

クロロホルムのラット及びマウスを用いた  
吸入によるがん原性試験報告書

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**TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE INHALATION STUDIES OF CHLOROFORM****Two-Year Study**

## &lt;Method of Administration&gt;

Inhalation

## &lt;Number of Group&gt;

Male 4, Female 4.

## &lt;Size of Study Group&gt;

50 males and 50 females of each group

## &lt;Animals&gt;

Strain and Species : F344/DuCrj(Fischer)rat and Crj:BDF<sub>1</sub> mouse

Animal Source : Charles River Japan, Inc.

During of Time Held Before Study : 2 weeks

Age When Placed on Study : 6 week old

Age When Killed : 110 week old~111 week old

## &lt;Chamber Concentration&gt;

Rat---0,10,30,90 ppm chloroform by inhalation

mouse--0, 5, 30(5/2wk, 10/2wk, 30/100wk),90(5/2wk, 10/2wk, 30/2wk, 90/98wk)ppm

chloroform by inhalation

## &lt;Date of First Exposure&gt;

Rat---3/30/1989 mouse---9/22/1989

## &lt;Date of Last Exposure&gt;

Rat---3/27/1991 mouse---9/19/1991

## &lt;Duration of Dosing&gt;

6 hr/day, 5 days/week, for 104 weeks

## &lt;Animal Maintenance&gt;

Feed : CRF-1; Oriental Yeast Co., Ltd., Sterilized by  $\gamma$ -ray.

Available ad libitum

Water : Sterilized by ultraviolet rays; Automatic Watering system.

Available ad libitum

Animals per Cage : Single; stainless steel wire

Animals Chambers Room Environment : Barrier system

Temperature :  $24 \pm 2^\circ\text{C}$  ; Humidity :  $55 \pm 10\%$  ;

Fluorescent light : 12hr/day ; 15~17 room air changes /hr

Inhalation Chamber Environment

Temperature :  $24 \pm 2^\circ\text{C}$  ; Humidity :  $55 \pm 10\%$  ;

Fluorescent light : 12hr/day ; 15~17 chamber air changes /hr

## &lt;Type and Frequency of Observation&gt;

Clinical Sign : Observed 1 day

Body Weight : Weighed 1 / week for 14-week; Weighed 1 / 2weeks thereafter

&lt;Food Consumption&gt; : Weighed 1 / week for 14-week; Weighed 1 / 4weeks thereafter

**TABLE 1      EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE INHALATION STUDIES OF CHLOROFORM**  
(Continued)

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Two-Year Study

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<Hematology>

Red blood cell(RBC), Hemoglobin, Hematocrit, Mean corpuscular volume(MCV)  
Mean corpuscular hemoglobin(MCH), mean corpuscular hemoglobin concentration,  
Platelete, White blood cell(WBC), Differential WBC

<Blood Biochemistry>

Total Protein, Albumin, A/G ratio, Total bilirubin, Glucose, Total cholesterol,  
Phospholipid<rat only>, Glutamic oxaloacetic transaminase(GOT),  
Glutamic pyruvic transaminase(GPT), Lactate dehydrogenase(LDH)  
Alkaline phosphatase(ALP)<rat only>,  $\gamma$ -Glutamyl transpeptidase(G-GTP),  
Creatine phosphokinase(CPK), Urea nitrogen, Creatinine<rat only>,  
Sodium, Potassium, Chloride, Calcium, Inorganic phosphorus.

<Urinalysis>

pH, Protein, Glucose, Ketone body, Bilirubin<rat only>, Occult blood, Urobilinogen

<Necropsy>

Necropsy performed on all animals.

<Organ Weight>

Organ weight measurement performed on schedule sacrificed animals.  
The following organs were weighed : brain, lung, liver, spleen, heart, kidney,  
adrenal, testis, ovary.

<Histopathologic Examination>

Histopathologic examination performed on all animals.  
The following organs were examined : skin, nasal cavity, nasopharynx, larynx, trachea  
lung, bone marrow, lymph node, thymus, spleen, heart, tongue, salivary gland, esophagus  
stomach, small intestine, large intestine, liver, pancreas, kidney, urinary bladder,  
pituitary, thyroid, adrenal, testis, epididymas, seminal vesicle, prostate, ovary,  
uterus, vagina, mammary gland, brain, spinal cord, peripheral nerve, eye, Harderian gland  
muscle, bone.

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TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE RAT  
(TWO-YEAR STUDY)

