356 (50)	91	50/50
42	399 (50)	50/50	390 (50)	98	50/50	396 (50)	99	50/50	358 (50)	90	50/50
46	405 (50)	50/50	398 (50)	98	50/50	402 (50)	99	50/50	363 (50)	90	50/50
50	410 (50)	50/50	404 (50)	99	50/50	408 (50)	100	50/50	371 (50)	90	50/50
54	413 (50)	50/50	407 (50)	99	50/50	410 (50)	99	50/50	370 (50)	90	50/50
58	417 (50)	50/50	410 (50)	98	50/50	413 (50)	99	50/50	368 (50)	88	50/50
62	419 (50)	50/50	412 (50)	98	50/50	415 (50)	99	50/50	366 (50)	87	50/50
66	422 (50)	50/50	415 (50)	98	50/50	419 (49)	99	49/50	368 (48)	87	48/50
70	426 (50)	50/50	418 (50)	98	50/50	419 (48)	98	48/50	365 (46)	86	46/50
74	428 (50)	50/50	418 (50)	98	50/50	421 (47)	98	47/50	364 (45)	85	45/50
78	428 (50)	50/50	419 (50)	98	50/50	419 (46)	98	46/50	354 (41)	83	41/50
82	429 (49)	49/50	419 (50)	98	50/50	416 (46)	97	46/50	357 (31)	83	31/50
86	422 (48)	48/50	417 (50)	99	50/50	416 (46)	99	46/50	357 (27)	85	27/50
90	421 (47)	47/50	416 (49)	99	49/50	412 (45)	98	45/50	347 (20)	82	20/50
94	410 (46)	46/50	408 (48)	100	48/50	405 (44)	99	44/50	344 (17)	84	17/50
98	404 (45)	45/50	403 (47)	100	47/50	399 (43)	99	43/50	334 (14)	83	14/50
102	396 (43)	43/50	399 (45)	101	45/50	398 (42)	101	42/50	335 (10)	85	10/50
104	394 (41)	41/50	394 (44)	100	44/50	388 (39)	98	39/50	315 ( 9)	80	9/50
< >:No. of effective animals, ( ):No. of measured animals											
Av. Wt.: g											

< >:No. of effective animals, ( ):No. of measured animals Av. Wt. : g

TABLE D2

BODY WEIGHT CHANGES AND SURVIVAL ANIMAL  
NUMBERS : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

Week on Study	Control		3.2ppm			8ppm			20ppm		
	Av. Wt.	No. of Surviv. <50>	Av. Wt.	% of cont. <50>	No. of Surviv.	Av. Wt.	% of cont. <50>	No. of Surviv.	Av. Wt.	% of cont. <50>	No. of Surviv.
0	97 (50)	50/50	97 (50)	100	50/50	97 (50)	100	50/50	97 (50)	100	50/50
1	112 (50)	50/50	110 (50)	98	50/50	111 (50)	99	50/50	106 (50)	95	50/50
2	126 (50)	50/50	125 (50)	99	50/50	125 (50)	99	50/50	119 (50)	94	50/50
3	136 (50)	50/50	134 (50)	99	50/50	134 (50)	99	50/50	129 (50)	95	50/50
4	144 (50)	50/50	144 (50)	100	50/50	143 (50)	99	50/50	137 (50)	95	50/50
5	151 (50)	50/50	151 (50)	100	50/50	150 (50)	99	50/50	145 (50)	96	50/50
6	157 (50)	50/50	158 (50)	101	50/50	155 (50)	99	50/50	150 (50)	96	50/50
7	161 (50)	50/50	162 (50)	101	50/50	160 (50)	99	50/50	157 (50)	98	50/50
8	165 (50)	50/50	167 (50)	101	50/50	164 (50)	99	50/50	161 (50)	98	50/50
9	168 (50)	50/50	170 (50)	101	50/50	167 (50)	99	50/50	167 (50)	99	50/50
10	172 (50)	50/50	174 (50)	101	50/50	172 (50)	100	50/50	170 (50)	99	50/50
11	174 (50)	50/50	178 (50)	102	50/50	174 (50)	100	50/50	172 (50)	99	50/50
12	178 (50)	50/50	183 (50)	103	50/50	178 (50)	100	50/50	176 (50)	99	50/50
13	180 (50)	50/50	184 (50)	102	50/50	180 (50)	100	50/50	177 (50)	98	50/50
14	182 (50)	50/50	186 (50)	102	50/50	181 (50)	99	50/50	180 (50)	99	50/50
18	188 (50)	50/50	194 (50)	103	50/50	190 (50)	101	50/50	186 (50)	99	50/50
22	193 (50)	50/50	199 (50)	103	50/50	195 (50)	101	50/50	192 (50)	99	50/50
26	197 (50)	50/50	202 (50)	103	50/50	199 (50)	101	50/50	197 (50)	100	50/50
30	203 (50)	50/50	209 (50)	103	50/50	205 (50)	101	50/50	201 (50)	99	50/50
34	209 (50)	50/50	213 (50)	102	50/50	207 (50)	99	50/50	206 (50)	99	50/50
38	213 (50)	50/50	216 (50)	101	50/50	211 (50)	99	50/50	208 (50)	98	50/50
42	216 (50)	50/50	218 (50)	101	50/50	214 (50)	99	50/50	209 (50)	97	50/50
46	219 (50)	50/50	223 (50)	102	50/50	219 (50)	100	50/50	213 (50)	97	50/50
50	225 (50)	50/50	229 (50)	102	50/50	224 (50)	100	50/50	219 (50)	97	50/50
54	229 (50)	50/50	233 (50)	102	50/50	227 (49)	99	49/50	219 (50)	96	50/50
58	234 (50)	50/50	237 (50)	101	50/50	230 (48)	98	48/50	221 (48)	94	48/50
62	240 (50)	50/50	245 (50)	102	50/50	235 (48)	98	48/50	225 (48)	94	48/50
66	246 (50)	50/50	251 (50)	102	50/50	244 (48)	99	48/50	230 (48)	93	48/50
70	253 (50)	50/50	257 (50)	102	50/50	249 (48)	98	48/50	230 (48)	91	48/50
74	259 (50)	50/50	263 (50)	102	50/50	253 (47)	98	47/50	232 (47)	90	47/50
78	263 (48)	48/50	267 (50)	102	50/50	256 (47)	97	47/50	234 (46)	89	46/50
82	270 (47)	47/50	272 (49)	101	49/50	258 (46)	96	46/50	237 (44)	88	44/50
86	274 (46)	46/50	277 (49)	101	49/50	258 (44)	94	44/50	242 (42)	88	42/50
90	279 (46)	46/50	281 (48)	101	48/50	262 (42)	94	42/50	246 (38)	88	38/50
94	280 (45)	45/50	280 (46)	100	46/50	265 (40)	95	40/50	246 (37)	88	37/50
98	283 (42)	42/50	285 (43)	101	43/50	266 (38)	94	38/50	242 (37)	86	37/50
102	287 (41)	41/50	281 (42)	98	42/50	270 (36)	94	36/50	251 (30)	87	30/50
104	287 (39)	39/50	286 (39)	100	39/50	265 (35)	92	35/50	249 (29)	87	29/50
< >:No. of effective animals, ( ):No. of measured animals											
Av. Wt.: g											

< >:No. of effective animals, ( ):No. of measured animals Av. Wt. : g

TABLE D3

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 1

Group Name	Administration		week											
	0		1		2		3		4		5		6	
Control	120±	6	151±	9	182±	11	206±	11	227±	13	242±	13	255±	14
3.2ppm	120±	6	150±	8	182±	10	206±	11	227±	12	243±	12	257±	13
8ppm	120±	6	151±	8	181±	10	205±	11	226±	12	242±	13	255±	14
20ppm	120±	6	141±	7**	167±	8**	187±	9**	205±	10**	222±	10**	235±	10**

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

Test of Dunnett

(HAN260)

BA1S5



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 2

Group Name	Administration week											
	7		8		9		10		11		12	
Control	269±	15	282±	17	292±	17	299±	18	304±	18	312±	18
3.2ppm	270±	13	283±	15	292±	15	300±	16	305±	16	314±	16
8ppm	268±	14	281±	15	292±	16	300±	15	306±	15	314±	16
20ppm	250±	10**	259±	11**	267±	11**	275±	11**	279±	11**	285±	11**

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

Test of Dunnett

(HAN260)

BAIS 5

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration week		14		18		22		26		30		34		38	
Control	323±	18	338±	19	352±	21	364±	21	375±	23	386±	24	393±	26		
3. 2ppm	325±	18	341±	18	352±	19	362±	20	373±	21	382±	22	386±	22		
8ppm	326±	17	343±	17	357±	18	367±	18	377±	18	386±	19	392±	19		
20ppm	297±	12**	312±	12**	326±	13**	333±	14**	344±	14**	353±	14**	356±	14**		
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett																
(HAN260)															BAIS 5	

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration week													
	42		46		50		54		58		62		66	
Control	399±	27	405±	27	410±	29	413±	30	417±	31	419±	32	422±	33
3. 2ppm	390±	23	398±	23	404±	23	407±	23	410±	24	412±	23	415±	24
8ppm	396±	19	402±	18	408±	19	410±	20	413±	19	415±	19	419±	19
20ppm	358±	15**	363±	15**	371±	15**	370±	16**	368±	16**	366±	22**	368±	25**
Significant difference ;    * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett														
(HAN260)													BAIS	

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 5

Group Name	Administration week		74		78		82		86		90		94	
	70													
Control	426±	33	428±	35	428±	35	429±	35	422±	37	421±	35	410±	34
3. 2ppm	418±	25	418±	24	419±	25	419±	26	417±	27	416±	28	408±	29
8ppm	419±	19	421±	18	419±	17	416±	18*	416±	18	412±	18	405±	20
20ppm	365±	19**	364±	21**	354±	28**	357±	22**	357±	25**	347±	26**	344±	21**

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

Test of Dunnett

(HAN260)

BAIS 5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week					
	98		102		104	
Control	404±	36	396±	41	394±	37
3, 2ppm	403±	32	399±	36	394±	37
8ppm	399±	26	398±	40	388±	52
20ppm	334±	24**	335±	28**	315±	42**

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

Test of Dunnett

TABLE D4

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 7

Group Name	Administration week		1		2		3		4		5		6	
	0													
Control	97±	3	112±	4	126±	5	136±	6	144±	7	151±	7	157±	8
3.2ppm	97±	3	110±	4	125±	5	134±	6	144±	7	151±	7	158±	8
8ppm	97±	3	111±	4	125±	5	134±	6	143±	7	150±	8	155±	8
20ppm	97±	3	106±	4**	119±	5**	129±	5**	137±	7**	145±	7**	150±	8**

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 8

Group Name	Administration week		7		8		9		10		11		12		13	
Control	161±	9	165±	10	168±	11	172±	11	174±	11	178±	11	180±	11		
3. 2ppm	162±	9	167±	10	170±	10	174±	10	178±	11	183±	11	184±	11		
8ppm	160±	9	164±	9	167±	10	172±	11	174±	10	178±	11	180±	10		
20ppm	157±	9*	161±	9	167±	11	170±	11	172±	11	176±	11	177±	11		

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

Test of Dunnett

(HAN260)

BAIS 5



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrI j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 9

Group Name	Administration week											
	14		18		22		26		30		34	38
Control	182± 12		188± 12		193± 13		197± 14		203± 14		209± 16	213± 16
3.2ppm	186± 11		194± 11		199± 12		202± 12		209± 12		213± 13	216± 13
8ppm	181± 10		190± 12		195± 12		199± 12		205± 13		207± 12	211± 13
20ppm	180± 11		186± 13		192± 13		197± 14		201± 13		206± 14	208± 15

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

Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 10

Group Name	Administration week											
	42		46		50		54		58		62	
Control	216±	17	219±	18	225±	19	229±	19	234±	20	240±	22
3.2ppm	218±	14	223±	13	229±	15	233±	16	237±	18	245±	19
8ppm	214±	14	219±	14	224±	15	227±	15	230±	17	235±	18
20ppm	209±	14*	213±	16	219±	17	219±	18**	221±	16**	225±	16**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett												
(HAN260)											BAIS 5	

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 11

Group Name	Administration week													
	70		74		78		82		86		90		94	
Control	253±	23	259±	23	263±	24	270±	25	274±	23	279±	24	280±	26
3. 2ppm	257±	21	263±	22	267±	24	272±	24	277±	26	281±	31	280±	36
8ppm	249±	26	253±	19	256±	20	258±	21*	258±	22**	262±	23*	265±	24*
20ppm	230±	18**	232±	18**	234±	18**	237±	19**	242±	22**	246±	21**	246±	26**
Significant difference :    * : $P \leq 0.05$ ** : $P \leq 0.01$														

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 12

Group Name	Administration week					
	98		102		104	
Control	283± 31		287± 33		287± 35	
3.2ppm	285± 41		281± 43		286± 43	
8ppm	266± 32		270± 34*		265± 33**	
20ppm	242± 30**		251± 26**		249± 25**	
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						
(HAN260)						BAIS5

TABLE E1

FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrI j [F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 1

Week-Day on Study	Control		3.2ppm			8ppm			20ppm		
	Av. FC.	No. of Surviv. <50>	Av. FC.	% of cont. <50>	No. of Surviv.	Av. FC.	% of cont. <50>	No. of Surviv.	Av. FC.	% of cont. <50>	No. of Surviv.
1-7	14.8 (50)	50/50	14.5 (50)	98	50/50	14.3 (50)	97	50/50	12.7 (50)	86	50/50
2-7	16.7 (50)	50/50	16.5 (50)	99	50/50	16.3 (50)	98	50/50	14.1 (50)	84	50/50
3-7	17.2 (50)	50/50	17.4 (50)	101	50/50	16.9 (50)	98	50/50	14.7 (50)	85	50/50
4-7	17.1 (50)	50/50	17.0 (50)	99	50/50	16.6 (50)	97	50/50	14.5 (50)	85	50/50
5-7	16.7 (50)	50/50	16.9 (50)	101	50/50	16.8 (50)	101	50/50	15.7 (50)	94	50/50
6-7	17.0 (50)	50/50	16.8 (50)	99	50/50	16.7 (50)	98	50/50	15.9 (50)	94	50/50
7-7	16.6 (50)	50/50	16.5 (50)	99	50/50	16.4 (50)	99	50/50	16.0 (50)	96	50/50
8-7	17.0 (50)	50/50	16.8 (50)	99	50/50	16.8 (50)	99	50/50	16.0 (50)	94	50/50
9-7	16.7 (50)	50/50	16.3 (50)	98	50/50	16.4 (50)	98	50/50	15.2 (50)	91	50/50
10-7	16.5 (50)	50/50	16.4 (50)	99	50/50	16.3 (50)	99	50/50	15.3 (50)	93	50/50
11-7	15.8 (50)	50/50	16.1 (50)	102	50/50	16.1 (50)	102	50/50	15.1 (50)	96	50/50
12-7	16.2 (50)	50/50	16.2 (50)	100	50/50	16.2 (50)	100	50/50	14.9 (50)	92	50/50
13-7	15.9 (50)	50/50	16.0 (50)	101	50/50	16.0 (50)	101	50/50	15.2 (50)	96	50/50
14-7	15.5 (50)	50/50	15.7 (50)	101	50/50	15.8 (50)	102	50/50	15.1 (50)	97	50/50
18-7	15.9 (50)	50/50	15.7 (50)	99	50/50	16.1 (50)	101	50/50	15.1 (50)	95	50/50
22-7	15.8 (50)	50/50	15.7 (50)	99	50/50	16.1 (50)	102	50/50	15.4 (50)	97	50/50
26-7	15.5 (50)	50/50	15.5 (50)	100	50/50	15.7 (50)	101	50/50	14.9 (50)	96	50/50
30-7	16.1 (50)	50/50	15.9 (50)	99	50/50	16.1 (50)	100	50/50	15.5 (50)	96	50/50
34-7	16.4 (50)	50/50	16.2 (50)	99	50/50	16.4 (50)	100	50/50	15.9 (50)	97	50/50
38-7	16.2 (50)	50/50	16.0 (50)	99	50/50	16.3 (50)	101	50/50	15.6 (50)	96	50/50
42-7	16.3 (50)	50/50	15.8 (50)	97	50/50	16.0 (50)	98	50/50	15.5 (50)	95	50/50
46-7	16.2 (50)	50/50	16.1 (50)	99	50/50	16.4 (50)	101	50/50	15.7 (50)	97	50/50
50-7	16.6 (50)	50/50	16.5 (50)	99	50/50	16.8 (50)	101	50/50	16.6 (50)	100	50/50
54-7	16.4 (50)	50/50	16.4 (50)	100	50/50	16.5 (50)	101	50/50	15.9 (50)	97	50/50
58-7	16.6 (50)	50/50	16.2 (50)	98	50/50	16.5 (50)	99	50/50	15.7 (50)	95	50/50
62-7	16.3 (50)	50/50	16.2 (50)	99	50/50	16.4 (50)	101	50/50	15.5 (50)	95	50/50
66-7	16.5 (50)	50/50	16.3 (50)	99	50/50	16.3 (49)	99	49/50	15.3 (48)	93	48/50
70-7	16.6 (50)	50/50	16.3 (50)	98	50/50	16.3 (48)	98	48/50	15.1 (46)	91	46/50
74-7	16.6 (50)	50/50	16.2 (50)	98	50/50	16.3 (47)	98	47/50	15.3 (45)	92	45/50
78-7	16.2 (50)	50/50	16.0 (50)	99	50/50	16.3 (46)	101	46/50	14.0 (41)	86	41/50
82-7	16.4 (49)	49/50	16.1 (50)	98	50/50	16.2 (46)	99	46/50	15.1 (31)	92	31/50
86-7	16.0 (48)	48/50	15.8 (50)	99	50/50	16.0 (46)	100	46/50	14.7 (27)	92	27/50
90-7	16.3 (47)	47/50	16.3 (49)	100	49/50	16.0 (45)	98	45/50	14.8 (20)	91	20/50
94-7	16.0 (46)	46/50	15.9 (48)	99	48/50	16.0 (44)	100	44/50	14.7 (17)	92	17/50
98-7	16.3 (45)	45/50	16.4 (47)	101	47/50	16.2 (43)	99	43/50	15.4 (14)	94	14/50
102-7	16.3 (43)	43/50	16.8 (45)	103	45/50	16.1 (42)	99	42/50	16.2 (10)	99	10/50
104-7	16.3 (41)	41/50	16.4 (44)	101	44/50	15.5 (39)	95	39/50	15.4 ( 9)	94	9/50