Week on Study	Control		10 ppm		30 ppm		90 ppm				
	Au.Wt. (g)	No.of Surviv. (50)	Au.Wt. (g)	% of cont. (50)	No.of Surviv. (50)	Au.Wt. (g)	% of cont. (50)	No.of Surviv. (50)	Au.Wt. (g)	% of cont. (50)	No.of Surviv. (50)
0	130 (50)	50/50	130 (50)	100	50/50	130 (50)	100	50/50	130 (50)	100	50/50
1	162 (50)	50/50	154 (50)	95	50/50	155 (50)	96	50/50	150 (50)	93	50/50
2	192 (50)	50/50	179 (50)	93	50/50	178 (50)	93	50/50	172 (50)	90	50/50
3	218 (50)	50/50	204 (50)	94	50/50	200 (50)	92	50/50	193 (50)	89	50/50
4	242 (50)	50/50	227 (50)	94	50/50	221 (50)	91	50/50	212 (50)	88	50/50
5	263 (50)	50/50	247 (50)	94	50/50	241 (50)	92	50/50	230 (50)	87	50/50
6	280 (50)	50/50	262 (50)	94	50/50	256 (50)	91	50/50	244 (50)	87	50/50
7	298 (50)	50/50	278 (50)	93	50/50	270 (50)	91	50/50	257 (50)	86	50/50
8	312 (50)	50/50	291 (50)	93	50/50	282 (50)	90	50/50	267 (50)	86	50/50
9	327 (50)	50/50	305 (50)	93	50/50	296 (50)	91	50/50	279 (50)	85	50/50
10	337 (50)	50/50	314 (50)	93	50/50	305 (50)	91	50/50	286 (50)	85	50/50
11	347 (50)	50/50	324 (50)	93	50/50	314 (50)	90	50/50	294 (50)	85	50/50
12	357 (50)	50/50	333 (50)	93	50/50	323 (50)	90	50/50	302 (50)	85	50/50
13	366 (50)	50/50	343 (50)	94	50/50	331 (50)	90	50/50	309 (50)	84	50/50
14	374 (50)	50/50	349 (50)	93	50/50	340 (50)	91	50/50	315 (50)	84	50/50
16	387 (50)	50/50	362 (50)	94	50/50	352 (50)	91	50/50	327 (50)	84	50/50
18	397 (50)	50/50	369 (50)	93	50/50	364 (50)	92	50/50	337 (50)	85	50/50
20	407 (50)	50/50	376 (50)	92	50/50	370 (50)	91	50/50	339 (50)	83	50/50
22	419 (50)	50/50	385 (50)	92	50/50	379 (50)	90	50/50	345 (50)	82	50/50
24	427 (50)	50/50	395 (50)	93	50/50	388 (50)	91	50/50	352 (50)	82	50/50
26	437 (50)	50/50	405 (50)	93	50/50	398 (50)	91	50/50	363 (50)	83	50/50
28	445 (50)	50/50	412 (50)	93	50/50	406 (50)	91	50/50	371 (50)	83	50/50
30	451 (50)	50/50	417 (50)	92	50/50	411 (50)	91	50/50	377 (50)	84	50/50
32	460 (50)	50/50	425 (50)	92	50/50	419 (50)	91	50/50	384 (50)	83	50/50
34	465 (50)	50/50	430 (50)	92	50/50	424 (50)	91	50/50	391 (50)	84	50/50
36	470 (50)	50/50	435 (50)	93	50/50	428 (50)	91	50/50	395 (50)	84	50/50
38	472 (50)	50/50	438 (50)	93	50/50	432 (50)	92	50/50	395 (50)	84	50/50
40	475 (50)	50/50	443 (50)	93	50/50	440 (50)	93	50/50	406 (50)	85	50/50
42	482 (48)	48/50	447 (50)	93	50/50	443 (50)	92	50/50	409 (50)	85	50/50
44	488 (48)	48/50	452 (50)	93	50/50	448 (50)	92	50/50	414 (50)	85	50/50
46	491 (48)	48/50	457 (50)	93	50/50	450 (50)	92	50/50	417 (50)	85	50/50
48	491 (48)	48/50	459 (50)	93	50/50	454 (50)	92	50/50	418 (50)	85	50/50
50	494 (47)	47/50	462 (50)	94	50/50	458 (50)	93	50/50	419 (50)	85	50/50
52	501 (46)	46/50	465 (50)	93	50/50	460 (50)	92	50/50	422 (50)	84	50/50
54	502 (46)	46/50	468 (50)	93	50/50	462 (50)	92	50/50	424 (50)	84	50/50
56	506 (46)	46/50	471 (50)	93	50/50	464 (49)	92	49/50	424 (50)	84	50/50
58	510 (46)	46/50	475 (50)	93	50/50	468 (49)	92	49/50	434 (49)	85	49/50
60	511 (46)	46/50	477 (50)	93	50/50	469 (49)	92	49/50	433 (49)	85	49/50
62	514 (45)	45/50	479 (50)	93	50/50	472 (49)	92	49/50	434 (49)	84	49/50
64	516 (45)	45/50	482 (50)	93	50/50	475 (49)	92	49/50	438 (49)	85	49/50
66	519 (45)	45/50	483 (49)	93	49/50	475 (49)	92	49/50	435 (49)	84	49/50
68	520 (45)	45/50	485 (49)	93	49/50	477 (49)	92	49/50	441 (49)	85	49/50
70	519 (45)	45/50	483 (49)	93	49/50	475 (49)	92	49/50	441 (49)	85	49/50
72	517 (45)	45/50	482 (49)	93	49/50	476 (48)	92	48/50	441 (49)	85	49/50
74	518 (45)	45/50	481 (49)	93	49/50	475 (48)	92	48/50	441 (48)	85	48/50
76	518 (45)	45/50	479 (48)	92	48/50	474 (48)	92	48/50	441 (48)	85	48/50
78	516 (45)	45/50	479 (48)	93	48/50	472 (48)	91	47/50	443 (48)	86	48/50
80	516 (44)	44/50	486 (47)	94	47/50	481 (46)	93	46/50	445 (48)	86	48/50
82	515 (44)	44/50	482 (47)	94	47/50	483 (45)	94	45/50	443 (48)	86	48/50
84	510 (44)	44/50	486 (46)	95	46/50	483 (45)	95	45/50	438 (48)	86	48/50
86	507 (43)	43/50	485 (45)	96	45/50	481 (45)	95	45/50	445 (45)	88	45/50
88	500 (43)	43/50	481 (45)	96	45/50	474 (45)	95	45/50	440 (45)	88	45/50
90	494 (42)	42/50	480 (45)	97	45/50	471 (44)	95	44/50	437 (44)	88	44/50
92	487 (42)	42/50	476 (45)	98	44/50	474 (41)	97	41/50	439 (44)	90	44/50
94	486 (40)	40/50	468 (44)	96	44/50	470 (41)	97	41/50	436 (44)	90	44/50
96	474 (39)	39/50	470 (43)	99	43/50	472 (40)	100	40/50	431 (44)	91	44/50
98	462 (38)	38/50	462 (43)	100	43/50	470 (40)	102	40/50	432 (42)	94	42/50
100	454 (34)	33/50	461 (41)	102	41/50	470 (39)	104	39/50	427 (42)	94	42/50
102	450 (29)	28/50	459 (39)	102	39/50	466 (37)	104	37/50	421 (41)	94	41/50
104	449 (27)	27/50	454 (39)	101	39/50	463 (37)	103	37/50	415 (39)	92	38/50