< >:No. of effective animals, ( ):No. of measured animals Av. FC. : g

TABLE E2

FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS : FEMALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

Week-Day on Study	Control		3.2ppm		8ppm		20ppm				
	Av. FC.	No. of Surviv. <50>	Av. FC.	% of cont. <50>	No. of Surviv.	Av. FC.	% of cont. <50>	No. of Surviv.	Av. FC.	% of cont. <50>	No. of Surviv.
1-7	11.3 (50)	50/50	11.2 (50)	99	50/50	11.0 (50)	97	50/50	10.1 (50)	89	50/50
2-7	12.0 (50)	50/50	12.0 (50)	100	50/50	11.7 (50)	98	50/50	10.8 (50)	90	50/50
3-7	11.8 (50)	50/50	11.7 (50)	99	50/50	11.7 (50)	99	50/50	10.9 (50)	92	50/50
4-7	11.7 (50)	50/50	11.7 (50)	100	50/50	11.4 (50)	97	50/50	10.4 (50)	89	50/50
5-7	11.5 (50)	50/50	11.7 (50)	102	50/50	11.5 (50)	100	50/50	11.5 (50)	100	50/50
6-7	11.7 (50)	50/50	11.9 (50)	102	50/50	11.7 (50)	100	50/50	11.6 (50)	99	50/50
7-7	11.0 (50)	50/50	11.3 (50)	103	50/50	11.0 (50)	100	50/50	11.3 (50)	103	50/50
8-7	11.1 (50)	50/50	11.5 (50)	104	50/50	10.7 (50)	96	50/50	11.5 (50)	104	50/50
9-7	10.6 (50)	50/50	10.8 (50)	102	50/50	10.6 (50)	100	50/50	11.0 (50)	104	50/50
10-7	10.9 (50)	50/50	11.1 (50)	102	50/50	10.8 (50)	99	50/50	11.0 (50)	101	50/50
11-7	10.5 (50)	50/50	10.7 (50)	102	50/50	10.5 (50)	100	50/50	10.7 (50)	102	50/50
12-7	10.8 (50)	50/50	11.4 (50)	106	50/50	10.9 (50)	101	50/50	11.0 (50)	102	50/50
13-7	10.7 (50)	50/50	11.6 (50)	108	50/50	10.6 (50)	99	50/50	11.1 (50)	104	50/50
14-7	10.5 (50)	50/50	10.9 (50)	104	50/50	10.5 (50)	100	50/50	11.1 (50)	106	50/50
18-7	10.8 (50)	50/50	11.2 (50)	104	50/50	11.1 (50)	103	50/50	10.7 (50)	99	50/50
22-7	10.8 (50)	50/50	11.2 (50)	104	50/50	10.9 (50)	101	50/50	11.1 (50)	103	50/50
26-7	10.5 (50)	50/50	10.4 (50)	99	50/50	10.3 (50)	98	50/50	10.4 (50)	99	50/50
30-7	11.1 (50)	50/50	11.4 (50)	103	50/50	11.0 (50)	99	50/50	11.0 (50)	99	50/50
34-7	11.3 (50)	50/50	11.1 (50)	98	50/50	10.6 (50)	94	50/50	11.3 (50)	100	50/50
38-7	11.1 (50)	50/50	11.1 (50)	100	50/50	11.1 (50)	100	50/50	11.3 (50)	102	50/50
42-7	11.4 (50)	50/50	11.2 (50)	98	50/50	11.0 (50)	96	50/50	10.9 (50)	96	50/50
46-7	11.1 (50)	50/50	11.1 (50)	100	50/50	11.2 (50)	101	50/50	11.7 (50)	105	50/50
50-7	11.6 (50)	50/50	11.8 (50)	102	50/50	11.7 (50)	101	50/50	12.1 (50)	104	50/50
54-7	11.6 (50)	50/50	11.9 (50)	103	50/50	11.4 (49)	98	49/50	11.5 (50)	99	50/50
58-7	11.9 (50)	50/50	11.9 (50)	100	50/50	11.4 (48)	96	48/50	11.3 (48)	95	48/50
62-7	11.7 (50)	50/50	12.0 (50)	103	50/50	11.7 (48)	100	48/50	11.6 (48)	99	48/50
66-7	12.1 (50)	50/50	12.1 (50)	100	50/50	11.7 (47)	97	48/50	11.6 (48)	96	48/50
70-7	12.0 (50)	50/50	12.2 (50)	102	50/50	12.1 (48)	101	48/50	11.4 (48)	95	48/50
74-7	12.0 (50)	50/50	12.2 (50)	102	50/50	11.7 (47)	98	47/50	11.3 (47)	94	47/50
78-7	12.0 (48)	48/50	12.1 (50)	101	50/50	11.7 (47)	98	47/50	11.2 (46)	93	46/50
82-7	12.6 (47)	47/50	12.5 (49)	99	49/50	11.9 (46)	94	46/50	11.8 (44)	94	44/50
86-7	12.1 (46)	46/50	12.3 (49)	102	49/50	11.2 (44)	93	44/50	11.3 (42)	93	42/50
90-7	12.7 (46)	46/50	12.5 (48)	98	48/50	11.7 (42)	92	42/50	11.8 (38)	93	38/50
94-7	12.7 (45)	45/50	12.4 (45)	98	46/50	12.3 (40)	97	40/50	12.0 (37)	94	37/50
98-7	12.8 (42)	42/50	13.2 (43)	103	43/50	11.7 (38)	91	38/50	11.9 (37)	93	37/50
102-7	13.2 (41)	41/50	12.8 (42)	97	42/50	12.6 (36)	95	36/50	12.7 (30)	96	30/50
104-7	12.8 (39)	39/50	12.9 (39)	101	39/50	12.4 (35)	97	35/50	12.2 (29)	95	29/50
< >:No. of effective animals, ( ):No. of measured animals											
Av. FC.: g											

< >:No. of effective animals, ( ):No. of measured animals Av. FC. : g



TABLE E3

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration 1-7 (7)	week-day(effective) 2-7 (7)	3-7 (7)	4-7 (7)	5-7 (7)	6-7 (7)	7-7 (7)
Control	14.8± 1.2	16.7± 1.6	17.2± 1.5	17.1± 1.4	16.7± 1.2	17.0± 1.5	16.6± 1.5
3.2ppm	14.5± 1.1	16.5± 1.3	17.4± 1.5	17.0± 1.3	16.9± 1.2	16.8± 1.1	16.5± 1.1
8ppm	14.3± 1.0	16.3± 1.3	16.9± 1.4	16.6± 1.2	16.8± 1.2	16.7± 1.3	16.4± 1.2
20ppm	12.7± 0.8**	14.1± 0.8**	14.7± 0.8**	14.5± 0.8**	15.7± 1.1**	15.9± 1.0**	16.0± 1.0

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

Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration 8-7 (7)	week-day(effective) 9-7 (7)	10-7 (7)	11-7 (7)	12-7 (7)	13-7 (7)	14-7 (7)
Control	17.0± 1.4	16.7± 1.4	16.5± 1.4	15.8± 1.2	16.2± 1.1	15.9± 1.1	15.5± 0.9
3.2ppm	16.8± 1.4	16.3± 1.2	16.4± 1.3	16.1± 1.1	16.2± 1.1	16.0± 1.0	15.7± 1.2
8ppm	16.8± 1.2	16.4± 1.1	16.3± 1.0	16.1± 1.0	16.2± 1.0	16.0± 1.0	15.8± 0.9
20ppm	16.0± 1.1**	15.2± 0.9**	15.3± 1.0**	15.1± 0.8**	14.9± 0.8**	15.2± 0.8**	15.1± 0.7*

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

Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration 18-7 (7)	week-day(effective) 22-7 (7)	26-7 (7)	30-7 (7)	34-7 (7)	38-7 (7)	42-7 (7)
Control	15.9± 0.9	15.8± 1.0	15.5± 0.9	16.1± 1.0	16.4± 1.0	16.2± 1.0	16.3± 1.0
3.2ppm	15.7± 1.1	15.7± 1.0	15.5± 0.9	15.9± 1.0	16.2± 1.0	16.0± 0.9	15.8± 1.0
8ppm	16.1± 0.9	16.1± 1.1	15.7± 0.9	16.1± 0.8	16.4± 0.9	16.3± 0.8	16.0± 0.8
20ppm	15.1± 0.7**	15.4± 0.7*	14.9± 0.8**	15.5± 0.7**	15.9± 0.8*	15.6± 0.7**	15.5± 0.7**

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

Test of Dunnett

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration week-day(effective)													
	46-7 (7)		50-7 (7)		54-7 (7)		58-7 (7)		62-7 (7)		66-7 (7)		70-7 (7)	
Control	16.2±	1.0	16.6±	1.1	16.4±	0.9	16.6±	1.1	16.3±	1.3	16.5±	1.2	16.6±	1.1
3.2ppm	16.1±	0.9	16.5±	0.9	16.4±	0.9	16.2±	0.9	16.2±	0.9	16.3±	1.0	16.3±	1.0
8ppm	16.4±	0.8	16.8±	0.8	16.5±	1.1	16.5±	0.9	16.4±	0.7	16.3±	1.2	16.3±	0.9
20ppm	15.7±	0.8*	16.6±	0.8	15.9±	0.8*	15.7±	0.8**	15.5±	1.7**	15.3±	0.9**	15.1±	0.9**

### Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 5

Group Name	Administration 74-7(7)	week-day(effective) 78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	16.6± 1.2	16.2± 1.3	16.4± 1.6	16.0± 1.7	16.3± 1.3	16.0± 1.2	16.3± 1.5
3.2ppm	16.2± 1.0	16.0± 0.9	16.1± 1.0	15.8± 0.9	16.3± 1.1	15.9± 1.6	16.4± 1.3
8ppm	16.3± 1.2	16.3± 0.7	16.2± 1.0	16.0± 1.0	16.0± 1.0	16.0± 1.1	16.2± 1.4
20ppm	15.3± 1.0**	14.0± 2.3**	15.1± 1.0**	14.7± 1.7**	14.8± 1.2**	14.7± 1.5**	15.4± 1.2

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 6

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	16.3± 1.7	16.3± 1.3
3.2ppm	16.8± 1.5	16.4± 1.5
8ppm	16.1± 2.3	15.5± 2.3*
20ppm	16.2± 0.6	15.4± 1.2

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

Test of Dunnett

TABLE E4

FOOD CONSUMPTION CHANGES : FEMALE



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 7

Group Name	Administration		week-day(effective)		3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
	1-7(7)		2-7(7)						
Control	11.3± 0.7		12.0± 0.9		11.8± 0.8	11.7± 0.8	11.5± 0.8	11.7± 1.0	11.0± 0.9
3.2ppm	11.2± 0.7		12.0± 0.8		11.7± 0.8	11.7± 1.0	11.7± 1.0	11.9± 1.1	11.3± 0.9
8ppm	11.0± 0.6		11.7± 0.9		11.7± 0.9	11.4± 1.0	11.5± 0.9	11.7± 1.1	11.0± 1.1
20ppm	10.1± 0.6**		10.8± 0.8**		10.9± 0.7**	10.4± 0.8**	11.5± 0.9	11.6± 1.2	11.3± 1.4
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett									

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 8

Group Name	Administration 8-7 (7)	week-day(effective) 9-7 (7)	10-7 (7)	11-7 (7)	12-7 (7)	13-7 (7)	14-7 (7)
Control	11.1± 1.0	10.6± 0.9	10.9± 0.8	10.5± 0.9	10.8± 0.8	10.7± 0.9	10.5± 1.1
3.2ppm	11.5± 1.0	10.8± 0.9	11.1± 1.1	10.7± 0.9	11.4± 0.8**	11.6± 1.2**	10.9± 0.9
8ppm	10.7± 0.9	10.6± 1.0	10.8± 1.1	10.5± 1.0	10.9± 0.9	10.6± 0.8	10.5± 0.8
20ppm	11.5± 1.4	11.0± 1.3	11.0± 1.1	10.7± 0.9	11.0± 1.1	11.1± 1.3	11.1± 1.3

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

Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 9

Group Name	Administration 18-7(7)	week-day(effective) 22-7(7)	26-7(7)	30-7(7)	34-7(7)	38-7(7)	42-7(7)
Control	10.8± 0.9	10.8± 0.9	10.5± 0.8	11.1± 0.9	11.3± 1.1	11.1± 0.9	11.4± 1.0
3.2ppm	11.2± 0.8	11.2± 1.0	10.4± 0.6	11.4± 0.9	11.1± 1.0	11.1± 0.7	11.2± 1.0
8ppm	11.1± 1.3	10.9± 1.1	10.3± 0.8	11.0± 1.1	10.6± 0.8**	11.1± 0.9	11.0± 1.2
20ppm	10.7± 1.1	11.1± 1.1	10.4± 1.1	11.0± 1.3	11.3± 1.2	11.3± 1.2	10.9± 1.0

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 10

Group Name	Administration		week-day(effective)						
	46-7 (7)		50-7 (7)		54-7 (7)			66-7 (7)	
Control	11.1± 0.8		11.6± 0.9		11.6± 1.0		11.9± 0.9	11.7± 1.0	12.1± 0.9
3.2ppm	11.1± 0.8		11.8± 0.7		11.9± 1.1		11.9± 1.0	12.0± 1.0	12.1± 1.2
8ppm	11.2± 0.9		11.7± 1.1		11.4± 1.2		11.4± 0.9*	11.7± 1.1	11.7± 0.9
20ppm	11.7± 1.2		12.1± 1.4		11.5± 1.4		11.3± 0.9**	11.6± 0.9	11.6± 0.9*

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

Test of Dunnett

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 104  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 11

Group Name	Administration 74-7(7)	week-day(effective) 78-7(7)	82-7(7)	86-7(7)	90-7(7)	94-7(7)	98-7(7)
Control	12.0± 0.8	12.0± 1.3	12.6± 0.9	12.1± 1.0	12.7± 1.1	12.7± 1.6	12.8± 1.7
3.2ppm	12.2± 1.0	12.1± 1.1	12.5± 1.2	12.3± 1.5	12.5± 1.6	12.4± 1.8	13.2± 2.0
8ppm	11.7± 0.9	11.7± 0.8	11.9± 0.8**	11.2± 1.9**	11.7± 1.1**	12.3± 1.2	11.7± 2.4*
20ppm	11.3± 0.9**	11.2± 0.7**	11.8± 1.0**	11.3± 1.5**	11.8± 1.3**	12.0± 1.7	11.9± 2.2

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
UNIT : g  
REPORT TYPE : A1 104  
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

PAGE : 12

Group Name	Administration week-day(effective)	
	102-7(7)	104-7(7)
Control	13.2± 2.1	12.8± 2.2
3.2ppm	12.8± 2.9	12.9± 2.7
8ppm	12.6± 1.9	12.4± 2.7
20ppm	12.7± 1.9	12.2± 1.7
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett		
(HAN260)		BAIS 5

TABLE F1

HEMATOLOGY : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : MALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 1 0 <sup>9</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 1 0 <sup>9</sup> /μl	
Control	40	8.01±	1.46	12.8±	2.3	39.0±	6.1	49.2±	5.3	16.1±	2.0	32.7±	1.5	920±	293
3.2ppm	44	7.59±	1.73	11.9±	3.1	36.8±	8.0	48.7±	2.8	15.6±	1.4	32.0±	2.2	1014±	339
8ppm	39	6.49±	2.15**	10.3±	3.5**	32.5±	9.0**	51.6±	7.9	16.0±	2.2	31.1±	2.4**	1085±	416
20ppm	9	7.79±	1.38	11.2±	2.1	35.8±	5.6	46.1±	3.1	14.5±	1.7	31.3±	1.9*	1077±	270

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 5



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : MALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %	
Control	40	4.6±	4.1
3.2ppm	44	6.0±	5.3
8ppm	39	9.8±	7.6**
20ppm	9	5.4±	3.4

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

Test of Dunnett

(HCL070)

BAIS 5

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential		WBC (%)		MONO		EOSINO		BASO		OTHER	
				NEUTRO		LYMPHO									
Control	40	3.75±	1.29	54±	8	40±	8	4±	1	1±	1	0±	0	1±	0
3.2ppm	44	4.49±	1.63	51±	9	43±	9	4±	1	1±	1	0±	0	1±	0
8ppm	39	9.80±	34.78	52±	14	40±	13	4±	1	1±	1*	0±	0	4±	15
20ppm	9	4.87±	2.22	62±	10	32±	9	4±	1	1±	1	0±	0	2±	1*

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

\*\* :  $P \leq 0.01$

Test of Dunnett

TABLE F2

HEMATOLOGY : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : FEMALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>9</sup> /μl	
Control	38	8.23±	0.75	14.7±	1.2	42.5±	2.9	51.8±	2.6	17.9±	0.8	34.5±	0.6	652±	68
3.2ppm	37	7.81±	1.00**	14.0±	1.7*	40.6±	4.2*	52.4±	3.1	18.0±	1.0	34.3±	1.3	668±	149
8ppm	32	7.61±	1.18**	13.7±	2.1*	39.9±	5.2*	52.7±	3.3	18.0±	1.4	34.1±	1.7	679±	186
20ppm	28	7.80±	1.20*	13.9±	2.0*	40.7±	4.7*	52.8±	4.5	17.9±	1.1	34.0±	1.6	668±	135