&lt; &gt;:No.of effective animals,( ) :No.of measured animals

Au.Wt.:g

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE RAT  
(TWO-YEAR STUDY)

Week on Study	Control			10 ppm			30 ppm			90 ppm		
	Au.Wt.	No. of Surviv. <50>		Au.Wt.	% of cont. <50>	No. of Surviv.	Au.Wt.	% of cont. <50>	No. of Surviv.	Au.Wt.	% of cont. <49>	No. of Surviv.
0	99 (50)	50/50		99 (50)	100	50/50	99 (50)	100	50/50	99 (49)	100	50/50
1	116 (50)	50/50		112 (50)	97	50/50	110 (50)	95	50/50	107 (49)	92	50/50
2	131 (50)	50/50		124 (50)	95	50/50	121 (50)	92	50/50	117 (49)	89	50/50
3	143 (50)	50/50		136 (50)	95	50/50	131 (50)	92	50/50	127 (49)	89	50/50
4	154 (50)	50/50		146 (50)	95	50/50	141 (50)	92	50/50	135 (49)	88	50/50
5	163 (50)	50/50		156 (50)	96	50/50	152 (50)	93	50/50	147 (49)	90	50/50
6	173 (50)	50/50		163 (50)	94	50/50	158 (50)	91	50/50	153 (49)	88	50/50
7	180 (50)	50/50		170 (50)	94	50/50	164 (50)	91	50/50	160 (49)	89	50/50
8	185 (50)	50/50		175 (50)	95	50/50	169 (50)	91	50/50	163 (49)	88	50/50
9	192 (50)	50/50		183 (50)	95	50/50	175 (50)	91	50/50	170 (49)	89	50/50
10	197 (50)	50/50		187 (50)	95	50/50	180 (50)	91	50/50	172 (49)	87	50/50
11	201 (50)	50/50		193 (50)	96	50/50	185 (50)	92	50/50	176 (49)	88	50/50
12	205 (50)	50/50		198 (50)	97	50/50	190 (50)	93	50/50	179 (49)	87	50/50
13	210 (50)	50/50		202 (50)	96	50/50	193 (50)	92	50/50	182 (49)	87	50/50
14	213 (50)	50/50		205 (50)	96	50/50	197 (50)	92	50/50	183 (49)	86	50/50
16	219 (50)	50/50		213 (50)	97	50/50	203 (50)	93	50/50	189 (49)	86	50/50
18	223 (50)	50/50		218 (50)	98	50/50	209 (50)	94	50/50	195 (49)	87	50/50
20	227 (50)	50/50		221 (50)	97	50/50	212 (50)	93	50/50	195 (49)	86	50/50
22	233 (50)	50/50		228 (50)	98	50/50	217 (50)	93	50/50	198 (49)	85	50/50
24	235 (50)	50/50		230 (50)	98	50/50	221 (50)	94	50/50	199 (49)	85	50/50
26	239 (50)	50/50		234 (50)	98	50/50	225 (50)	94	50/50	203 (49)	85	50/50
28	242 (50)	50/50		238 (50)	98	50/50	229 (50)	95	50/50	208 (49)	86	50/50
30	245 (50)	50/50		239 (50)	98	50/50	231 (50)	94	50/50	210 (49)	86	49/49
32	250 (50)	50/50		244 (50)	98	50/50	237 (50)	95	50/50	210 (49)	84	49/49
34	253 (50)	50/50		249 (50)	98	50/50	240 (50)	95	50/50	214 (49)	85	49/49
36	255 (50)	50/50		251 (50)	98	50/50	242 (50)	95	50/50	218 (49)	85	49/49
38	258 (50)	50/50		253 (50)	98	50/50	245 (50)	95	50/50	220 (49)	85	49/49
40	261 (50)	50/50		259 (50)	99	50/50	251 (50)	96	50/50	226 (49)	87	49/49
42	264 (50)	50/50		261 (50)	99	50/50	253 (50)	96	50/50	228 (49)	86	49/49
44	269 (50)	50/50		266 (50)	99	50/50	258 (50)	96	50/50	231 (49)	86	49/49
46	271 (50)	50/50		269 (50)	99	50/50	261 (50)	96	50/50	234 (49)	86	49/49
48	273 (50)	50/50		271 (50)	99	50/50	264 (50)	97	50/50	235 (49)	86	49/49
50	276 (50)	50/50		275 (50)	100	50/50	266 (50)	96	50/50	237 (49)	86	49/49
52	280 (50)	50/50		279 (50)	100	50/50	269 (50)	96	50/50	237 (49)	85	48/49
54	282 (50)	50/50		283 (50)	100	50/50	273 (50)	97	50/50	241 (48)	85	48/49
56	286 (50)	50/50		290 (50)	101	50/50	276 (50)	97	50/50	240 (48)	84	48/49
58	292 (50)	50/50		294 (50)	101	50/50	279 (50)	96	50/50	246 (48)	84	48/49
60	297 (50)	50/50		300 (50)	101	50/50	285 (50)	96	50/50	247 (48)	83	48/49
62	300 (50)	50/50		302 (50)	101	50/50	289 (50)	96	50/50	250 (48)	83	48/49
64	304 (50)	50/50		307 (50)	101	50/50	294 (50)	97	50/50	253 (48)	83	48/49
66	307 (50)	50/50		309 (50)	101	50/50	297 (50)	97	50/50	254 (47)	83	47/49
68	312 (50)	50/50		315 (50)	101	50/50	301 (50)	96	50/50	259 (46)	83	46/49
70	312 (50)	50/50		312 (50)	100	50/50	300 (50)	96	50/50	258 (46)	83	46/49
72	312 (50)	50/50		312 (50)	100	50/50	303 (50)	97	50/50	261 (46)	84	46/49
74	316 (50)	50/50		315 (50)	100	50/50	304 (50)	96	50/50	264 (46)	84	46/49
76	319 (50)	50/50		316 (50)	99	50/50	306 (50)	96	50/50	266 (46)	83	46/49
78	318 (50)	50/50		317 (49)	100	49/50	307 (50)	97	50/50	266 (46)	84	46/49
80	320 (50)	50/50		323 (48)	101	48/50	309 (50)	97	50/50	269 (45)	84	45/49
82	323 (49)	48/50		326 (48)	101	48/50	314 (50)	97	50/50	275 (45)	85	45/49
84	327 (48)	47/50		329 (48)	101	48/50	316 (49)	97	49/50	274 (44)	84	44/49
86	327 (47)	47/50		328 (48)	100	48/50	316 (49)	97	49/50	275 (43)	84	43/49
88	328 (44)	44/50		326 (47)	99	47/50	312 (49)	95	49/50	271 (41)	83	41/49
90	328 (44)	44/50		323 (47)	98	47/50	310 (48)	95	48/50	268 (41)	82	41/49
92	326 (44)	44/50		321 (46)	98	46/50	309 (48)	95	48/50	268 (40)	82	40/49
94	326 (44)	44/50		326 (43)	100	43/50	308 (47)	94	47/50	267 (39)	82	39/49
96	326 (43)	43/50		326 (43)	100	43/50	308 (46)	94	46/50	268 (38)	82	38/49
98	322 (43)	42/50		325 (41)	101	41/50	311 (44)	97	44/50	270 (37)	84	37/49
100	326 (41)	41/50		328 (40)	101	40/50	314 (42)	96	42/50	271 (35)	83	35/49
102	323 (41)	41/50		325 (38)	101	37/50	314 (41)	97	41/50	273 (35)	85	35/49
104	328 (39)	38/50		329 (36)	100	36/50	313 (41)	95	40/50	277 (34)	84	34/49