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

Test of Dunnett

(HCL070)

BAIS5

STUDY NO. : 0794

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %	
Control	38	2.4±	1.1
3.2ppm	37	3.5±	4.0
8ppm	32	3.6±	3.1
20ppm	28	4.1±	6.5

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

Test of Dunnett

(HCL070)

BAIS5

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC		Differential		WBC (%)									
		10 <sup>3</sup> /μl		NEUTRO		LYMPHO		MONO		EOSINO		BASO		OTHER	
Control	38	2.54±	2.02	42±	12	52±	12	3±	1	2±	1	0±	0	1±	0
3.2ppm	37	3.85±	3.44*	44±	16	47±	16	3±	1	1±	1	0±	1	4±	13
8ppm	32	3.31±	4.06	46±	13	47±	12	3±	1	2±	1	0±	1	1±	1
20ppm	28	3.26±	2.39	47±	11	48±	12	3±	1	2±	1	0±	0	1±	1

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 5

TABLE G1

BIOCHEMISTRY : MALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	40	6.5±	0.3	2.8±	0.2	0.8±	0.1	0.12±	0.23	169±	31	163±	66	82±	69
3.2ppm	44	6.3±	0.3	2.8±	0.3	0.8±	0.1	0.08±	0.05	170±	27	151±	34	75±	54
8ppm	39	6.2±	0.5	2.6±	0.3*	0.7±	0.1	0.15±	0.44	160±	26	145±	41	84±	86
20ppm	9	5.8±	0.8*	2.4±	0.5**	0.7±	0.2	1.43±	4.08	130±	50*	162±	61	49±	19

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

Test of Dunnett



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST U/L		ALT U/L		LDH U/L		ALP U/L		G-GTP U/L		CK U/L	
Control	40	241±	94	89±	49	37±	11	128±	53	353±	167	6.9±	4.5	103±	35
3.2ppm	44	223±	41	102±	77	45±	54	140±	87	362±	101	7.0±	3.7	108±	34
8ppm	39	223±	56	110±	134	36±	22	144±	140	367±	159	6.2±	4.3	114±	39
20ppm	9	275±	192	410±	992	71±	118	246±	370	566±	524	8.0±	10.3	199±	271

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

Test of Dunnett

(HCL074)

BAIS 5

STUDY NO. : 0794

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	40	18.5±	3.5	0.37±	0.08	143±	2	3.9±	0.4	107±	2	10.3±	0.4	3.9±	0.6
3.2ppm	44	19.8±	4.7	0.35±	0.04	144±	2	4.0±	0.3	107±	2	10.2±	0.3	4.0±	0.5
8ppm	39	20.1±	6.2	0.35±	0.06	143±	1	4.0±	0.4	107±	1	10.2±	0.3	4.3±	0.6**
20ppm	9	26.0±	25.7	0.29±	0.04**	145±	3	4.2±	0.4	108±	2	10.0±	0.3*	4.6±	1.8

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

Test of Dunnett

(HCL074)

BAIS5

TABLE G2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	39	6.8±	0.6	3.5±	0.3	1.0±	0.1	0.06±	0.02	161±	22	140±	39	72±	56
3.2ppm	38	6.8±	0.5	3.5±	0.4	1.1±	0.2	0.07±	0.04	156±	21	141±	47	74±	57
8ppm	35	6.7±	0.5	3.5±	0.4	1.1±	0.1	0.07±	0.04	158±	21	126±	22	61±	39
20ppm	28	6.4±	0.8	3.3±	0.5	1.1±	0.1	0.09±	0.20	152±	33	123±	27	59±	35

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
MEASURE. TIME : 1  
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
ALL ANIMALS (105W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST U/L		ALT U/L		LDH U/L		ALP U/L		G-GTP U/L		CK U/L	
Control	39	247±	64	124±	74	59±	35	151±	57	205±	92	2.4±	1.3	92±	23
3.2ppm	38	250±	75	134±	85	59±	33	163±	86	228±	139	3.0±	3.3	97±	32
8ppm	35	227±	39	129±	86	54±	17	125±	47	220±	82	2.3±	1.7	94±	25
20ppm	28	227±	48	136±	79	56±	27	154±	101	248±	180	2.8±	2.6	113±	116

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

Test of Dunnett

STUDY NO. : 0794

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (105W)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	39	17.5±	2.5	0.30±	0.05	143±	2	3.7±	0.4	105±	1	10.3±	0.4	3.6±	0.7
3.2ppm	38	17.0±	2.3	0.29±	0.04	142±	1	3.7±	0.4	104±	2	10.5±	0.3	3.8±	0.6
8ppm	35	17.7±	4.1	0.28±	0.04	143±	2	3.6±	0.3	105±	2	10.2±	0.4	3.6±	0.9
20ppm	28	20.1±	9.6	0.26±	0.04**	142±	2	3.9±	0.8	105±	2	10.2±	0.3	4.2±	1.6

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

Test of Dunnett

TABLE H1

URINALYSIS : MALE

STUDY NO. : 0794

ANIMAL : RAT F344/DuCrj[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

## URINALYSIS

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein							CHI	Glucose							CHI	Ketone body							CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		—	±	+	2+	3+	4+	—		±	+	2+	3+	4+	—	±		+	2+	3+	4+	—	+	2+		3+				
Control	42	0	1	4	3	15	10	9		0	0	1	21	20	0		42	0	0	0	0	0		32	8	1	1	0	0		42	0	0	0				
3.2ppm	45	0	0	2	4	22	12	5		0	0	1	16	28	0		45	0	0	0	0	0		40	5	0	0	0	0		45	0	0	0				
8ppm	39	0	0	1	7	12	8	11		0	0	0	7	31	1	*	39	0	0	0	0	0		22	14	3	0	0	0		37	1	0	1				
20ppm	9	0	0	0	3	4	2	0		0	0	1	4	4	0		9	0	0	0	0	0		9	0	0	0	0	0		8	0	0	1	*			

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

Test of CHI SQUARE

(HCL101)

BAIS5



STUDY NO. : 0794

ANIMAL : RAT F344/DuCrIj[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	42	36	4	0	1	1		42	0	0	0	0	
3.2ppm	45	40	1	2	1	1		45	0	0	0	0	
8ppm	39	34	0	2	1	2		39	0	0	0	0	
20ppm	9	6	1	1	0	1		9	0	0	0	0	

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

\*\* :  $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS 5

## TABLE H2

### URINALYSIS : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : FEMALE

# URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin				CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		—	±	+	2+	3+	4+		—	±	+	2+	3+	4+		—	±	+	2+	3+	4+		—	+	2+	3+	
Control	39	0	0	0	0	5	12	22		0	5	7	11	16	0		39	0	0	0	0	0		9	27	2	1	0	0		39	0	0	0	
3.2ppm	41	0	2	1	3	3	11	21		1	5	11	7	17	0		41	0	0	0	0	0		15	23	3	0	0	0		40	1	0	0	
8ppm	36	0	1	2	1	3	3	26		1	4	15	7	9	0		36	0	0	0	0	0		13	22	1	0	0	0		36	0	0	0	
20ppm	30	0	2	1	2	0	9	16		1	8	11	7	3	0	*	30	0	0	0	0	0		9	20	0	1	0	0		30	0	0	0	

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

Test of CHI SQUARE

STUDY NO. : 0794

ANIMAL : RAT F344/DuCrIj[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	39	36	0	0	1	2		39	0	0	0	0	
3.2ppm	41	38	1	0	2	0		41	0	0	0	0	
8ppm	36	35	0	0	0	1		36	0	0	0	0	
20ppm	30	25	0	2	0	3		30	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS5

TABLE I 1

GROSS FINDINGS : MALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
skin/app	nodule		1	( 2)	8	( 16)	5	( 10)	8	( 16)
subcutis	jaundice		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	mass		11	( 22)	9	( 18)	10	( 20)	14	( 28)
nasal cavit	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	nodule		0	( 0)	1	( 2)	2	( 4)	14	( 28)
lung	white zone		2	( 4)	3	( 6)	4	( 8)	2	( 4)
	red zone		2	( 4)	1	( 2)	1	( 2)	2	( 4)
	nodule		1	( 2)	1	( 2)	3	( 6)	2	( 4)
	voluminous		0	( 0)	0	( 0)	0	( 0)	4	( 8)
lymph node	enlarged		1	( 2)	0	( 0)	1	( 2)	3	( 6)
thymus	enlarged		0	( 0)	0	( 0)	1	( 2)	0	( 0)
spleen	enlarged		6	( 12)	8	( 16)	8	( 16)	5	( 10)
	white zone		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	nodule		0	( 0)	0	( 0)	2	( 4)	0	( 0)
	adhesion		0	( 0)	0	( 0)	0	( 0)	1	( 2)
heart	white zone		1	( 2)	0	( 0)	1	( 2)	0	( 0)
oral cavity	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
tongue	white zone		0	( 0)	1	( 2)	0	( 0)	0	( 0)
stomach	gas		0	( 0)	0	( 0)	0	( 0)	4	( 8)
	forestomach:nodule		0	( 0)	0	( 0)	1	( 2)	2	( 4)
	glandular stomach:erosion		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	glandular stomach:nodule		1	( 2)	0	( 0)	1	( 2)	0	( 0)

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	Control		3. 2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
stomach	glandular stomach:black zone		0	( 0)	1	( 2)	0	( 0)	1	( 2)
	glandular stomach:thick		1	( 2)	0	( 0)	0	( 0)	0	( 0)
small intes	gas		0	( 0)	0	( 0)	0	( 0)	5	( 10)
large intes	gas		0	( 0)	0	( 0)	0	( 0)	5	( 10)
liver	enlarged		2	( 4)	1	( 2)	3	( 6)	2	( 4)
	white zone		1	( 2)	0	( 0)	0	( 0)	1	( 2)
	nodule		0	( 0)	2	( 4)	2	( 4)	1	( 2)
	cyst		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	rough		1	( 2)	0	( 0)	4	( 8)	0	( 0)
	herniation		7	( 14)	9	( 18)	5	( 10)	11	( 22)
pancreas	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
kidney	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	cyst		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	granular		4	( 8)	1	( 2)	2	( 4)	0	( 0)
urin bladd	urine:marked retention		1	( 2)	1	( 2)	1	( 2)	1	( 2)
pituitary	enlarged		6	( 12)	3	( 6)	4	( 8)	0	( 0)
	red zone		6	( 12)	7	( 14)	3	( 6)	1	( 2)
	nodule		3	( 6)	3	( 6)	3	( 6)	0	( 0)
	cyst		0	( 0)	0	( 0)	1	( 2)	0	( 0)
thyroid	enlarged		3	( 6)	3	( 6)	3	( 6)	1	( 2)
	red zone		0	( 0)	0	( 0)	1	( 2)	0	( 0)
adrenal	enlarged		0	( 0)	0	( 0)	1	( 2)	1	( 2)

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

GROSS FINDINGS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
testis	nodule		39	( 78)	46	( 92)	44	( 88)	24	( 48)
brain	enlarged		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	red zone		1	( 2)	0	( 0)	0	( 0)	3	( 6)
	nodule		0	( 0)	0	( 0)	1	( 2)	2	( 4)
spinal cord	red zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	black zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
eye	turbid		0	( 0)	0	( 0)	0	( 0)	4	( 8)
	white		6	( 12)	5	( 10)	8	( 16)	2	( 4)
	red		0	( 0)	0	( 0)	0	( 0)	1	( 2)
Zymbal gl	nodule		1	( 2)	0	( 0)	1	( 2)	0	( 0)
muscle	nodule		1	( 2)	0	( 0)	1	( 2)	1	( 2)
pleura	nodule		0	( 0)	0	( 0)	0	( 0)	2	( 4)
peritoneum	nodule		2	( 4)	7	( 14)	14	( 28)	11	( 22)
abdominal c	hemorrhage		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	ascites		0	( 0)	1	( 2)	11	( 22)	8	( 16)
thoracic ca	pleural fluid		1	( 2)	2	( 4)	1	( 2)	0	( 0)
other	lip:nodule		1	( 2)	1	( 2)	0	( 0)	1	( 2)
	eye lid:nodule		1	( 2)	0	( 0)	1	( 2)	0	( 0)
	ear:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	hindlimb:swollen		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	3	( 6)
	nose:nodule		1	( 2)	0	( 0)	0	( 0)	13	( 26)



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 4

Organ_____	Findings_____	Group Name	Control		3.2ppm		8ppm		20ppm	
		NO. of Animals	50	(%)	50	(%)	50	(%)	50	(%)
whole body	anemic		0	( 0)	0	( 0)	0	( 0)	3	( 6)

(HPT080)

BAIS 5

TABLE I 2

GROSS FINDINGS : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 5

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
skin/app	nodule		0	( 0)	1	( 2)	3	( 6)	0	( 0)
	erosion		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	scab		0	( 0)	0	( 0)	1	( 2)	0	( 0)
subcutis	jaundice		0	( 0)	1	( 2)	3	( 6)	1	( 2)
	mass		8	( 16)	19	( 38)	19	( 38)	29	( 58)
nasal cavit	nodule		0	( 0)	0	( 0)	1	( 2)	6	( 12)
lung	white zone		0	( 0)	1	( 2)	0	( 0)	2	( 4)
	red zone		1	( 2)	0	( 0)	1	( 2)	0	( 0)
	nodule		0	( 0)	2	( 4)	0	( 0)	0	( 0)
lymph node	enlarged		1	( 2)	0	( 0)	1	( 2)	1	( 2)
thymus	enlarged		0	( 0)	0	( 0)	0	( 0)	1	( 2)
spleen	enlarged		5	( 10)	7	( 14)	9	( 18)	7	( 14)
	nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
heart	white zone		0	( 0)	0	( 0)	0	( 0)	1	( 2)
tongue	nodule		0	( 0)	2	( 4)	0	( 0)	2	( 4)
stomach	forestomach:ulcer		1	( 2)	2	( 4)	0	( 0)	1	( 2)
	forestomach:erosion		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	forestomach:nodule		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	glandular stomach:ulcer		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	glandular stomach:erosion		1	( 2)	0	( 0)	1	( 2)	1	( 2)
	glandular stomach:nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	glandular stomach:black zone		0	( 0)	0	( 0)	1	( 2)	0	( 0)

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 6

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
small intes	adhesion		0	( 0)	0	( 0)	0	( 0)	1	( 2)
liver	white zone		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	red zone		0	( 0)	1	( 2)	1	( 2)	1	( 2)
	nodule		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	cyst		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	rough		0	( 0)	3	( 6)	3	( 6)	0	( 0)
	nodular		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	herniation		13	( 26)	10	( 20)	10	( 20)	12	( 24)
pancreas	nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
kidney	small		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	cyst		1	( 2)	1	( 2)	0	( 0)	0	( 0)
	deformed		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	granular		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	hydronephrosis		0	( 0)	0	( 0)	0	( 0)	1	( 2)
urin bladd	urine:marked retention		0	( 0)	0	( 0)	2	( 4)	2	( 4)
	urine:red		0	( 0)	0	( 0)	0	( 0)	1	( 2)
pituitary	enlarged		12	( 24)	15	( 30)	9	( 18)	5	( 10)
	red zone		12	( 24)	14	( 28)	6	( 12)	5	( 10)
	nodule		1	( 2)	2	( 4)	3	( 6)	3	( 6)
thyroid	enlarged		0	( 0)	0	( 0)	4	( 8)	1	( 2)
adrenal	enlarged		1	( 2)	0	( 0)	1	( 2)	0	( 0)
ovary	enlarged		0	( 0)	0	( 0)	1	( 2)	2	( 4)

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 7

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
ovary	cyst		2	( 4)	1	( 2)	3	( 6)	0	( 0)
uterus	black zone		0	( 0)	1	( 2)	1	( 2)	1	( 2)
	nodule		5	( 10)	4	( 8)	4	( 8)	11	( 22)
	dilated lumen		0	( 0)	0	( 0)	1	( 2)	2	( 4)
vagina	nodule		0	( 0)	0	( 0)	1	( 2)	1	( 2)
	prolapse		0	( 0)	1	( 2)	0	( 0)	0	( 0)
brain	hemorrhage		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
eye	turbid		0	( 0)	0	( 0)	0	( 0)	1	( 2)
	white		5	( 10)	2	( 4)	2	( 4)	1	( 2)
	red		1	( 2)	0	( 0)	0	( 0)	0	( 0)
muscle	nodule		0	( 0)	1	( 2)	1	( 2)	0	( 0)
pleura	nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
peritoneum	nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
retroperit	mass		0	( 0)	0	( 0)	1	( 2)	0	( 0)
abdominal c	hemorrhage		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	ascites		0	( 0)	0	( 0)	1	( 2)	2	( 4)
thoracic ca	pleural fluid		0	( 0)	0	( 0)	1	( 2)	1	( 2)
other	lip:nodule		0	( 0)	1	( 2)	0	( 0)	0	( 0)
	ear:nodule		0	( 0)	0	( 0)	1	( 2)	0	( 0)
	upper jaw:nodule		1	( 2)	0	( 0)	0	( 0)	0	( 0)
	nose:elevated		0	( 0)	0	( 0)	0	( 0)	1	( 2)

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 8

Organ	Findings	Group Name NO. of Animals	Control		3.2ppm		8ppm		20ppm	
			50	(%)	50	(%)	50	(%)	50	(%)
other	nose:nodule		0	( 0)	0	( 0)	0	( 0)	1	( 2)
whole body	anemic		0	( 0)	1	( 2)	0	( 0)	2	( 4)

(HPT080)

BAIS 5

TABLE J1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 1

Group Name	NO. of Animals	Body Weight		ADRENALS		TESTES		HEART		LUNGS		KIDNEYS	
Control	40	373±	28	0.077±	0.016	3.216±	1.300	1.165±	0.103	1.355±	0.103	2.649±	0.224
3.2ppm	44	369±	35	0.075±	0.013	3.723±	1.270	1.198±	0.109	1.455±	0.351	2.682±	0.182
8ppm	39	363±	53*	0.080±	0.015	3.790±	1.523	1.239±	0.125*	1.439±	0.233	2.733±	0.229
20ppm	9	295±	39**	0.105±	0.112	3.278±	1.261	1.150±	0.162	1.302±	0.166	2.583±	0.213

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

Test of Dunnett



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIGrlJ[F344/DuCrJ]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 2

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	40	1.141±	1.287	10.400±	1.679	2.065±	0.068
3.2ppm	44	1.093±	0.856	10.427±	1.539	2.057±	0.070
8ppm	39	1.519±	2.386**	10.643±	1.938	2.059±	0.058
20ppm	9	0.729±	0.230	8.934±	0.871	2.005±	0.060

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

Test of Dunnett

(HCL040)

BAIS5

TABLE J2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 3

Group Name	NO. of Animals	Body Weight		ADRENALS		OVARIES		HEART		LUNGS		KIDNEYS	
Control	39	269±	36	0.081±	0.027	0.125±	0.031	0.844±	0.066	0.961±	0.052	1.802±	0.143
3.2ppm	38	265±	35	0.077±	0.014	0.141±	0.085	0.875±	0.073	1.010±	0.160	1.819±	0.180
8ppm	35	247±	33*	0.111±	0.216	0.700±	3.283	0.827±	0.074	0.984±	0.147	1.753±	0.122
20ppm	28	232±	25**	0.076±	0.017	0.134±	0.068	0.836±	0.063	0.995±	0.132	1.807±	0.129

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

Test of Dunnett

(HCL040)

BAIS5

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrJ]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 4

Group Name	NO. of Animals	SPLEEN		LIVER		BRAIN	
Control	39	0.589±	0.217	6.759±	1.376	1.888±	0.082
3.2ppm	38	0.824±	0.911	6.932±	1.412	1.880±	0.067
8ppm	35	0.862±	1.302	6.311±	0.970	1.852±	0.081*
20ppm	28	0.595±	0.459	6.544±	2.461	1.862±	0.051*

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

Test of Dunnett

TABLE K1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	TESTES	HEART	LUNGS	KIDNEYS
Control	40	373± 28	0.021± 0.004	0.869± 0.370	0.314± 0.030	0.365± 0.029	0.712± 0.051
3.2ppm	44	369± 35	0.021± 0.003	1.023± 0.369	0.327± 0.039	0.396± 0.092	0.732± 0.068
8ppm	39	363± 53*	0.022± 0.006	1.048± 0.406	0.346± 0.050**	0.404± 0.098**	0.764± 0.110**
20ppm	9	295± 39**	0.037± 0.040*	1.089± 0.335	0.393± 0.047**	0.448± 0.075**	0.887± 0.103**

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrJ]  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 2

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	40	0.304± 0.331	2.790± 0.405	0.557± 0.036
3.2ppm	44	0.294± 0.221	2.833± 0.339	0.562± 0.052
8ppm	39	0.435± 0.805**	2.958± 0.598	0.576± 0.068
20ppm	9	0.247± 0.075	3.078± 0.487*	0.693± 0.114**

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

Test of Dunnett

(HCL042)

BAIS 5

TABLE K2

ORGAN WEIGHT, RELATIVE : FEMALE



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
 SURVIVAL ANIMALS (105W)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	ADRENALS	OVARIES	HEART	LUNGS	KIDNEYS
Control	39	269± 36	0.030± 0.012	0.047± 0.012	0.316± 0.028	0.361± 0.041	0.675± 0.062
3.2ppm	38	265± 35	0.029± 0.004	0.054± 0.034	0.334± 0.038	0.385± 0.065	0.693± 0.072
8ppm	35	247± 33*	0.044± 0.082	0.267± 1.224	0.338± 0.044*	0.405± 0.089*	0.719± 0.101
20ppm	28	232± 25**	0.033± 0.006*	0.059± 0.035*	0.363± 0.035**	0.434± 0.080**	0.783± 0.050**

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

Test of Dunnett

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS (105W)

PAGE : 4

Group Name	NO. of Animals	SPLEEN	LIVER	BRAIN
Control	39	0.221± 0.086	2.510± 0.364	0.711± 0.083
3.2ppm	38	0.309± 0.334	2.615± 0.368	0.720± 0.084
8ppm	35	0.371± 0.613	2.570± 0.397	0.758± 0.081*
20ppm	28	0.263± 0.233	2.861± 1.277**	0.811± 0.082**

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

Test of Dunnett

TABLE L1

HISTOPATHOLOGICAL FINDINGS :  
NON-NEOPLASTIC LESIONS : MALE

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 1

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Integumentary system/appandage]																		
subcutis			<50>				<50>				<50>				<50>			
	inflammation		0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	inflammatory infiltration		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
[Respiratory system]																		
nasal cavit			<50>				<50>				<50>				<50>			
	thrombus		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	mineralization		41 ( 82 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	46 ( 92 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	42 ( 84 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	22 ( 44 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	squamous cell hyperplasia with atypia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	16 ( 32 )	7 ( 14 )	0 ( 0 )
	eosinophilic change:olfactory epithelium		42 ( 84 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	43 ( 86 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	40 ( 80 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	17 ( 34 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	eosinophilic change:respiratory epithelium		6 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	12 ( 24 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	11 ( 22 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 2

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	inflammation:foreign body		11 ( 22)	5 ( 10)	0 ( 0)	0 ( 0)	19 ( 38)	7 ( 14)	0 ( 0)	0 ( 0)	14 ( 28)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ** ( 0)
	inflammation:respiratory epithelium		9 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)	17 ( 34)	0 ( 0)	0 ( 0)	0 ( 0)	9 ( 18)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	0 ( 0)	0 ( 0)	0 ( 0)
	respiratory metaplasia:olfactory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 14)	0 ( 0)	0 ( 0)	0 * ( 0)	14 ( 28)	0 ( 0)	0 ( 0)	0 ** ( 0)
	respiratory metaplasia:gland		46 ( 92)	2 ( 4)	0 ( 0)	0 ( 0)	40 ( 80)	6 ( 12)	0 ( 0)	0 ( 0)	36 ( 72)	9 ( 18)	0 ( 0)	0 * ( 0)	23 ( 46)	3 ( 6)	0 ( 0)	0 ** ( 0)
	squamous cell metaplasia:respiratory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	8 ( 16)	0 ( 0)	0 ( 0)	0 ** ( 0)	4 ( 8)	3 ( 6)	0 ( 0)	0 * ( 0)
	squamous cell metaplasia:olfactory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)
	ulcer:respiratory epithelium		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	2 ( 4)	1 ( 2)	0 ( 0)
	ulcer:olfactory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 3

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit																		
	squamous cell metaplasia with atypia:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	10 ( 20 )	15 ( 30 )	0 ( 0 )	0 ** ( 0 )	2 ( 4 )	4 ( 8 )	0 ( 0 )	0 * ( 0 )
	hyperplasia:nasal gland		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	hyperplasia:transitional epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	15 ( 30 )	1 ( 2 )	0 ( 0 )	0 ** ( 0 )	26 ( 52 )	7 ( 14 )	2 ( 4 )	0 ** ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	regeneration:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	regeneration:olfactory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	atrophy:olfactory epithelium		2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	10 ( 20 )	4 ( 8 )	0 ( 0 )	0 ** ( 0 )	16 ( 32 )	3 ( 6 )	0 ( 0 )	0 ** ( 0 )
	necrosis:olfactory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	7 ( 14 )	0 ( 0 )	0 ( 0 )	0 * ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	necrosis:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 4

Organ	Findings	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit	hyperplasia:respiratory epithelium		<50>				<50>				<50>				<50>			
			0	0	0	0	3	1	1	0	1	0	0	0	2	2	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 2 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 4 )	( 0 )	( 0 )
larynx	inflammation cell		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammation		3	0	0	0	1	0	0	0	2	0	0	0	1	0	0	0
			( 6 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
lung	congestion		<50>				<50>				<50>				<50>			
			1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	hemorrhage		0	0	0	0	1	1	0	0	2	0	0	0	3	1	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )
	edema		2	0	0	0	0	0	0	0	1	0	0	0	3	0	0	0
		( 4 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	
	inflammatory infiltration		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 5

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung			<50>				<50>				<50>				<50>			
	lymphocytic infiltration		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	fibrosis:focal		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	bronchiolar-alveolar cell hyperplasia		5 ( 10 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	1 ( 2 )	2 ( 4 )	0 ( 0 )	0 ( 0 )
	accumulation of histiocyte		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
{Hematopoietic system}																		
bone marrow			<50>				<50>				<50>				<50>			
	granulation		0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	increased hematopoiesis		7 ( 14 )	3 ( 6 )	3 ( 6 )	0 ( 0 )	10 ( 20 )	7 ( 14 )	3 ( 6 )	0 ( 0 )	9 ( 18 )	14 ( 28 )	8 ( 16 )	0 ( 0 ) **	7 ( 14 )	9 ( 18 )	6 ( 12 )	0 ( 0 )
lymph node			<50>				<50>				<50>				<50>			
	congestion		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 6

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
lymph node	inflammatory infiltration		<50>				<50>				<50>				<50>			
		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
spleen	congestion		<50>				<50>				<50>				<50>			
		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
	deposit of hemosiderin		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
		fibrosis:focal		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	extramedullary hematopoiesis		17 ( 34 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	9 ( 18 )	10 ( 20 )	4 ( 8 )	0 * ( 0 )	8 ( 16 )	12 ( 24 )	11 ( 22 )	0 ** ( 0 )	7 ( 14 )	5 ( 10 )	10 ( 20 )	0 ** ( 0 )
{Circulatory system}																		
heart	thrombus		<50>				<50>				<50>				<50>			
		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 7

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart	mineralization		<50>				<50>				<50>				<50>			
		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
		( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	myocardial fibrosis		34	10	0	0	32	6	0	0	34	11	0	0	32	7	0	0
		( 68)	( 20)	( 0)	( 0)	( 64)	( 12)	( 0)	( 0)	( 68)	( 22)	( 0)	( 0)	( 64)	( 14)	( 0)	( 0)	
	subendocardial fibrosis		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
artery/aort	mineralization		<50>				<50>				<50>				<50>			
		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
{Digestive system}																		
tongue	squamous cell hyperplasia		<50>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	
		( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
	mineralization:artery		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrI j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 8

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
esophagus			<50>				<50>				<50>				<50>			
	inflammation		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
stomach			<50>				<50>				<50>				<50>			
	erosion:forestomach		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	ulcer:forestomach		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)
	hyperplasia:forestomach		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	1 ( 2)	0 ( 0)	0 ( 0)	5 ( 10)	3 ( 6)	0 ( 0)	0 * ( 0)
	erosion:glandular stomach		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
	ulcer:glandular stomach		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)
	hyperplasia:glandular stomach		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)
	mineralization:glandular stomach		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 9

Organ	Findings	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
small intes			<50>				<50>				<50>				<50>			
	hyperplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
liver			<50>				<50>				<50>				<50>			
	herniation		7 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	9 ( 18 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	11 ( 22 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	necrosis:central		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	granulation		8 ( 16 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 ) *
	inflammatory cell nest		7 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	extramedullary hematopoiesis		2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	clear cell focus		1 ( 2 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	acidophilic cell focus		24 ( 48 )	3 ( 6 )	1 ( 2 )	0 ( 0 )	28 ( 56 )	5 ( 10 )	2 ( 4 )	0 ( 0 )	32 ( 64 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	9 ( 18 )	0 ( 0 )	0 ( 0 )	0 ( 0 ) **

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 10

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)
{Digestive system}																		
liver	basophilic cell focus		11 ( 22 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	17 ( 34 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	16 ( 32 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	7 ( 14 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	spongiosis hepatitis		5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	bile duct hyperplasia		26 ( 52 )	24 ( 48 )	0 ( 0 )	0 ( 0 )	27 ( 54 )	22 ( 44 )	0 ( 0 )	0 ( 0 )	29 ( 58 )	20 ( 40 )	0 ( 0 )	0 ( 0 )	38 ( 76 )	12 ( 24 )	0 ( 0 )	0 *
	biliary cyst		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
pancreas	atrophy		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 12 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	islet cell hyperplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	2 ( 4 )	0 ( 0 )	0 ( 0 )
{Urinary system}																		
kidney	cyst		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study				Control				3.2ppm				8ppm				20ppm			
		Grade				50				50				50				50			
		1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																					
kidney		<50>				<50>				<50>				<50>				<50>			
	osseous metaplasia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	chronic nephropathy	25	15	7	1	26	18	4	0	18	25	3	0	39	3	0	0	0	0	0	**
		( 50 )	( 30 )	( 14 )	( 2 )	( 52 )	( 36 )	( 8 )	( 0 )	( 36 )	( 50 )	( 6 )	( 0 )	( 78 )	( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:papilla	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	mineralization:pelvis	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	urothelial hyperplasia:pelvis	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	atypical tubule hyperplasia	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	dilated pelvis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
urin bladd		<50>				<50>				<50>				<50>				<50>			
	dilatation	1	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0	1	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study				Control				3.2ppm				8ppm				20ppm			
		Grade				50				50				50				50			
		1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																					
urin bladd		<50>				<50>				<50>				<50>				<50>			
	papillary and/or nodular hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
{Endocrine system}																					
pituitary		<50>				<50>				<50>				<50>				<50>			
	angiectasis	0	0	1	0	2	1	0	0	0	0	0	0	0	0	0	0	2	0	0	0
		( 0 )	( 0 )	( 2 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	cyst	3	0	0	0	2	0	0	0	3	0	0	0	3	0	0	0	2	0	0	0
		( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	hyperplasia	14	5	0	0	11	3	0	0	18	5	0	0	18	5	0	0	15	1	0	0
		( 28 )	( 10 )	( 0 )	( 0 )	( 22 )	( 6 )	( 0 )	( 0 )	( 36 )	( 10 )	( 0 )	( 0 )	( 36 )	( 10 )	( 0 )	( 0 )	( 30 )	( 2 )	( 0 )	( 0 )
	Rathke pouch	1	0	0	0	3	0	0	0	4	0	0	0	4	0	0	0	4	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )
thyroid		<50>				<50>				<50>				<50>				<50>			
	inflammatory infiltration	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 13

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)
{Endocrine system}																		
thyroid			<50>				<50>				<50>				<50>			
	follicular hyperplasia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	C-cell hyperplasia		12 ( 24 )	2 ( 4 )	1 ( 2 )	0 ( 0 )	5 ( 10 )	3 ( 6 )	4 ( 8 )	0 ( 0 )	8 ( 16 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	4 ( 8 )	1 ( 2 )	1 ( 2 )	0 ( 0 )
adrenal			<50>				<50>				<50>				<50>			
	angiectasis		2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	peliosis-like lesion		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	fatty change		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	extramedullary hematopoiesis		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyperplasia:cortical cell		9 ( 18 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyperplasia:medulla		4 ( 8 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	1 ( 2 )	1 ( 2 )	0 ( 0 )

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



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 14

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Endocrine system]																		
adrenal	accessory cortical nodule		<50>				<50>				<50>				<50>			
		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)
	focal fatty change:cortex		3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	1 ( 2)	0 ( 0)	0 ( 0)	7 ( 14)	1 ( 2)	0 ( 0)	0 ( 0)	7 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)
[Reproductive system]																		
testis	mineralization		<50>				<50>				<50>				<50>			
		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	
	inflammation		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	interstitial cell hyperplasia		4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)
semin ves	inflammation		<50>				<50>				<50>				<50>			
		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control 50				3. 2ppm 50				8ppm 50				20ppm 50			
			1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)
{Reproductive system}																		
prostate	inflammation		<50>				<50>				<50>				<50>			
			9 ( 18)	2 ( 4)	0 ( 0)	0 ( 0)	8 ( 16)	0 ( 0)	0 ( 0)	0 ( 0)	20 ( 40)	0 ( 0)	0 ( 0)	0 ( 0)	0 *	2 ( 4)	0 ( 0)	0 ( 0)
	hyperplasia		7 ( 14)	1 ( 2)	0 ( 0)	0 ( 0)	7 ( 14)	1 ( 2)	0 ( 0)	0 ( 0)	8 ( 16)	2 ( 4)	0 ( 0)	0 ( 0)	6 ( 12)	0 ( 0)	0 ( 0)	0 ( 0)
mammary gl	galactoceles		<50>				<50>				<50>				<50>			
			2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
prep/cli gl	hyperplasia		<50>				<50>				<50>				<50>			
			0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
{Nervous system}																		
brain	hemorrhage		<50>				<50>				<50>				<50>			
			1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)
	gliosis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)
Grade	1+ : Slight	2+ : Moderate	3+ : Marked	4+ : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
( c )	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 16

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Special sense organs/appendage]																		
eye			<50>				<50>				<50>				<50>			
	cataract		6 ( 12)	2 ( 4)	0 ( 0)	0 ( 0)	2 ( 4)	4 ( 8)	0 ( 0)	0 ( 0)	3 ( 6)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 *
	retinal atrophy		0 ( 0)	2 ( 4)	5 ( 10)	0 ( 0)	1 ( 2)	1 ( 2)	5 ( 10)	0 ( 0)	1 ( 2)	2 ( 4)	6 ( 12)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0
	keratitis		2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	13 ( 26)	7 ( 14)	1 ( 2)	0 **
	iritis		2 ( 4)	3 ( 6)	0 ( 0)	0 ( 0)	5 ( 10)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)	8 ( 16)	4 ( 8)	0 ( 0)	0
	degeneration:cornea		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0
	ulcer:cornea		0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	6 ( 12)	1 ( 2)	0 *
Harder gl			<50>				<50>				<50>				<50>			
	lymphocytic infiltration		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0
	hyperplasia		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 17