&lt; &gt;:No. of effective animals, ( ):No. of measured animals

Au.Wt.: g

TABLE 4 INCIDENCE AND TIME OF MASS OCCURRENCE (CLINICAL OBSERVATION) :RAT :MALE

Time of mass occurrence	Dosing week								
	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
The kind of mass	No. of animals with mass (No. of dead and moribund animals with mass)								
Internal mass									
Control	0	0	0	0	0	0	1	1	2 (2)
10 ppm	0	0	0	0	1	1	1	2	4 (3)
30 ppm	0	0	0	0	0	0	2	3	4 (2)
90 ppm	0	0	0	0	0	0	2	4	6 (5)
External mass									
Control	0	0	0	6	12	14	14	21	33 (12)
10 ppm	0	0	1	2	8	9	13	18	24 (6)
30 ppm	0	0	0	2	10	11	13	20	25 (5)
90 ppm	0	0	0	2	6	9	11	17	23 (5)

TABLE 5 INCIDENCE AND TIME OF MASS OCCURRENCE (CLINICAL OBSERVATION) :RAT :FEMALE

Time of mass occurrence	Dosing week								
	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
The kind of mass	No. of animals with mass (No. of dead and moribund animals with mass)								
Internal mass									
Control	0	0	0	0	0	0	2	5	7 (5)
10 ppm	0	0	0	0	0	1	2	2	5 (4)
30 ppm	0	0	0	0	0	0	1	3	4 (3)
90 ppm	0	0	0	0	0	0	3	3	5 (5)
External mass									
Control	0	0	0	1	2	5	10	15	20 (5)
10 ppm	0	0	0	1	2	4	6	17	19 (9)
30 ppm	0	0	0	7	5	2	14	18	25 (4)
90 ppm	0	0	0	0	3	7	11	10	18 (7)

TABLE 6 FOOD CONSUMPTION IN MALE RAT (TWO-YEAR STUDY)

Week on Study	Control		10 ppm		30 ppm		90 ppm				
	Au.F.C. (50)	No. of Surviv. (50)	Au.F.C. (50)	% of cont. (50)	No. of Surviv. (50)	Au.F.C. (50)	% of cont. (50)	No. of Surviv. (50)	Au.F.C. (50)	% of cont. (50)	No. of Surviv. (50)
1	15.5 (50)	50/50	13.7 (50)	88	50/50	13.6 (50)	88	50/50	13.2 (50)	85	50/50
2	17.2 (50)	50/50	15.6 (50)	91	50/50	15.5 (50)	90	50/50	15.8 (50)	92	50/50
3	18.2 (50)	50/50	16.4 (50)	90	50/50	16.4 (50)	90	50/50	17.6 (50)	97	50/50
4	18.5 (50)	50/50	16.9 (50)	91	50/50	16.9 (50)	91	50/50	18.4 (50)	99	50/50
5	18.6 (50)	50/50	17.6 (50)	95	50/50	17.4 (49)	94	50/50	19.2 (50)	103	50/50
6	18.4 (50)	50/50	17.1 (50)	93	50/50	17.1 (50)	93	50/50	17.7 (50)	96	50/50
7	18.6 (50)	50/50	17.2 (50)	92	50/50	16.9 (50)	91	50/50	18.6 (50)	100	50/50
8	18.4 (50)	50/50	17.1 (50)	93	50/50	16.9 (50)	92	50/50	18.8 (50)	102	50/50
9	18.7 (50)	50/50	17.4 (50)	93	50/50	18.0 (50)	96	50/50	19.9 (49)	106	50/50
10	18.3 (50)	50/50	17.2 (50)	94	50/50	17.5 (50)	96	50/50	19.8 (50)	108	50/50
11	17.9 (50)	50/50	17.3 (50)	97	50/50	17.6 (50)	98	50/50	20.0 (49)	112	50/50
12	18.3 (50)	50/50	17.8 (50)	97	50/50	17.5 (50)	96	50/50	20.0 (49)	109	50/50
13	18.1 (50)	50/50	17.7 (50)	98	50/50	17.6 (50)	97	50/50	19.3 (50)	107	50/50
14	17.8 (50)	50/50	17.0 (50)	96	50/50	17.5 (50)	98	50/50	19.6 (50)	110	50/50
18	17.5 (50)	50/50	17.1 (50)	98	50/50	17.7 (50)	101	50/50	19.9 (50)	114	50/50
22	18.2 (50)	50/50	17.5 (50)	96	50/50	18.0 (50)	99	50/50	21.1 (50)	116	50/50
26	19.1 (50)	50/50	18.4 (50)	96	50/50	19.1 (50)	100	50/50	20.1 (50)	105	50/50
30	18.7 (50)	50/50	18.2 (50)	97	50/50	18.9 (50)	101	50/50	19.8 (50)	106	50/50
34	18.3 (50)	50/50	17.5 (50)	96	50/50	18.9 (50)	103	50/50	20.3 (50)	111	50/50
38	18.6 (50)	50/50	17.9 (50)	96	50/50	18.6 (50)	100	50/50	19.6 (50)	105	50/50
42	17.9 (50)	48/50	18.1 (50)	101	50/50	18.9 (50)	106	50/50	19.9 (50)	111	50/50
46	18.4 (48)	48/50	18.0 (50)	98	50/50	18.7 (50)	102	50/50	20.8 (50)	113	50/50
50	18.9 (47)	47/50	18.3 (50)	97	50/50	19.4 (50)	103	50/50	21.6 (48)	114	50/50
52	18.3 (47)	46/50	18.2 (50)	99	50/50	19.6 (50)	107	50/50	21.4 (49)	117	50/50
54	18.8 (46)	46/50	18.4 (50)	98	50/50	19.2 (50)	102	50/50	21.5 (50)	114	50/50
58	19.3 (46)	46/50	18.5 (50)	96	50/50	19.1 (49)	99	49/50	20.8 (49)	108	49/50
62	19.0 (45)	45/50	18.4 (50)	97	50/50	19.3 (49)	102	49/50	21.8 (48)	115	49/50
66	18.9 (45)	45/50	18.1 (49)	96	49/50	19.4 (49)	103	49/50	22.1 (45)	117	49/50
70	18.4 (45)	45/50	17.3 (49)	94	49/50	18.3 (49)	99	49/50	20.6 (49)	112	49/50
74	18.4 (45)	45/50	17.2 (49)	93	49/50	18.2 (48)	99	48/50	20.3 (49)	110	48/50
78	19.1 (45)	45/50	18.0 (48)	94	48/50	19.2 (48)	101	47/50	21.4 (48)	112	48/50
82	18.8 (44)	44/50	17.7 (47)	94	47/50	19.1 (41)	102	45/50	20.5 (48)	109	48/50
86	18.3 (44)	43/50	18.0 (45)	98	45/50	19.9 (44)	109	45/50	21.5 (43)	117	45/50
90	18.1 (42)	42/50	17.9 (45)	99	45/50	18.7 (44)	103	44/50	20.4 (45)	113	44/50
94	18.4 (41)	40/50	17.8 (44)	97	44/50	19.3 (41)	105	41/50	21.9 (44)	119	44/50
98	19.4 (38)	38/50	17.9 (43)	92	43/50	19.6 (40)	101	40/50	21.1 (42)	109	42/50
102	17.1 (29)	28/50	18.0 (39)	105	39/50	19.0 (38)	111	37/50	19.6 (42)	115	41/50
104	18.0 (27)	27/50	18.0 (39)	100	39/50	19.1 (37)	106	37/50	19.6 (39)	109	38/50