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Musculoskeletal system}																		
bone			<50>				<50>				<50>				<50>			
	fracture		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	ostitis fibrosa		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)
Grade	1+ : Slight	2+ : Moderate	3+ : Marked	4+ : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
( c )	c : b / a * 100																	
Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square																		

(HPT150)

BAISS

TABLE L2

HISTOPATHOLOGICAL FINDINGS :  
NON-NEOPLASTIC LESIONS : FEMALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 18

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Integumentary system/appandage}																		
skin/app			<50>				<50>				<50>				<50>			
	erosion		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	inflammation		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	scab		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	thrombus		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	mineralization		20 ( 40 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	34 ( 68 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	26 ( 52 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	30 ( 60 )	0 ( 0 )	0 ( 0 )
	hyperplasia:gland		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	squamous cell hyperplasia with atypia		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	7 ( 14 )	2 ( 4 )	0 ( 0 )

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 19

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<50>				<50>				<50>				<50>			
	eosinophilic change:olfactory epithelium		16 ( 32)	29 ( 58)	3 ( 6)	0 ( 0)	25 ( 50)	25 ( 50)	0 ( 0)	0 ( 0)	29 ( 58)	19 ( 38)	0 ( 0)	0 * ( 0)	37 ( 74)	7 ( 14)	0 ( 0)	0 ** ( 0)
	eosinophilic change:respiratory epithelium		33 ( 66)	0 ( 0)	0 ( 0)	0 ( 0)	35 ( 70)	0 ( 0)	0 ( 0)	0 ( 0)	22 ( 44)	0 ( 0)	0 ( 0)	0 * ( 0)	9 ( 18)	0 ( 0)	0 ( 0)	0 ** ( 0)
	inflammation:foreign body		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	inflammation:respiratory epithelium		7 ( 14)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	0 ( 0)	0 ( 0)	0 ( 0)	22 ( 44)	0 ( 0)	0 ( 0)	0 ** ( 0)	30 ( 60)	0 ( 0)	0 ( 0)	0 ** ( 0)
	respiratory metaplasia:olfactory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	15 ( 30)	0 ( 0)	0 ( 0)	0 ** ( 0)
	respiratory metaplasia:gland		49 ( 98)	0 ( 0)	0 ( 0)	0 ( 0)	47 ( 94)	1 ( 2)	0 ( 0)	0 ( 0)	41 ( 82)	3 ( 6)	0 ( 0)	0 * ( 0)	39 ( 78)	6 ( 12)	0 ( 0)	0 ** ( 0)
	squamous cell metaplasia:respiratory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 12)	0 ( 0)	0 ( 0)	0 * ( 0)	21 ( 42)	7 ( 14)	0 ( 0)	0 ** ( 0)	13 ( 26)	5 ( 10)	0 ( 0)	0 ** ( 0)
	squamous cell metaplasia:olfactory epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 20

Organ_____	Findings_____	Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	squamous cell metaplasia with atypia:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	7 ( 14 )	9 ( 18 )	2 ( 4 )	0 ( 0 ) **
	hyperplasia:nasal gland		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyperplasia:transitional epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	4 ( 8 )	0 ( 0 )	0 ( 0 ) *	23 ( 46 )	15 ( 30 )	0 ( 0 )	0 ( 0 ) **	13 ( 26 )	20 ( 40 )	0 ( 0 )	0 ( 0 ) **
	regeneration:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	regeneration:olfactory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	10 ( 20 )	0 ( 0 )	0 ( 0 )	0 ( 0 ) **
	atrophy:olfactory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	7 ( 14 )	3 ( 6 )	0 ( 0 )	0 ( 0 ) **	21 ( 42 )	24 ( 48 )	0 ( 0 )	0 ( 0 ) **
	necrosis:olfactory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	necrosis:respiratory epithelium		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

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



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 21

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit			<50>				<50>				<50>				<50>			
	hyperplasia:respiratory epithelium		0	0	0	0	3	1	0	0	2	0	0	0	3	0	1	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 2 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 2 )	( 0 )
larynx			<50>				<50>				<50>				<50>			
	inflammation		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
lung			<50>				<50>				<50>				<50>			
	congestion		0	0	0	0	2	0	0	0	1	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
	hemorrhage		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 2 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	edema		1	0	0	0	2	0	0	0	1	0	0	0	3	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )
	inflammatory infiltration		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	accumulation of foamy cells		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 22

Organ	Findings	Group Name No. of Animals on Study Grade	Control				3.2ppm				8ppm				20ppm			
			1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
lung	bronchiolar-alveolar cell hyperplasia		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
{Hematopoietic system}																		
bone marrow	congestion		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	granulation		1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	increased hematopoiesis		5	1	0	0	3	5	2	0	5	5	2	0	1	9	2	0 **
			( 10 )	( 2 )	( 0 )	( 0 )	( 6 )	( 10 )	( 4 )	( 0 )	( 10 )	( 10 )	( 4 )	( 0 )	( 2 )	( 18 )	( 4 )	( 0 )
lymph node	deposit of hemosiderin		<50>				<50>				<50>				<50>			
			0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
spleen	congestion		<50>				<50>				<50>				<50>			
			0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 23

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}																		
spleen			<50>				<50>				<50>				<50>			
	deposit of hemosiderin		8	0	0	0	4	0	0	0	5	0	0	0	7	1	0	0
			( 16)	( 0)	( 0)	( 0)	( 8)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 14)	( 2)	( 0)	( 0)
	extramedullary hematopoiesis		23	8	1	0	16	8	3	0	20	10	3	0	11	6	9	0 **
			( 46)	( 16)	( 2)	( 0)	( 32)	( 16)	( 6)	( 0)	( 40)	( 20)	( 6)	( 0)	( 22)	( 12)	( 18)	( 0)
{Circulatory system}																		
heart			<50>				<50>				<50>				<50>			
	thrombus		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	inflammatory infiltration		1	0	0	0	1	0	0	0	2	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	myocardial fibrosis		33	3	0	0	29	2	0	0	25	3	0	0	28	4	0	0
			( 66)	( 6)	( 0)	( 0)	( 58)	( 4)	( 0)	( 0)	( 50)	( 6)	( 0)	( 0)	( 56)	( 8)	( 0)	( 0)
	subendocardial fibrosis		1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 24

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)	1+ (%)	2+ (%)	3+ (%)	4+ (%)
{Circulatory system}																		
artery/aort	mineralization		<50>				<50>				<50>				<50>			
		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	
{Digestive system}																		
oral cavity	inflammation		<50>				<50>				<50>				<50>			
		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	
stomach	erosion:forestomach		<50>				<50>				<50>				<50>			
		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	
	ulcer:forestomach		1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	2 ( 4)	1 ( 2)	1 ( 2)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	3 ( 6)	3 ( 6)	0 ( 0)	0 ( 0)
		hyperplasia:forestomach		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	4 ( 8)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	2 ( 4)	1 ( 2)	0 ( 0)	10 ( 20)	2 ( 4)	0 ( 0)
	erosion:glandular stomach		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)	2 ( 4)	0 ( 0)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrjCrj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 25

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
stomach			<50>				<50>				<50>				<50>			
	ulcer:glandular stomach		0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hyperplasia:glandular stomach		0	0	0	0	1	0	0	0	1	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)
	mineralization:glandular stomach		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
liver			<50>				<50>				<50>				<50>			
	herniation		13	0	0	0	11	0	0	0	11	0	0	0	12	0	0	0
			( 26)	( 0)	( 0)	( 0)	( 22)	( 0)	( 0)	( 0)	( 22)	( 0)	( 0)	( 0)	( 24)	( 0)	( 0)	( 0)
	peliosis-like lesion		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	necrosis:focal		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
	inflammatory infiltration		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	
			( 2)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
	lymphocytic infiltration		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
			( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 26

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver																		
	granulation		<50>				<50>				<50>				<50>			
			17	1	0	0	7	1	0	0	10	1	0	0	4	1	0	0 **
			( 34 )	( 2 )	( 0 )	( 0 )	( 14 )	( 2 )	( 0 )	( 0 )	( 20 )	( 2 )	( 0 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )
	inflammatory cell nest		6	0	0	0	6	0	0	0	6	1	0	0	5	1	0	0
			( 12 )	( 0 )	( 0 )	( 0 )	( 12 )	( 0 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )
	extramedullary hematopoiesis		1	0	0	0	5	0	0	0	2	0	0	0	1	0	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	clear cell focus		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	acidophilic cell focus		4	3	2	0	6	2	0	0	4	0	0	0	1	0	0	0
			( 8 )	( 6 )	( 4 )	( 0 )	( 12 )	( 4 )	( 0 )	( 0 )	( 8 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	basophilic cell focus		36	2	0	0	41	1	0	0	40	0	0	0	40	1	0	0
			( 72 )	( 4 )	( 0 )	( 0 )	( 82 )	( 2 )	( 0 )	( 0 )	( 80 )	( 0 )	( 0 )	( 0 )	( 80 )	( 2 )	( 0 )	( 0 )
	bile duct hyperplasia		14	0	0	0	22	3	0	0 *	19	3	0	0	18	1	0	0
			( 28 )	( 0 )	( 0 )	( 0 )	( 44 )	( 6 )	( 0 )	( 0 )	( 38 )	( 6 )	( 0 )	( 0 )	( 36 )	( 2 )	( 0 )	( 0 )
	bile ductular proliferation		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 27

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver	choleangiofibrosis		<50>				<50>				<50>				<50>			
		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	biliary cyst	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
( 0 )		( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
pancreas	atrophy		<50>				<50>				<50>				<50>			
		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	
	inflammatory infiltration	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
( 0 )		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
{Urinary system}																		
kidney	aplasia		<50>				<50>				<50>				<50>			
		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	
	angiectasis	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
( 0 )		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 28

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney																		
			<50>				<50>				<50>				<50>			
	cyst		0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyaline droplet		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	chronic nephropathy		25 ( 50 )	5 ( 10 )	2 ( 4 )	0 ( 0 )	23 ( 46 )	4 ( 8 )	1 ( 2 )	0 ( 0 )	30 ( 60 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	19 ( 38 )	1 ( 2 )	0 ( 0 )	0 * ( 0 )
	hydronephrosis		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	mineralization:cortico-medullary junction		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	mineralization:papilla		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	dilatation:tubular lumen		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	dilated pelvis		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 4 )	1 ( 2 )	0 ( 0 )	0 ( 0 )

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



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 29

		Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
Organ_____	Findings_____	Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<50>				<50>				<50>				<50>			
	squamous cell metaplasia:pelvis		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
urin bladd			<50>				<50>				<50>				<50>			
	dilatation		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)
	simple hyperplasia:transitional epithelium		0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	papillary and/or nodular hyperplasia		1 ( 2)	0 ( 0)	0 ( 0)	0 ( 0)	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}																		
pituitary			<50>				<50>				<50>				<50>			
	angiectasis		2 ( 4)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)	3 ( 6)	1 ( 2)	0 ( 0)	0 ( 0)	3 ( 6)	2 ( 4)	0 ( 0)	0 ( 0)
	cyst		18 ( 36)	2 ( 4)	0 ( 0)	0 ( 0)	13 ( 26)	2 ( 4)	0 ( 0)	0 ( 0)	17 ( 34)	2 ( 4)	0 ( 0)	0 ( 0)	21 ( 42)	2 ( 4)	0 ( 0)	0 ( 0)

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

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 30

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
pituitary	hyperplasia		<50>				<50>				<50>				<50>			
		14	2	0	0	14	1	0	0	13	3	0	0	10	0	0	0	
		( 28)	( 4)	( 0)	( 0)	( 28)	( 2)	( 0)	( 0)	( 26)	( 6)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	
Rathke pouch		2	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)		
	thyroid	follicular hyperplasia		<50>				<50>				<50>				<50>		
1			0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
( 2)			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)	
C-cell hyperplasia		17	4	0	0	13	4	0	0	8	1	0	0 *	9	2	0	0	
	( 34)	( 8)	( 0)	( 0)	( 26)	( 8)	( 0)	( 0)	( 16)	( 2)	( 0)	( 0)	( 18)	( 4)	( 0)	( 0)		
	adrenal	angiectasis		<50>				<50>				<50>				<50>		
4			0	0	0	2	0	0	0	0	0	0	0	3	1	0	0	
( 8)			( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 6)	( 2)	( 0)	( 0)	
hemorrhage		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)	( 0)	( 0)	( 0)		
	peliosis-like lesion		3	0	0	0	2	0	0	0	0	0	0	0	2	0	0	0
( 6)		( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 4)	( 0)	( 0)	( 0)		

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 31

Organ_____	Findings_____	Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
		Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
adrenal	cyst		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	extramedullary hematopoiesis		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyperplasia:cortical cell		9 ( 18 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	6 ( 12 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	12 ( 24 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	hyperplasia:medulla		1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	3 ( 6 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	focal fatty change:cortex		5 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	4 ( 8 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	11 ( 22 )	1 ( 2 )	1 ( 2 )	0 ( 0 )	12 ( 24 )	1 ( 2 )	0 ( 0 )	0 ( 0 )
	necrosis:cortex		0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	1 ( 2 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )

{Reproductive system}

ovary	cyst	<50>				<50>				<50>				<50>			
		2	1	0	0	0	0	0	0	2	3	0	0	1	0	0	0
		( 4 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 6 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 32

		Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
Organ_____	Findings_____	Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Reproductive system}																		
ovary			<50>				<50>				<50>				<50>			
	inflammatory infiltration		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	lymphocytic infiltration		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	hyperplasia		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
uterus			<50>				<50>				<50>				<50>			
	cystic endometrial hyperplasia		1	0	0	0	5	1	0	0	4	1	0	0	6	1	0	0
			( 2 )	( 0 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )	( 8 )	( 2 )	( 0 )	( 0 )	( 12 )	( 2 )	( 0 )	( 0 )
mammary gl			<50>				<50>				<50>				<50>			
	hyperplasia		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Nervous system}																		
brain			<50>				<50>				<50>				<50>			
	necrosis:focal		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 33

		Group Name	Control				3. 2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
Organ_____	Findings_____	Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Nervous system}																		
brain			<50>				<50>				<50>				<50>			
	mineralization		0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	degeneration:focal		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )
	gliosis		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
spinal cord			<50>				<50>				<50>				<50>			
	degeneration:focal		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
{Special sense organs/appendage}																		
eye			<50>				<50>				<50>				<50>			
	cataract		3	3	0	0	0	2	0	0	0	2	0	0	1	1	0	0
			( 6 )	( 6 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 2 )	( 2 )	( 0 )	( 0 )
	retinal atrophy		0	0	5	0	0	0	2	0	0	0	2	0	0	0	1	0
			( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )

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

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 34

		Group Name	Control				3.2ppm				8ppm				20ppm			
		No. of Animals on Study	50				50				50				50			
Organ_____	Findings_____	Grade	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+	1+	2+	3+	4+
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Special sense organs/appendage}																		
eye			<50>				<50>				<50>				<50>			
	keratitis		3	0	0	0	0	0	0	0	3	0	0	0	5	4	0	0
			( 6 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 10 )	( 8 )	( 0 )	( 0 )
	iritis		2	0	0	0	1	0	0	0	2	1	0	0	5	1	0	0
			( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 2 )	( 0 )	( 0 )	( 10 )	( 2 )	( 0 )	( 0 )
	mineralization:cornea		0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	
	ulcer:cornea		0	0	0	0	0	0	0	0	2	0	0	0	2	0	0	
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	
Harder gl			<50>				<50>				<50>				<50>			
	degeneration:focal		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	lymphocytic infiltration		4	0	0	0	2	0	0	0	1	0	0	0	2	0	0	0
			( 8 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )	( 2 )	( 0 )	( 0 )	( 0 )	( 4 )	( 0 )	( 0 )	( 0 )
{Musculoskeletal system}																		
bone			<50>				<50>				<50>				<50>			
	osteosclerosis		4	1	0	0	3	0	0	0	4	5	0	0	3	3	0	0
		( 8 )	( 2 )	( 0 )	( 0 )	( 6 )	( 0 )	( 0 )	( 0 )	( 8 )	( 10 )	( 0 )	( 0 )	( 6 )	( 6 )	( 0 )	( 0 )	

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

TABLE M1

NUMBER OF ANIMALS WITH TUMORS  
AND NUMBER OF TUMORS-TIME RELATED : MALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 1

Time-related Weeks	Items	Group Name	Control	3. 2ppm	8ppm	20ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	0	0
	NO. OF ANIMALS WITH TUMORS		0	0	0	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	0	0
	NO. OF TOTAL TUMORS		0	0	0	0
53 - 78	NO. OF EXAMINED ANIMALS		0	0	4	9
	NO. OF ANIMALS WITH TUMORS		0	0	3	9
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	0	6
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	3	3
	NO. OF BENIGN TUMORS		0	0	2	5
	NO. OF MALIGNANT TUMORS		0	0	4	9
	NO. OF TOTAL TUMORS		0	0	6	14
79 - 104	NO. OF EXAMINED ANIMALS		9	6	7	32
	NO. OF ANIMALS WITH TUMORS		9	6	7	32
	NO. OF ANIMALS WITH SINGLE TUMORS		4	0	0	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		5	6	7	29
	NO. OF BENIGN TUMORS		10	12	10	45
	NO. OF MALIGNANT TUMORS		9	4	7	42
	NO. OF TOTAL TUMORS		19	16	17	87
105 - 105	NO. OF EXAMINED ANIMALS		41	44	39	9
	NO. OF ANIMALS WITH TUMORS		40	44	39	9
	NO. OF ANIMALS WITH SINGLE TUMORS		17	12	7	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		23	32	32	9
	NO. OF BENIGN TUMORS		65	83	76	26
	NO. OF MALIGNANT TUMORS		6	18	28	14
	NO. OF TOTAL TUMORS		71	101	104	40