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

Au.F.C.: g

(Study No. 0115, 0116)

TABLE 7 FOOD CONSUMPTION IN FEMALE RAT (TWO-YEAR STUDY)

Week on Study	Control		10 ppm		30 ppm		90 ppm				
	Au.F.C. (50)	No.of Surviv. (50)	Au.F.C. (50)	% of cont. (50)	No.of Surviv. (50)	Au.F.C. (50)	% of cont. (50)	No.of Surviv. (50)	Au.F.C. (49)	% of cont. (49)	No.of Surviv. (49)
1	11.5 (50)	50/50	10.4 (50)	90	50/50	9.9 (50)	86	50/50	9.6 (49)	83	50/50
2	12.1 (50)	50/50	11.7 (50)	97	50/50	11.0 (50)	91	50/50	11.0 (49)	91	50/50
3	12.3 (50)	50/50	11.7 (50)	95	50/50	11.3 (50)	92	50/50	11.5 (49)	93	50/50
4	12.8 (50)	50/50	12.0 (50)	94	50/50	11.7 (49)	91	50/50	12.1 (48)	95	50/50
5	12.7 (50)	50/50	12.5 (49)	98	50/50	12.3 (49)	97	50/50	13.0 (48)	102	50/50
6	12.8 (50)	50/50	12.2 (49)	95	50/50	11.9 (50)	93	50/50	12.5 (48)	98	50/50
7	12.5 (50)	50/50	12.3 (50)	98	50/50	11.9 (50)	95	50/50	13.5 (49)	108	50/50
8	12.5 (50)	50/50	12.1 (50)	97	50/50	12.0 (50)	96	50/50	13.0 (49)	104	50/50
9	12.6 (50)	50/50	12.0 (50)	95	50/50	12.4 (50)	98	50/50	13.7 (49)	109	50/50
10	12.8 (50)	50/50	12.8 (50)	100	50/50	12.9 (50)	101	50/50	13.9 (49)	109	50/50
11	12.2 (48)	50/50	12.5 (49)	102	50/50	12.9 (49)	106	50/50	13.8 (46)	113	50/50
12	12.5 (50)	50/50	12.9 (50)	103	50/50	13.1 (50)	105	50/50	13.8 (43)	110	50/50
13	11.9 (49)	50/50	12.5 (50)	105	50/50	12.4 (49)	104	50/50	13.8 (47)	116	50/50
14	12.1 (50)	50/50	12.2 (50)	101	50/50	13.0 (50)	107	50/50	13.9 (49)	115	50/50
18	12.2 (50)	50/50	12.9 (50)	106	50/50	13.4 (50)	110	50/50	14.3 (48)	117	50/50
22	12.9 (50)	50/50	13.8 (50)	107	50/50	13.6 (50)	105	50/50	15.2 (45)	118	50/50
26	13.0 (50)	50/50	13.3 (50)	102	50/50	13.8 (50)	106	50/50	14.9 (48)	115	50/50
30	12.8 (50)	50/50	12.5 (50)	98	50/50	13.2 (50)	103	50/50	14.0 (46)	109	49/49
34	13.1 (50)	50/50	13.5 (50)	103	50/50	14.0 (50)	107	50/50	14.2 (49)	108	49/49
38	12.7 (50)	50/50	13.1 (50)	103	50/50	13.1 (50)	103	50/50	13.7 (48)	108	49/49
42	12.9 (50)	50/50	13.4 (50)	104	50/50	13.8 (50)	107	50/50	14.4 (49)	112	49/49
46	12.9 (50)	50/50	13.6 (50)	105	50/50	14.1 (50)	109	50/50	15.0 (49)	116	49/49
50	13.4 (50)	50/50	13.5 (50)	101	50/50	14.5 (50)	108	50/50	15.3 (49)	114	49/49
52	13.6 (50)	50/50	13.9 (50)	102	50/50	14.2 (50)	104	50/50	14.6 (49)	107	48/49
54	13.3 (50)	50/50	14.0 (50)	105	50/50	14.7 (50)	111	50/50	15.7 (47)	118	48/49
58	13.6 (49)	50/50	14.0 (50)	103	50/50	14.2 (50)	104	50/50	15.6 (48)	115	48/49
62	13.5 (50)	50/50	13.5 (50)	100	50/50	14.6 (50)	108	50/50	15.7 (48)	116	48/49
66	13.4 (50)	50/50	13.5 (50)	101	50/50	14.9 (50)	111	50/50	15.7 (47)	117	47/49
70	12.5 (50)	50/50	12.5 (50)	100	50/50	13.3 (50)	106	50/50	14.4 (46)	115	46/49
74	13.4 (50)	50/50	13.5 (50)	101	50/50	14.1 (50)	105	50/50	15.2 (43)	113	46/49
78	13.5 (50)	50/50	13.6 (49)	101	49/50	14.9 (49)	110	50/50	14.9 (42)	110	46/49
82	13.8 (49)	48/50	14.7 (48)	107	48/50	15.4 (50)	112	50/50	16.2 (45)	117	45/49
86	13.5 (47)	47/50	14.2 (48)	105	48/50	15.9 (49)	118	49/50	16.1 (43)	119	43/49
90	13.7 (44)	44/50	14.0 (47)	102	47/50	14.8 (48)	108	48/50	15.5 (41)	113	41/49
94	14.8 (44)	44/50	14.8 (45)	100	43/50	15.9 (47)	107	47/50	16.3 (39)	110	39/49
98	15.4 (43)	42/50	15.5 (42)	101	41/50	16.0 (44)	104	44/50	15.9 (38)	103	37/49
102	14.1 (41)	41/50	15.3 (39)	109	37/50	15.8 (42)	112	41/50	16.6 (34)	118	35/49
104	14.5 (41)	38/50	15.0 (37)	103	36/50	15.8 (41)	109	40/50	16.3 (35)	112	34/49

< >:No.of effective animals,( ):No.of measured animals Au.F.C.:g

(Study No. 0115, 0116)

TABLE 8 CAUSE OF DEATH :RAT

Group	Male				Female			
	Control	10ppm	30ppm	90ppm	Control	10ppm	30ppm	90ppm
Number of dead/moribund animal	23	11	13	12	12	14	10	15
Cardiovascular lesion	0	1	0	0	0	0	0	0
Chronic nephropathy	1	0	0	0	0	0	0	0
Arteritis	0	0	0	1	0	0	0	0
Tumor death : leukemia	7	5	4	9	5	7	5	5
: subcutis	2	1	1	0	0	0	0	1
: oral cavity	1	0	0	0	0	0	0	0
: small intestine	0	1	0	0	0	0	0	0
: kidney	0	0	0	0	0	0	0	1
: pituitary gland	5	2	3	0	5	5	3	2
: thyroid	0	0	1	0	0	0	0	0
: adrenal	0	0	1	1	0	0	0	2
: uterus	0	0	0	0	0	1	0	0
: mammary gland	0	0	0	0	0	0	0	2
: prep./cli. gland	1	1	0	0	0	0	1	1
: brain	2	0	1	0	0	0	1	0
: peripheral nerves	0	0	1	0	0	0	0	0
: Zymbal gland	2	0	0	0	2	0	0	0
: vertebra	0	0	0	0	0	0	0	1
: pleura	1	0	0	0	0	0	0	0
: peritoneum	1	0	1	1	0	1	0	0

TABLE 9 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN MALE MOUSE  
(TWO-YEAR STUDY)