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 2

Time-related Weeks	Items	Group Name	Control	3. 2ppm	8ppm	20ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		49	50	49	50
	NO. OF ANIMALS WITH SINGLE TUMORS		21	12	7	9
	NO. OF ANIMALS WITH MULTIPLE TUMORS		28	38	42	41
	NO. OF BENIGN TUMORS		75	95	88	76
	NO. OF MALIGNANT TUMORS		15	22	39	65
	NO. OF TOTAL TUMORS		90	117	127	141
(HPT070)			BAIS5			

**TABLE M2**

**NUMBER OF ANIMALS WITH TUMORS  
AND NUMBER OF TUMORS-TIME RELATED : FEMALE**

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 3

Time-related Weeks	Items	Group Name	Control	3.2ppm	8ppm	20ppm
0 - 52	NO. OF EXAMINED ANIMALS		0	0	1	0
	NO. OF ANIMALS WITH TUMORS		0	0	1	0
	NO. OF ANIMALS WITH SINGLE TUMORS		0	0	1	0
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	0
	NO. OF BENIGN TUMORS		0	0	0	0
	NO. OF MALIGNANT TUMORS		0	0	1	0
	NO. OF TOTAL TUMORS		0	0	1	0
53 - 78	NO. OF EXAMINED ANIMALS		2	0	2	4
	NO. OF ANIMALS WITH TUMORS		2	0	2	4
	NO. OF ANIMALS WITH SINGLE TUMORS		2	0	2	3
	NO. OF ANIMALS WITH MULTIPLE TUMORS		0	0	0	1
	NO. OF BENIGN TUMORS		2	0	1	1
	NO. OF MALIGNANT TUMORS		0	0	1	4
	NO. OF TOTAL TUMORS		2	0	2	5
79 - 104	NO. OF EXAMINED ANIMALS		9	11	12	17
	NO. OF ANIMALS WITH TUMORS		8	11	11	17
	NO. OF ANIMALS WITH SINGLE TUMORS		5	4	4	6
	NO. OF ANIMALS WITH MULTIPLE TUMORS		3	7	7	11
	NO. OF BENIGN TUMORS		9	11	14	19
	NO. OF MALIGNANT TUMORS		4	8	7	16
	NO. OF TOTAL TUMORS		13	19	21	35
105 - 105	NO. OF EXAMINED ANIMALS		39	39	35	29
	NO. OF ANIMALS WITH TUMORS		22	30	28	26
	NO. OF ANIMALS WITH SINGLE TUMORS		15	10	12	9
	NO. OF ANIMALS WITH MULTIPLE TUMORS		7	20	16	17
	NO. OF BENIGN TUMORS		24	42	45	37
	NO. OF MALIGNANT TUMORS		5	11	5	13
	NO. OF TOTAL TUMORS		29	53	50	50

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrI J [F344/DuCrJ]  
REPORT TYPE : A1  
SEX : FEMALE

NUMBER OF ANIMALS WITH TUMORS AND NUMBER OF TUMORS - TIME RELATED

PAGE : 4

Time-related Weeks	Items	Group Name	Control	3. 2ppm	8ppm	20ppm
0 - 105	NO. OF EXAMINED ANIMALS		50	50	50	50
	NO. OF ANIMALS WITH TUMORS		32	41	42	47
	NO. OF ANIMALS WITH SINGLE TUMORS		22	14	19	18
	NO. OF ANIMALS WITH MULTIPLE TUMORS		10	27	23	29
	NO. OF BENIGN TUMORS		35	53	60	57
	NO. OF MALIGNANT TUMORS		9	19	14	33
	NO. OF TOTAL TUMORS		44	72	74	90
(HPT070)			BAIS5			

TABLE N1

HISTOPATHOLOGICAL FINDINGS :  
NEOPLASTIC LESIONS : MALE

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 1

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Integumentary system/appandage}						
skin/app			<50>	<50>	<50>	<50>
	squamous cell papilloma		2 ( 4%)	1 ( 2%)	2 ( 4%)	1 ( 2%)
	trichoepithelioma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
	basal cell epithelioma		0 ( 0%)	1 ( 2%)	1 ( 2%)	4 ( 8%)
	keratoacanthoma		0 ( 0%)	4 ( 8%)	3 ( 6%)	3 ( 6%)
	tricho lemoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	squamous cell carcinoma		0 ( 0%)	2 ( 4%)	1 ( 2%)	2 ( 4%)
	trichoepithelioma:malignant		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
subcutis	basal cell carcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
			<50>	<50>	<50>	<50>
	fibroma		5 ( 10%)	4 ( 8%)	4 ( 8%)	13 ( 26%)
	lipoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	schwannoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	hemangioma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	fibrosarcoma		0 ( 0%)	2 ( 4%)	1 ( 2%)	0 ( 0%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrIj[F344/DuCrJ]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 2

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Integumentary system/appandage}						
subcutis			<50>	<50>	<50>	<50>
	leiomyosarcoma		1 ( 2%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	histiocytic sarcoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	sarcoma:NOS		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	adenoma		0 ( 0%)	7 ( 14%)	9 ( 18%)	0 ( 0%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	29 ( 58%)
	adenocarcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)
	sarcoma:NOS		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	adenosquamous carcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	1 ( 2%)
	esthesioneuroepithelioma		0 ( 0%)	0 ( 0%)	0 ( 0%)	7 ( 14%)
lung			<50>	<50>	<50>	<50>
	bronchiolar-alveolar adenoma		2 ( 4%)	4 ( 8%)	2 ( 4%)	0 ( 0%)
	bronchiolar-alveolar carcinoma		0 ( 0%)	0 ( 0%)	2 ( 4%)	1 ( 2%)

< a > a : Number of animals examined at the site  
b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 3

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Hematopoietic system}						
bone marrow			<50>	<50>	<50>	<50>
	histiocytic sarcoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
spleen			<50>	<50>	<50>	<50>
	hemangioma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	mononuclear cell leukemia		4 ( 8%)	6 ( 12%)	3 ( 6%)	4 ( 8%)
{Digestive system}						
oral cavity			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
tongue			<50>	<50>	<50>	<50>
	squamous cell carcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
stomach			<50>	<50>	<50>	<50>
	squamous cell papilloma		0 ( 0%)	1 ( 2%)	0 ( 0%)	1 ( 2%)
	neuroendocrine cell tumor:benign		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
liver			<50>	<50>	<50>	<50>
	hepatocellular adenoma		1 ( 2%)	1 ( 2%)	1 ( 2%)	2 ( 4%)
pancreas			<50>	<50>	<50>	<50>
	islet cell adenoma		2 ( 4%)	4 ( 8%)	2 ( 4%)	2 ( 4%)
	acinar cell adenoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	islet cell adenocarcinoma		1 ( 2%)	1 ( 2%)	2 ( 4%)	2 ( 4%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 4

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Endocrine system}						
pituitary			<50>	<50>	<50>	<50>
	adenoma	13	( 26%)	7 ( 14%)	5 ( 10%)	0 ( 0%)
thyroid			<50>	<50>	<50>	<50>
	C-cell adenoma	4	( 8%)	5 ( 10%)	3 ( 6%)	4 ( 8%)
	follicular adenoma	0	( 0%)	1 ( 2%)	0 ( 0%)	1 ( 2%)
	C-cell carcinoma	1	( 2%)	1 ( 2%)	3 ( 6%)	1 ( 2%)
	follicular adenocarcinoma	0	( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
parathyroid			<50>	<50>	<50>	<50>
	adenoma	0	( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
adrenal			<50>	<50>	<50>	<50>
	pheochromocytoma	3	( 6%)	1 ( 2%)	0 ( 0%)	2 ( 4%)
	cortical adenoma	0	( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
	pheochromocytoma:malignant	1	( 2%)	0 ( 0%)	2 ( 4%)	0 ( 0%)
{Reproductive system}						
testis			<50>	<50>	<50>	<50>
	interstitial cell tumor	40	( 80%)	46 ( 92%)	47 ( 94%)	36 ( 72%)
prostate			<50>	<50>	<50>	<50>
	adenoma	0	( 0%)	1 ( 2%)	1 ( 2%)	0 ( 0%)
mammary gl			<50>	<50>	<50>	<50>
	adenoma	0	( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)

< a > a : Number of animals examined at the site  
b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 5

Organ	Findings	Group Name No. of animals on Study	Control 50	3. 2ppm 50	8ppm 50	20ppm 50
{Reproductive system}						
mammary gl	fibroadenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 2 ( 4%)	<50> 1 ( 2%)
	adenocarcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
prep/cli gl	adenoma		<50> 2 ( 4%)	<50> 1 ( 2%)	<50> 1 ( 2%)	<50> 1 ( 2%)
{Nervous system}						
brain	leiomyosarcoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	glioma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
{Special sense organs/appendage}						
Harder gl	adenoma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
Zymbal gl	Zymbal gland tumor:malignant		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
{Musculoskeletal system}						
muscle	rhabdomyosarcoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
bone	osteosarcoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
{Body cavities}						
peritoneum	leiomyosarcoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 6

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Body cavities}						
peritoneum	mesothelioma		<50> 1 ( 2%)	<50> 7 ( 14%)	<50> 16 ( 32%)	<50> 14 ( 28%)
adipose	lipoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)

< a > a : Number of animals examined at the site  
b ( c ) b : Number of animals with neoplasm c : b / a \* 100

(HPT085)

BA1S5

**TABLE N2**

**HISTOPATHOLOGICAL FINDINGS :  
NEOPLASTIC LESIONS : FEMALE**

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 7

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Integumentary system/appandage}						
skin/app	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	basal cell epithelioma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	basal cell carcinoma		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
subcutis	fibroma		<50> 0 ( 0%)	<50> 2 ( 4%)	<50> 2 ( 4%)	<50> 3 ( 6%)
	lipoma		1 ( 2%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	schwannoma		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
	sarcoma:NOS		0 ( 0%)	0 ( 0%)	1 ( 2%)	0 ( 0%)
{Respiratory system}						
nasal cavit	adenoma		<50> 0 ( 0%)	<50> 3 ( 6%)	<50> 3 ( 6%)	<50> 1 ( 2%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	10 ( 20%)
	adenosquamous carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	esthesioneuroepithelioma		0 ( 0%)	0 ( 0%)	0 ( 0%)	2 ( 4%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 8

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Respiratory system}						
nasal cavit	hemangiosarcoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
lung	bronchiolar-alveolar adenoma		<50> 1 ( 2%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)
	bronchiolar-alveolar carcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
{Hematopoietic system}						
spleen	mononuclear cell leukemia		<50> 5 ( 10%)	<50> 10 ( 20%)	<50> 8 ( 16%)	<50> 6 ( 12%)
{Digestive system}						
oral cavity	squamous cell papilloma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
tongue	squamous cell papilloma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
stomach	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	squamous cell carcinoma		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
liver	hepatocellular adenoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
pancreas	islet cell adenoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 1 ( 2%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCrIj[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 9

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Digestive system}						
pancreas	acinar cell adenoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
	islet cell adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
{Urinary system}						
urin bladd	transitional cell papilloma		<50> 2 ( 4%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)
{Endocrine system}						
pituitary	adenoma		<50> 11 ( 22%)	<50> 16 ( 32%)	<50> 13 ( 26%)	<50> 8 ( 16%)
	adenocarcinoma		1 ( 2%)	2 ( 4%)	0 ( 0%)	0 ( 0%)
thyroid	C-cell adenoma		<50> 1 ( 2%)	<50> 1 ( 2%)	<50> 3 ( 6%)	<50> 4 ( 8%)
	follicular adenoma		1 ( 2%)	2 ( 4%)	3 ( 6%)	1 ( 2%)
	C-cell carcinoma		0 ( 0%)	0 ( 0%)	2 ( 4%)	0 ( 0%)
adrenal	pheochromocytoma		<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 2 ( 4%)	<50> 0 ( 0%)
	pheochromocytoma:malignant		1 ( 2%)	0 ( 0%)	0 ( 0%)	0 ( 0%)
{Reproductive system}						
ovary	granular cell tumor		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 10

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Reproductive system}						
ovary	granulosa-theca cell tumor		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	Sertoli cell tumor:malignant		0 ( 0%)	0 ( 0%)	0 ( 0%)	1 ( 2%)
	granulosa cell tumor:malignant		0 ( 0%)	1 ( 2%)	0 ( 0%)	0 ( 0%)
uterus	adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 2 ( 4%)
	endometrial stromal polyp		6 ( 12%)	10 ( 20%)	7 ( 14%)	7 ( 14%)
	adenocarcinoma		0 ( 0%)	1 ( 2%)	0 ( 0%)	1 ( 2%)
	endometrial stromal sarcoma		1 ( 2%)	1 ( 2%)	1 ( 2%)	5 ( 10%)
vagina	squamous cell papilloma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
mammary gl	adenoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)
	fibroadenoma		7 ( 14%)	14 ( 28%)	14 ( 28%)	23 ( 46%)
	adenocarcinoma		0 ( 0%)	1 ( 2%)	1 ( 2%)	1 ( 2%)
prep/cli gl	adenoma		<50> 0 ( 0%)	<50> 3 ( 6%)	<50> 3 ( 6%)	<50> 4 ( 8%)
{Special sense organs/appendage}						
Zymbal gl	Zymbal gland tumor:malignant		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)

< a > a : Number of animals examined at the site  
 b ( c ) b : Number of animals with neoplasm c : b / a \* 100



STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : NEOPLASTIC LESIONS (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 11

Organ	Findings	Group Name No. of animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Musculoskeletal system}						
muscle	leiomyosarcoma		<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)	<50> 0 ( 0%)
{Body cavities}						
pleura	histiocytic sarcoma		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)
peritoneum	sarcoma:NOS		<50> 0 ( 0%)	<50> 0 ( 0%)	<50> 1 ( 2%)	<50> 0 ( 0%)

< a > a : Number of animals examined at the site  
b ( c ) b : Number of animals with neoplasm c : b / a \* 100

(HPT085)

BA1S5

TABLE O1

NEOPLASTIC LESIONS-INCIDENCE  
AND STATISTICAL ANALYSIS : MALE

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : skin/appendage TUMOR : basal cell epithelioma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	1/50( 2.0)	4/50( 8.0)
Adjusted rates(b)	0.0	2.27	2.56	23.08
Terminal rates(c)	0/41( 0.0)	1/44( 2.3)	1/39( 2.6)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0003**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0154*			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.0587
SITE : skin/appendage TUMOR : keratoacanthoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	4/50( 8.0)	3/50( 6.0)	3/50( 6.0)
Adjusted rates(b)	0.0	8.00	7.69	23.08
Terminal rates(c)	0/41( 0.0)	2/44( 4.5)	3/39( 7.7)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0250*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.4221			
Fisher Exact test(e)		P = 0.0587	P = 0.1212	P = 0.1212
SITE : skin/appendage TUMOR : squamous cell papilloma, keratoacanthoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	5/50( 10.0)	4/50( 8.0)	4/50( 8.0)
Adjusted rates(b)	4.44	10.00	10.26	23.08
Terminal rates(c)	1/41( 2.4)	2/44( 4.5)	4/39( 10.3)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0720			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.6975			
Fisher Exact test(e)		P = 0.2180	P = 0.3389	P = 0.3389

STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : skin/appendage TUMOR : basal cell epithelioma,basal cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	1/50( 2.0)	2/50( 4.0)	5/50( 10.0)
Adjusted rates(b)	0.0	2.27	2.56	23.08
Terminal rates(c)	0/41( 0.0)	1/44( 2.3)	1/39( 2.6)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.2314			
Prevalence method(d)	P = 0.0001**			
Combined analysis(d)	P = 0.0001**			
Cochran-Armitage test(e)	P = 0.0070**			
Fisher Exact test(e)		P = 0.5000	P = 0.2475	P = 0.0281*
SITE : skin/appendage TUMOR : squamous cell papilloma,keratoacanthoma,squamous cell carcinoma				
Tumor rate				
Overall rates(a)	2/50( 4.0)	7/50( 14.0)	5/50( 10.0)	6/50( 12.0)
Adjusted rates(b)	4.44	12.24	12.82	30.77
Terminal rates(c)	1/41( 2.4)	3/44( 6.8)	5/39( 12.8)	2/ 9( 22.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.4952			
Prevalence method(d)	P = 0.0132*			
Combined analysis(d)	P = 0.0180*			
Cochran-Armitage test(e)	P = 0.4128			
Fisher Exact test(e)		P = 0.0798	P = 0.2180	P = 0.1343
SITE : subcutis TUMOR : fibroma				
Tumor rate				
Overall rates(a)	5/50( 10.0)	4/50( 8.0)	4/50( 8.0)	13/50( 26.0)
Adjusted rates(b)	10.64	9.09	10.26	60.00
Terminal rates(c)	3/41( 7.3)	4/44( 9.1)	4/39( 10.3)	5/ 9( 55.6)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0048**			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.0332*

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 SEX : MALE

NEOPLASTIC LESIONS—INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : subcutis TUMOR : fibroma, fibrosarcoma				
Tumor rate				
Overall rates(a)	5/50( 10.0)	6/50( 12.0)	5/50( 10.0)	13/50( 26.0)
Adjusted rates(b)	10.64	13.64	12.82	60.00
Terminal rates(c)	3/41( 7.3)	6/44( 13.6)	5/39( 12.8)	5/ 9( 55.6)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0002**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0140*			
Fisher Exact test(e)		P = 0.5000	P = 0.6297	P = 0.0332*
SITE : nasal cavity TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	7/50( 14.0)	9/50( 18.0)	0/50( 0.0)
Adjusted rates(b)	0.0	15.91	20.51	0.0
Terminal rates(c)	0/41( 0.0)	7/44( 15.9)	8/39( 20.5)	0/ 9( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.2473			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.2970			
Fisher Exact test(e)		P = 0.0062**	P = 0.0013**	P = N.C.
SITE : nasal cavity TUMOR : squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	29/50( 58.0)
Adjusted rates(b)	0.0	0.0	0.0	40.00
Terminal rates(c)	0/41( 0.0)	0/44( 0.0)	0/39( 0.0)	3/ 9( 33.3)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N.C.	P = N.C.	P < 0.0001**

STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : nasal cavity TUMOR : esthesioneuroepithelioma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	7/50( 14.0)
Adjusted rates(b)	0.0	0.0	0.0	6.67
Terminal rates(c)	0/41( 0.0)	0/44( 0.0)	0/39( 0.0)	0/ 9( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P = 0.0328* ?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N.C.	P = N.C.	P = 0.0062**
SITE : nasal cavity TUMOR : squamous cell papilloma, squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	30/50( 60.0)
Adjusted rates(b)	0.0	0.0	0.0	50.00
Terminal rates(c)	0/41( 0.0)	0/44( 0.0)	0/39( 0.0)	4/ 9( 44.4)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N.C.	P = N.C.	P < 0.0001**
SITE : nasal cavity TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	7/50( 14.0)	9/50( 18.0)	2/50( 4.0)
Adjusted rates(b)	0.0	15.91	20.51	11.11
Terminal rates(c)	0/41( 0.0)	7/44( 15.9)	8/39( 20.5)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0508 ?			
Prevalence method(d)	P = 0.0916			
Combined analysis(d)	P = 0.0320*			
Cochran-Armitage test(e)	P = 0.8453			
Fisher Exact test(e)		P = 0.0062**	P = 0.0013**	P = 0.2475

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : nasal cavity TUMOR : squamous cell carcinoma, adenocarcinoma, adenosquamous carcinoma, esthesioneuroepithelioma				
Tumor rate				
Overall rates(a)	0/50 ( 0.0)	0/50 ( 0.0)	1/50 ( 2.0)	38/50 ( 76.0)
Adjusted rates(b)	0.0	0.0	2.56	63.64
Terminal rates(c)	0/41 ( 0.0)	0/44 ( 0.0)	1/39 ( 2.6)	5/ 9 ( 55.6)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N.C.	P = 0.5000	P < 0.0001**
SITE : nasal cavity TUMOR : squamous cell papilloma, adenoma, squamous cell carcinoma, adenocarcinoma, adenosquamous carcinoma				
Tumor rate				
Overall rates(a)	0/50 ( 0.0)	7/50 ( 14.0)	10/50 ( 20.0)	33/50 ( 66.0)
Adjusted rates(b)	0.0	15.91	23.08	70.00
Terminal rates(c)	0/41 ( 0.0)	7/44 ( 15.9)	9/39 ( 23.1)	6/ 9 ( 66.7)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.0062**	P = 0.0006**	P < 0.0001**
SITE : lung TUMOR : bronchiolar-alveolar adenoma				
Tumor rate				
Overall rates(a)	2/50 ( 4.0)	4/50 ( 8.0)	2/50 ( 4.0)	0/50 ( 0.0)
Adjusted rates(b)	4.88	9.09	4.55	0.0
Terminal rates(c)	2/41 ( 4.9)	4/44 ( 9.1)	1/39 ( 2.6)	0/ 9 ( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.7960			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1105			
Fisher Exact test(e)		P = 0.3389	P = 0.6913	P = 0.2475

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : lung TUMOR : bronchiolar-alveolar adenoma, bronchiolar-alveolar carcinoma				
Tumor rate				
Overall rates(a)	2/50 ( 4.0)	4/50 ( 8.0)	4/50 ( 8.0)	1/50 ( 2.0)
Adjusted rates(b)	4.88	9.09	8.16	11.11
Terminal rates(c)	2/41 ( 4.9)	4/44 ( 9.1)	2/39 ( 5.1)	1/ 9 ( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.5456			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.3913			
Fisher Exact test(e)		P = 0.3389	P = 0.3389	P = 0.5000
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	4/50 ( 8.0)	6/50 ( 12.0)	3/50 ( 6.0)	4/50 ( 8.0)
Adjusted rates(b)	2.44	6.82	5.13	0.0
Terminal rates(c)	1/41 ( 2.4)	3/44 ( 6.8)	2/39 ( 5.1)	0/ 9 ( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0456*			
Prevalence method(d)	P = 0.5503			
Combined analysis(d)	P = 0.0865			
Cochran-Armitage test(e)	P = 0.7537			
Fisher Exact test(e)		P = 0.3703	P = 0.5000	P = 0.6425
SITE : pancreas TUMOR : islet cell adenoma				
Tumor rate				
Overall rates(a)	2/50 ( 4.0)	4/50 ( 8.0)	2/50 ( 4.0)	2/50 ( 4.0)
Adjusted rates(b)	4.88	9.09	5.13	11.11
Terminal rates(c)	2/41 ( 4.9)	4/44 ( 9.1)	2/39 ( 5.1)	1/ 9 ( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.1905			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.6944			
Fisher Exact test(e)		P = 0.3389	P = 0.6913	P = 0.6913



STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 7

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : pancreas TUMOR : islet cell adenoma, islet cell adenocarcinoma				
Tumor rate				
Overall rates(a)	3/50( 6.0)	5/50( 10.0)	4/50( 8.0)	4/50( 8.0)
Adjusted rates(b)	7.32	11.36	10.26	22.22
Terminal rates(c)	3/41( 7.3)	5/44( 11.4)	4/39( 10.3)	2/ 9( 22.2)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0406*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9126			
Fisher Exact test(e)		P = 0.3575	P = 0.5000	P = 0.5000
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	13/50( 26.0)	7/50( 14.0)	5/50( 10.0)	0/50( 0.0)
Adjusted rates(b)	25.00	11.36	10.26	0.0
Terminal rates(c)	10/41( 24.4)	5/44( 11.4)	4/39( 10.3)	0/ 9( 0.0)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.6722			
Prevalence method(d)	P = 0.9991			
Combined analysis(d)	P = 0.9990			
Cochran-Armitage test(e)	P = 0.0002**			
Fisher Exact test(e)		P = 0.1054	P = 0.0332*	P < 0.0001**
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	4/50( 8.0)	5/50( 10.0)	3/50( 6.0)	4/50( 8.0)
Adjusted rates(b)	9.76	11.36	6.98	33.33
Terminal rates(c)	4/41( 9.8)	5/44( 11.4)	2/39( 5.1)	3/ 9( 33.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0783			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8692			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.6425

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 8

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : thyroid TUMOR : C-cell carcinoma				
Tumor rate				
Overall rates(a)	1/50 ( 2.0)	1/50 ( 2.0)	3/50 ( 6.0)	1/50 ( 2.0)
Adjusted rates(b)	2.44	2.27	7.69	11.11
Terminal rates(c)	1/41 ( 2.4)	1/44 ( 2.3)	3/39 ( 7.7)	1/ 9 ( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0809			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.9826			
Fisher Exact test(e)		P = 0.7525	P = 0.3087	P = 0.7525
SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma				
Tumor rate				
Overall rates(a)	5/50 ( 10.0)	6/50 ( 12.0)	6/50 ( 12.0)	5/50 ( 10.0)
Adjusted rates(b)	12.20	13.64	13.95	44.44
Terminal rates(c)	5/41 ( 12.2)	6/44 ( 13.6)	5/39 ( 12.8)	4/ 9 ( 44.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0234*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8959			
Fisher Exact test(e)		P = 0.5000	P = 0.5000	P = 0.6297
SITE : adrenal gland TUMOR : pheochromocytoma				
Tumor rate				
Overall rates(a)	3/50 ( 6.0)	1/50 ( 2.0)	0/50 ( 0.0)	2/50 ( 4.0)
Adjusted rates(b)	7.32	2.13	0.0	11.11
Terminal rates(c)	3/41 ( 7.3)	0/44 ( 0.0)	0/39 ( 0.0)	1/ 9 ( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4240			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8443			
Fisher Exact test(e)		P = 0.3087	P = 0.1212	P = 0.5000

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 9

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : adrenal gland TUMOR : pheochromocytoma, pheochromocytoma:malignant				
Tumor rate				
Overall rates(a)	4/50( 8.0)	1/50( 2.0)	2/50( 4.0)	2/50( 4.0)
Adjusted rates(b)	9.76	2.13	4.44	11.11
Terminal rates(c)	4/41( 9.8)	0/44( 0.0)	1/39( 2.6)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.5013			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.6214			
Fisher Exact test(e)		P = 0.1811	P = 0.3389	P = 0.3389
SITE : testis TUMOR : interstitial cell tumor				
Tumor rate				
Overall rates(a)	40/50( 80.0)	46/50( 92.0)	47/50( 94.0)	36/50( 72.0)
Adjusted rates(b)	88.10	92.00	100.00	100.00
Terminal rates(c)	36/41( 87.8)	40/44( 90.9)	39/39(100.0)	9/ 9(100.0)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0031**			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.0538			
Fisher Exact test(e)		P = 0.0739	P = 0.0357*	P = 0.2415
SITE : mammary gland TUMOR : adenoma, fibroadenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	3/50( 6.0)	1/50( 2.0)
Adjusted rates(b)	0.0	0.0	7.69	11.11
Terminal rates(c)	0/41( 0.0)	0/44( 0.0)	3/39( 7.7)	1/ 9( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0200*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.3948			
Fisher Exact test(e)		P = N.C.	P = 0.1212	P = 0.5000

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 SEX : MALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 10

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : mammary gland TUMOR : adenoma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	1/50 ( 2.0)	0/50 ( 0.0)	3/50 ( 6.0)	1/50 ( 2.0)
Adjusted rates(b)	2.44	0.0	7.69	11.11
Terminal rates(c)	1/41 ( 2.4)	0/44 ( 0.0)	3/39 ( 7.7)	1/ 9 ( 11.1)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0551			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.7656			
Fisher Exact test(e)		P = 0.5000	P = 0.3087	P = 0.7525
SITE : peritoneum TUMOR : mesothelioma				
Tumor rate				
Overall rates(a)	1/50 ( 2.0)	7/50 ( 14.0)	16/50 ( 32.0)	14/50 ( 28.0)
Adjusted rates(b)	0.0	15.91	33.33	55.56
Terminal rates(c)	0/41 ( 0.0)	7/44 ( 15.9)	13/39 ( 33.3)	5/ 9 ( 55.6)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0005**			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.0015**			
Fisher Exact test(e)		P = 0.0297*	P < 0.0001**	P = 0.0002**

(HPT360A)

BA1S5

- (a): Number of tumor-bearing animals/number of animals examined at the site.  
 (b): Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.  
 (c): Observed tumor incidence at terminal kill.  
 (d): Beneath the control incidence are the P-values associated with the trend test.  
     Standard method : Death analysis  
     Prevalence method : Incidental tumor test  
     Combined analysis : Death analysis + Incidental tumor test  
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.  
 ? : The conditional probabilities of the largest and smallest possible outcomes cannot be estimated or this P-value is beyond the estimated P-value.  
 ----- : There is no data which should be statistical analysis.  
 Significant difference : \* :  $P \leq 0.05$     \*\* :  $P \leq 0.01$   
 N.C.:Statistical value cannot be calculated and was not significant.

**TABLE O2**

**NEOPLASTIC LESIONS-INCIDENCE  
AND STATISTICAL ANALYSIS : FEMALE**

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 1

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : subcutis TUMOR : fibroma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	2/50( 4.0)	2/50( 4.0)	3/50( 6.0)
Adjusted rates(b)	0.0	0.0	5.71	7.69
Terminal rates(c)	0/39( 0.0)	0/39( 0.0)	2/35( 5.7)	2/29( 6.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.7271			
Prevalence method(d)	P = 0.0126*			
Combined analysis(d)	P = 0.0608			
Cochran-Armitage test(e)	P = 0.1592			
Fisher Exact test(e)		P = 0.2475	P = 0.2475	P = 0.1212
SITE : nasal cavity TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	3/50( 6.0)	1/50( 2.0)
Adjusted rates(b)	0.0	7.69	5.71	3.45
Terminal rates(c)	0/39( 0.0)	3/39( 7.7)	2/35( 5.7)	1/29( 3.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.3519			
Prevalence method(d)	P = 0.3883			
Combined analysis(d)	P = 0.3809			
Cochran-Armitage test(e)	P = 0.9596			
Fisher Exact test(e)		P = 0.1212	P = 0.1212	P = 0.5000
SITE : nasal cavity TUMOR : squamous cell carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	10/50( 20.0)
Adjusted rates(b)	0.0	0.0	0.0	16.67
Terminal rates(c)	0/39( 0.0)	0/39( 0.0)	0/35( 0.0)	4/29( 13.8)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = N. C.	P = 0.0006**

STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : FEMALE

NEOPLASTIC LESIONS—INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 2

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : nasal cavity TUMOR : adenoma, squamous cell carcinoma, adenosquamous carcinoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	3/50( 6.0)	12/50( 24.0)
Adjusted rates(b)	0.0	7.69	5.71	20.00
Terminal rates(c)	0/39( 0.0)	3/39( 7.7)	2/35( 5.7)	5/29( 17.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0001**			
Prevalence method(d)	P = 0.0028**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = 0.1212	P = 0.1212	P = 0.0001**
SITE : nasal cavity TUMOR : squamous cell carcinoma, adenosquamous carcinoma, esthesioneuroepithelioma, hemangiosarcoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	0/50( 0.0)	0/50( 0.0)	14/50( 28.0)
Adjusted rates(b)	0.0	0.0	0.0	25.81
Terminal rates(c)	0/39( 0.0)	0/39( 0.0)	0/35( 0.0)	6/29( 20.7)
Statistical analysis				
Peto test				
Standard method(d)	P < 0.0001**?			
Prevalence method(d)	P < 0.0001**?			
Combined analysis(d)	P < 0.0001**?			
Cochran-Armitage test(e)	P < 0.0001**			
Fisher Exact test(e)		P = N. C.	P = N. C.	P < 0.0001**
SITE : spleen TUMOR : mononuclear cell leukemia				
Tumor rate				
Overall rates(a)	5/50( 10.0)	10/50( 20.0)	8/50( 16.0)	6/50( 12.0)
Adjusted rates(b)	5.13	15.38	5.71	3.45
Terminal rates(c)	2/39( 5.1)	6/39( 15.4)	2/35( 5.7)	1/29( 3.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1795			
Prevalence method(d)	P = 0.8143			
Combined analysis(d)	P = 0.4110			
Cochran-Armitage test(e)	P = 0.7875			
Fisher Exact test(e)		P = 0.1312	P = 0.2768	P = 0.5000

STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : FEMALE

NEOPLASTIC LESIONS—INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 3

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : pituitary gland TUMOR : adenoma				
Tumor rate				
Overall rates(a)	11/50 ( 22.0)	16/50 ( 32.0)	13/50 ( 26.0)	8/50 ( 16.0)
Adjusted rates(b)	16.67	35.00	26.32	15.91
Terminal rates(c)	6/39 ( 15.4)	13/39 ( 33.3)	8/35 ( 22.9)	3/29 ( 10.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.8246			
Prevalence method(d)	P = 0.6858			
Combined analysis(d)	P = 0.8159			
Cochran-Armitage test(e)	P = 0.1970			
Fisher Exact test(e)		P = 0.1839	P = 0.4076	P = 0.3055
SITE : pituitary gland TUMOR : adenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	12/50 ( 24.0)	18/50 ( 36.0)	13/50 ( 26.0)	8/50 ( 16.0)
Adjusted rates(b)	17.07	35.00	26.32	15.91
Terminal rates(c)	6/39 ( 15.4)	13/39 ( 33.3)	8/35 ( 22.9)	3/29 ( 10.3)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9242			
Prevalence method(d)	P = 0.7149			
Combined analysis(d)	P = 0.8951			
Cochran-Armitage test(e)	P = 0.1037			
Fisher Exact test(e)		P = 0.1376	P = 0.5000	P = 0.2270
SITE : thyroid TUMOR : C-cell adenoma				
Tumor rate				
Overall rates(a)	1/50 ( 2.0)	1/50 ( 2.0)	3/50 ( 6.0)	4/50 ( 8.0)
Adjusted rates(b)	2.44	2.56	8.57	11.43
Terminal rates(c)	0/39 ( 0.0)	1/39 ( 2.6)	3/35 ( 8.6)	3/29 ( 10.3)
Statistical analysis				
Peto test				
Standard method(d)	P = ———			
Prevalence method(d)	P = 0.0327*			
Combined analysis(d)	P = ———			
Cochran-Armitage test(e)	P = 0.0967			
Fisher Exact test(e)		P = 0.7525	P = 0.3087	P = 0.1811



STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 4

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : thyroid TUMOR : follicular adenoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	2/50( 4.0)	3/50( 6.0)	1/50( 2.0)
Adjusted rates(b)	2.56	4.88	6.98	3.45
Terminal rates(c)	1/39( 2.6)	1/39( 2.6)	2/35( 5.7)	1/29( 3.4)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.4757			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.8316			
Fisher Exact test(e)		P = 0.5000	P = 0.3087	P = 0.7525
SITE : thyroid TUMOR : C-cell adenoma, C-cell carcinoma				
Tumor rate				
Overall rates(a)	1/50( 2.0)	1/50( 2.0)	5/50( 10.0)	4/50( 8.0)
Adjusted rates(b)	2.44	2.56	14.29	11.43
Terminal rates(c)	0/39( 0.0)	1/39( 2.6)	5/35( 14.3)	3/29( 10.3)
Statistical analysis				
Peto test				
Standard method(d)	P = -----			
Prevalence method(d)	P = 0.0396*			
Combined analysis(d)	P = -----			
Cochran-Armitage test(e)	P = 0.1268			
Fisher Exact test(e)		P = 0.7525	P = 0.1022	P = 0.1811
SITE : uterus TUMOR : endometrial stromal polyp				
Tumor rate				
Overall rates(a)	6/50( 12.0)	10/50( 20.0)	7/50( 14.0)	7/50( 14.0)
Adjusted rates(b)	9.52	21.28	20.00	17.24
Terminal rates(c)	3/39( 7.7)	8/39( 20.5)	7/35( 20.0)	5/29( 17.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.9637			
Prevalence method(d)	P = 0.2895			
Combined analysis(d)	P = 0.4454			
Cochran-Armitage test(e)	P = 0.8757			
Fisher Exact test(e)		P = 0.2070	P = 0.5000	P = 0.5000

STUDY No. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : FEMALE

NEOPLASTIC LESIONS-INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 5

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : uterus TUMOR : endometrial stromal sarcoma				
Tumor rate				
Overall rates(a)	1/50 ( 2.0)	1/50 ( 2.0)	1/50 ( 2.0)	5/50 ( 10.0)
Adjusted rates(b)	2.56	0.0	0.0	6.90
Terminal rates(c)	1/39 ( 2.6)	0/39 ( 0.0)	0/35 ( 0.0)	2/29 ( 6.9)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0286*			
Prevalence method(d)	P = 0.0809			
Combined analysis(d)	P = 0.0083**			
Cochran-Armitage test(e)	P = 0.0205*			
Fisher Exact test(e)		P = 0.7525	P = 0.7525	P = 0.1022
SITE : mammary gland TUMOR : fibroadenoma				
Tumor rate				
Overall rates(a)	7/50 ( 14.0)	14/50 ( 28.0)	14/50 ( 28.0)	23/50 ( 46.0)
Adjusted rates(b)	16.28	31.71	36.11	57.89
Terminal rates(c)	6/39 ( 15.4)	12/39 ( 30.8)	12/35 ( 34.3)	16/29 ( 55.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1182			
Prevalence method(d)	P < 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.0007**			
Fisher Exact test(e)		P = 0.0698	P = 0.0698	P = 0.0004**
SITE : mammary gland TUMOR : adenoma, fibroadenoma, adenocarcinoma				
Tumor rate				
Overall rates(a)	7/50 ( 14.0)	15/50 ( 30.0)	15/50 ( 30.0)	23/50 ( 46.0)
Adjusted rates(b)	16.28	31.71	38.46	57.89
Terminal rates(c)	6/39 ( 15.4)	12/39 ( 30.8)	12/35 ( 34.3)	16/29 ( 55.2)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.1182			
Prevalence method(d)	P = 0.0001**			
Combined analysis(d)	P < 0.0001**			
Cochran-Armitage test(e)	P = 0.0012**			
Fisher Exact test(e)		P = 0.0448*	P = 0.0448*	P = 0.0004**

STUDY No. : 0794  
 ANIMAL : RAT F344/DuCrI CrIj[F344/DuCrj]  
 SEX : FEMALE

NEOPLASTIC LESIONS--INCIDENCE AND STATISTICAL ANALYSIS

PAGE : 6

Group Name	Control	3.2ppm	8ppm	20ppm
SITE : preputial/clitoral gland				
TUMOR : adenoma				
Tumor rate				
Overall rates(a)	0/50( 0.0)	3/50( 6.0)	3/50( 6.0)	4/50( 8.0)
Adjusted rates(b)	0.0	7.69	5.71	4.35
Terminal rates(c)	0/39( 0.0)	3/39( 7.7)	2/35( 5.7)	1/29( 3.4)
Statistical analysis				
Peto test				
Standard method(d)	P = 0.0346*			
Prevalence method(d)	P = 0.2199			
Combined analysis(d)	P = 0.0467*			
Cochran-Armitage test(e)	P = 0.1284			
Fisher Exact test(e)		P = 0.1212	P = 0.1212	P = 0.0587

(HPT360A)

BAIS5

- (a): Number of tumor-bearing animals/number of animals examined at the site.  
 (b): Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality.  
 (c): Observed tumor incidence at terminal kill.  
 (d): Beneath the control incidence are the P-values associated with the trend test.  
     Standard method : Death analysis  
     Prevalence method : Incidental tumor test  
     Combined analysis : Death analysis + Incidental tumor test  
 (e): The Cochran-Armitage and Fisher exact test compare directly the overall incidence rates.  
 ? : The conditional probabilities of the largest and smallest possible outcomes cannot be estimated or this P-value is beyond the estimated P-value.  
 ----- : There is no data which should be statistical analysis.  
 Significant difference ; \* :  $P \leq 0.05$     \*\* :  $P \leq 0.01$   
 N.C. : Statistical value cannot be calculated and was not significant.

**TABLE P1**

**HISTOPATHOLOGICAL FINDINGS :**

**METASTASIS OF TUMOR :**

**MALE**

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
 REPORT TYPE : A1  
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 1

		Group Name	Control	3.2ppm	8ppm	20ppm
		No. of Animals on Study	50	50	50	50
Organ	Findings					
{Respiratory system}						
nasal cavit			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	0	0	0
nasopharynx			<50>	<50>	<50>	<50>
	metastasis: nasal tumor		0	0	0	4
lung			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	5	2	3
	metastasis: adrenal tumor		0	0	1	0
	metastasis: subcutis tumor		0	0	1	0
	metastasis: bone tumor		0	0	1	0
	metastasis: Zymbal gland tumor		1	0	0	0
	metastasis: skin/appendage tumor		0	0	1	0
{Hematopoietic system}						
bone marrow			<50>	<50>	<50>	<50>
	leukemic cell infiltration		4	3	2	4
lymph node			<50>	<50>	<50>	<50>
	leukemic cell infiltration		2	3	2	1
	metastasis: bone tumor		0	0	1	0
	metastasis: skin/appendage tumor		0	0	1	0
thymus			<50>	<50>	<50>	<50>
	leukemic cell infiltration		0	0	1	0
spleen			<50>	<50>	<50>	<50>
	metastasis: skin/appendage tumor		0	0	1	0

< a > a : Number of animals examined at the site  
 b b : Number of animals with lesion

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCrI CrIj [F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 2

Group Name No. of Animals on Study		Control 50	3. 2ppm 50	8ppm 50	20ppm 50
Organ	Findings				
{Circulatory system}					
heart	leukemic cell infiltration	<50> 1	<50> 2	<50> 0	<50> 1
	metastasis:subcutis tumor	0	0	1	0
{Digestive system}					
salivary gl	leukemic cell infiltration	<50> 1	<50> 0	<50> 0	<50> 0
	stomach	<50> 0	<50> 1	<50> 0	<50> 0
liver	leukemic cell infiltration	<50> 4	<50> 5	<50> 2	<50> 4
	metastasis:bone tumor	0	0	1	0
pancreas	leukemic cell infiltration	<50> 1	<50> 1	<50> 0	<50> 0
	metastasis:subcutis tumor	0	0	0	1
	metastasis:bone tumor	0	0	1	0
{Urinary system}					
kidney	leukemic cell infiltration	<50> 0	<50> 2	<50> 0	<50> 0
{Endocrine system}					
pituitary	leukemic cell infiltration	<50> 1	<50> 1	<50> 0	<50> 1

< a > a : Number of animals examined at the site  
b b : Number of animals with lesion

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1J[F344/DuCrJ]  
REPORT TYPE : A1  
SEX : MALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study	Control 50	3. 2ppm 50	8ppm 50	20ppm 50
{Endocrine system}						
thyroid	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
adrenal	leukemic cell infiltration		<50> 1	<50> 3	<50> 2	<50> 2
{Nervous system}						
brain	leukemic cell infiltration		<50> 1	<50> 3	<50> 1	<50> 1
	metastasis: nasal tumor		0	0	0	5
spinal cord	leukemic cell infiltration		<50> 0	<50> 1	<50> 0	<50> 2
{Musculoskeletal system}						
muscle	metastasis: peritoneum tumor		<50> 0	<50> 0	<50> 0	<50> 1
	metastasis: subcutis tumor		0	0	1	0
{Body cavities}						
pleura	metastasis: peritoneum tumor		<50> 0	<50> 1	<50> 0	<50> 0
	metastasis: lung tumor		0	0	0	1
peritoneum	metastasis: bone tumor		<50> 0	<50> 0	<50> 1	<50> 0

< a > a : Number of animals examined at the site  
b b : Number of animals with lesion

**TABLE P2**

**HISTOPATHOLOGICAL FINDINGS :**

**METASTASIS OF TUMOR :**

**FEMALE**



STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 4

		Group Name	Control	3.2ppm	8ppm	20ppm
		No. of Animals on Study	50	50	50	50
Organ	Findings					
{Integumentary system/appandage}						
subcutis	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
{Respiratory system}						
nasal cavit	leukemic cell infiltration		<50> 3	<50> 0	<50> 0	<50> 0
nasopharynx	leukemic cell infiltration		<50> 1	<50> 0	<50> 0	<50> 0
	metastasis:nasal tumor		0	0	0	1
larynx	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
lung	leukemic cell infiltration		<50> 3	<50> 7	<50> 8	<50> 5
	metastasis:adrenal tumor		1	0	0	0
	metastasis:pleura tumor		0	0	0	1
{Hematopoietic system}						
bone marrow	leukemic cell infiltration		<50> 3	<50> 4	<50> 4	<50> 5
	metastasis:pleura tumor		0	0	0	1
lymph node	leukemic cell infiltration		<50> 1	<50> 1	<50> 2	<50> 2
thymus	metastasis:pleura tumor		<50> 0	<50> 0	<50> 0	<50> 1

< a > a : Number of animals examined at the site  
 b b : Number of animals with lesion

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study	Control 50	3.2ppm 50	8ppm 50	20ppm 50
{Circulatory system}						
heart	leukemic cell infiltration		<50> 1	<50> 2	<50> 2	<50> 2
{Digestive system}						
large intes	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
	metastasis:uterus tumor		0	0	0	1
liver	leukemic cell infiltration		<50> 5	<50> 9	<50> 7	<50> 5
	metastasis:pleura tumor		0	0	0	1
pancreas	leukemic cell infiltration		<50> 0	<50> 0	<50> 2	<50> 0
{Urinary system}						
kidney	leukemic cell infiltration		<50> 2	<50> 0	<50> 1	<50> 3
urin bladd	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
	metastasis:uterus tumor		0	0	0	1
{Endocrine system}						
pituitary	leukemic cell infiltration		<50> 0	<50> 1	<50> 1	<50> 0
< a > b : Number of animals with lesion						

STUDY NO. : 0794  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
 ALL ANIMALS (0-105W)

PAGE : 6

Group Name No. of Animals on Study		Control 50	3. 2ppm 50	8ppm 50	20ppm 50
Organ	Findings				
{Endocrine system}					
thyroid	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0
adrenal	leukemic cell infiltration	<50> 3	<50> 4	<50> 5	<50> 5
{Reproductive system}					
ovary	leukemic cell infiltration	<50> 4	<50> 2	<50> 5	<50> 3
	metastasis:pleura tumor	0	0	0	1
uterus	leukemic cell infiltration	<50> 1	<50> 0	<50> 2	<50> 0
vagina	leukemic cell infiltration	<50> 1	<50> 0	<50> 1	<50> 0
	metastasis:uterus tumor	0	1	1	2
{Nervous system}					
brain	leukemic cell infiltration	<50> 1	<50> 0	<50> 1	<50> 2
	metastasis:pituitary tumor	2	2	0	0
	metastasis:nasal tumor	0	0	0	1
spinal cord	leukemic cell infiltration	<50> 1	<50> 0	<50> 0	<50> 1
{Special sense organs/appendage}					
Harder gl	leukemic cell infiltration	<50> 0	<50> 0	<50> 1	<50> 0

< a > a : Number of animals examined at the site  
 b b : Number of animals with lesion

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS : METASTASIS OF TUMOR (SUMMARY)  
ALL ANIMALS (0-105W)

PAGE : 7

		Group Name	Control	3.2ppm	8ppm	20ppm
Organ	Findings	No. of Animals on Study	50	50	50	50
{Musculoskeletal system}						
muscle	leukemic cell infiltration		<50> 0	<50> 0	<50> 1	<50> 0
< a >	a : Number of animals examined at the site					
b	b : Number of animals with lesion					

(JPT150)

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TABLE Q1

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC  
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER :  
F344/DuCr1Cr1j MALE RATS

TABLE Q1 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS  
IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrIjCrIj MALE

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Skin	3048			
Basal cell epithelioma <sup>1)</sup>		2	0.1	0 - 2
Basal cell carcinoma <sup>2)</sup>		2	0.1	0 - 2
1) + 2)		4	0.1	0 - 2
Keratoacanthoma		100	3.3	0 - 14
Subcutis	3048			
Fibroma		258	8.5	2 - 20
Nasal cavity	3048			
Adenoma		3	0.1	0 - 2
Adenocarcinoma		0	0.0	0 - 0
Adenosquamous carcinoma		0	0.0	0 - 0
Squamous cell papilloma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Esthesioneuroepithelioma		0	0.0	0 - 0
Spleen	3048			
Mononuclear cell leukemia		345	11.3	2 - 22
Pancreas	3047			
Islet cell adenoma <sup>1)</sup>		217	7.1	0 - 14
Islet cell adenocarcinoma <sup>2)</sup>		17	0.6	0 - 4
1) + 2)		234	7.7	0 - 14
Thyroid	3041			
C-cell adenoma <sup>1)</sup>		461	15.2	2 - 36
C-cell carcinoma <sup>2)</sup>		72	2.4	0 - 12
1) + 2)		532	17.5	4 - 38
Mammary	3048			
Adenoma <sup>1)</sup>		16	0.5	0 - 4
Fibroadenoma <sup>2)</sup>		55	1.8	0 - 6
1) + 2)		71	2.3	0 - 8
Testis	3047			
Interstitial cell tumor		2508	82.3	56 - 98
Peritoneum	3046			
Mesothelioma		76	2.5	0 - 8

61 carcinogenicity studies examined in Japan Bioassay Research Center were used.

Study No. : 0043, 0059, 0061, 0063, 0065, 0067, 0095, 0104, 0115, 0130, 0141, 0158, 0162, 0189, 0205, 0210, 0224, 0242, 0246, 0267, 0269, 0278, 0284, 0288, 0294, 0296, 0318, 0328, 0342, 0347, 0365, 0371, 0396, 0399, 0401, 0407, 0417, 0421, 0437, 0448, 0457, 0461, 0497, 0535, 0560, 0579, 0581, 0610, 0612, 0641, 0667, 0675, 0684, 0686, 0691, 0704, 0711, 0731, 0739, 0753, 0774

TABLE Q2

HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC  
LESIONS IN JAPAN BIOASSAY RESEARCH CENTER :  
F344/DuCr1Cr1j FEMALE RATS

TABLE Q2 HISTORICAL CONTROL DATA OF SELECTED NEOPLASTIC LESIONS  
IN JAPAN BIOASSAY RESEARCH CENTER : F344/DuCrIcrlj FEMALE

Organs Tumors	No. of animals examined	No. of animals bearing tumor	Incidence (%)	Min. - Max. (%)
Subcutis	2847			
Fibroma		31	1.1	0 - 8
Nasal cavity	2847			
Adenoma		2	0.1	0 - 2
Adenosquamous carcinoma		0	0.0	0 - 0
Squamous cell carcinoma		0	0.0	0 - 0
Esthesioneuroepithelioma		0	0.0	0 - 0
Hemangiosarcoma		0	0.0	0 - 0
Thyroid	2838			
C-cell adenoma		296	10.4	0 - 20
Uterus	2846			
Endometrial stromal sarcoma		54	1.9	0 - 8
Mammary gland	2847			
Adenoma <sup>1)</sup>		60	2.1	0 - 18
Fibroadenoma <sup>2)</sup>		329	11.6	0 - 28
Adenocarcinoma <sup>3)</sup>		35	1.2	0 - 6
1) + 2) + 3)		416	14.6	4 - 30
Clitoral gland	2847			
Adenoma		85	3.0	0 - 10

57 carcinogenicity studies examined in Japan Bioassay Research Center were used.

Study No. : 0043, 0059, 0061, 0063, 0065, 0067, 0095, 0104, 0115, 0130, 0141, 0158, 0162, 0189, 0205, 0210, 0224, 0242, 0246, 0267, 0269, 0278, 0284, 0296, 0303, 0318, 0328, 0342, 0347, 0365, 0371, 0399, 0401, 0417, 0421, 0437, 0448, 0457, 0461, 0497, 0535, 0560, 0579, 0610, 0612, 0641, 0667, 0675, 0684, 0686, 0691, 0704, 0711, 0731, 0739, 0753, 0774



**TABLE R1**

**CAUSE OF DEATH : MALE**

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : MALE

COUSE OF DEATH (SUMMARY)  
(0-105W)

PAGE : 1

Group Name	Control	3.2ppm	8ppm	20ppm
Number of Dead and Moribund Animal	9	6	11	41
no microscop confirm	0	0	1	0
chronic nephropathy	1	0	0	0
nasal lesion	0	0	0	1
tumor d:leukemia	3	3	1	4
tumor d:skin/app	0	1	1	0
tumor d:subcutis	1	0	2	0
tumor d:nasal cavit	0	0	0	31
tumor d:pituitary	1	2	1	0
tumor d:brain	1	0	1	0
tumor d:bone	0	0	1	0
tumor d:peritoneum	2	0	3	5

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**TABLE R2**

**CAUSE OF DEATH : FEMALE**

STUDY NO. : 0794  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
SEX : FEMALE

COUSE OF DEATH (SUMMARY)  
(0-105W)

PAGE : 2

Group Name	Control	3.2ppm	8ppm	20ppm
Number of Dead and Moribund Animal	11	11	15	21
deglutition disorder	1	0	1	0
tumor d:leukemia	3	4	6	5
tumor d:subcutis	0	2	1	0
tumor d:nasal cavit	0	0	1	6
tumor d:tongue	0	0	0	1
tumor d:pituitary	5	4	3	1
tumor d:ovary	0	0	0	1
tumor d:uterus	2	1	1	3
tumor d:mammary gl	0	0	0	1
tumor d:prep/cli gl	0	0	1	2
tumor d:Zymbal gl	0	0	0	1
tumor d:peritoneum	0	0	1	0

(B10120)

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