Week on Study	Control		5 ppm			30 ppm			90 ppm		
	Au.Wt.	No. of Surviv. <50>	Au.Wt.	% of cont. <50>	No. of Surviv.	Au.Wt.	% of cont. <50>	No. of Surviv.	Au.Wt.	% of cont. <49>	No. of Surviv.
0	22.1 (50)	50/50	22.1 (50)	100	50/50	22.1 (50)	100	50/50	22.1 (49)	100	50/50
1	23.9 (50)	50/50	22.6 (50)	95	50/50	22.9 (50)	96	50/50	22.5 (49)	94	50/50
2	25.1 (50)	50/50	23.4 (50)	93	50/50	24.2 (50)	96	50/50	23.8 (49)	95	50/50
3	26.0 (50)	50/50	24.1 (49)	93	49/50	24.3 (50)	93	50/50	23.9 (49)	92	50/50
4	26.5 (50)	50/50	24.3 (49)	92	49/50	24.7 (50)	93	50/50	24.2 (49)	91	50/50
5	27.0 (50)	50/50	24.7 (49)	91	49/50	25.1 (50)	93	50/50	24.6 (48)	91	49/50
6	27.9 (50)	50/50	24.9 (49)	89	49/50	25.5 (50)	91	50/50	24.8 (48)	89	49/50
7	28.4 (50)	50/50	25.4 (49)	89	49/50	25.8 (50)	91	50/50	24.6 (48)	87	49/50
8	29.2 (50)	50/50	25.8 (49)	88	49/50	26.3 (50)	90	50/50	25.1 (48)	86	49/50
9	29.9 (50)	50/50	26.7 (49)	89	49/50	27.5 (50)	92	50/50	26.4 (48)	88	49/50
10	30.5 (50)	50/50	26.2 (49)	86	49/50	27.2 (50)	89	50/50	25.7 (48)	84	49/50
11	31.3 (50)	50/50	27.3 (49)	87	49/50	27.3 (50)	87	50/50	26.1 (48)	83	49/50
12	32.0 (50)	50/50	27.5 (49)	86	49/50	27.6 (50)	86	50/50	26.3 (48)	82	49/50
13	32.8 (50)	50/50	28.1 (49)	86	49/50	28.1 (50)	86	50/50	26.7 (48)	81	49/50
14	33.5 (50)	50/50	29.0 (49)	87	49/50	29.2 (50)	87	50/50	27.5 (48)	82	49/50
16	34.9 (50)	50/50	29.9 (49)	86	49/50	27.5 (50)	79	50/50	25.2 (45)	72	46/50
18	36.2 (50)	50/50	30.1 (49)	83	49/50	29.2 (50)	81	50/50	26.9 (45)	74	46/50
20	37.2 (50)	50/50	31.0 (49)	83	49/50	30.0 (50)	81	50/50	27.8 (45)	75	46/50
22	38.5 (50)	50/50	31.9 (49)	83	49/50	30.8 (50)	80	50/50	28.2 (45)	73	45/49
24	39.3 (50)	50/50	32.4 (49)	82	49/50	31.3 (50)	80	50/50	28.4 (45)	72	45/49
26	40.5 (50)	50/50	33.5 (49)	83	49/50	32.1 (50)	79	50/50	29.5 (45)	73	45/49
28	41.4 (50)	50/50	33.7 (49)	81	49/50	32.7 (50)	79	50/50	29.5 (45)	71	45/49
30	42.4 (50)	50/50	34.2 (49)	81	49/50	33.2 (50)	78	50/50	30.1 (45)	71	45/49
32	43.4 (50)	50/50	35.4 (49)	82	49/50	34.2 (50)	79	50/50	31.3 (45)	72	45/49
34	43.9 (50)	50/50	35.2 (49)	80	49/50	34.6 (50)	79	50/50	31.1 (45)	71	45/49
36	44.8 (49)	49/50	35.7 (49)	80	49/50	34.9 (49)	78	49/50	31.5 (45)	70	45/49
38	45.4 (49)	49/50	35.9 (49)	79	49/50	35.1 (49)	77	48/50	32.1 (45)	71	45/49
40	45.8 (49)	49/50	36.2 (49)	79	49/50	35.5 (48)	78	48/50	32.2 (45)	70	45/49
42	45.9 (49)	49/50	36.5 (49)	80	49/50	35.9 (48)	78	48/50	32.9 (45)	72	45/49
44	46.6 (49)	49/50	37.2 (49)	80	49/50	36.4 (48)	78	48/50	33.2 (45)	71	45/49
46	47.2 (49)	49/50	38.2 (49)	81	49/50	37.1 (48)	79	48/50	33.7 (44)	71	44/49
48	47.6 (49)	49/50	38.5 (49)	81	49/50	37.3 (48)	78	48/50	33.9 (44)	71	44/49
50	48.0 (49)	49/50	39.0 (49)	81	49/50	37.6 (48)	78	48/50	34.1 (44)	71	44/49
52	47.7 (49)	49/50	39.3 (49)	82	49/50	37.5 (48)	79	48/50	34.3 (44)	72	44/49
54	48.2 (49)	49/50	39.6 (48)	82	48/50	37.9 (48)	79	48/50	34.1 (44)	71	44/49
56	48.7 (49)	49/50	40.3 (48)	83	48/50	38.6 (48)	79	48/50	35.1 (44)	72	44/49
58	48.9 (49)	49/50	40.2 (48)	82	48/50	38.7 (48)	79	48/50	35.1 (44)	72	44/49
60	49.0 (49)	49/50	40.2 (48)	82	48/50	38.7 (48)	79	48/50	35.4 (44)	72	44/49
62	49.4 (49)	49/50	40.6 (48)	82	48/50	38.6 (48)	78	48/50	35.9 (44)	73	44/49
64	49.3 (49)	49/50	40.9 (48)	83	48/50	38.6 (48)	78	48/50	35.4 (44)	72	44/49
66	49.5 (49)	49/50	40.8 (48)	82	48/50	39.0 (48)	79	48/50	35.8 (44)	72	44/49
68	49.3 (49)	49/50	40.4 (48)	82	48/50	39.3 (47)	80	47/50	35.8 (44)	73	44/49
70	48.6 (49)	49/50	40.4 (48)	83	47/50	39.8 (46)	82	46/50	36.3 (44)	75	44/49
72	49.3 (49)	49/50	40.6 (47)	82	47/50	39.8 (46)	81	46/50	36.5 (44)	74	44/49
74	50.0 (49)	49/50	41.3 (47)	83	47/50	39.9 (46)	80	46/50	36.5 (44)	73	44/49
76	50.3 (49)	49/50	41.7 (46)	83	46/50	40.7 (45)	81	45/50	36.7 (44)	73	44/49
78	50.6 (49)	49/50	41.8 (46)	83	46/50	40.6 (44)	80	44/50	36.8 (44)	73	44/49
80	50.1 (49)	49/50	41.3 (46)	82	46/50	40.6 (44)	81	44/50	37.1 (44)	74	44/49
82	50.2 (49)	49/50	41.4 (46)	82	46/50	40.9 (44)	81	44/50	37.2 (44)	74	44/49
84	50.6 (48)	48/50	42.0 (46)	83	46/50	41.2 (44)	81	44/50	37.2 (44)	74	44/49
86	51.3 (46)	46/50	42.0 (46)	82	46/50	41.4 (43)	81	43/50	37.5 (43)	73	43/49
88	51.8 (44)	44/50	41.8 (46)	81	46/50	41.4 (43)	80	43/50	37.5 (43)	72	43/49
90	51.7 (44)	44/50	41.4 (46)	80	45/50	41.4 (43)	80	43/50	37.9 (42)	73	42/49
92	52.3 (43)	43/50	42.1 (44)	80	44/50	41.6 (43)	80	43/50	37.4 (42)	72	42/49
94	51.3 (43)	43/50	42.4 (43)	83	43/50	41.4 (42)	81	42/50	37.0 (41)	72	41/49
96	50.6 (41)	41/50	42.4 (43)	84	43/50	41.5 (42)	82	42/50	37.0 (40)	73	40/49
98	50.0 (39)	39/50	42.1 (43)	84	43/50	41.1 (41)	82	41/50	36.3 (39)	73	39/49
100	50.7 (35)	35/50	42.0 (41)	83	41/50	41.0 (41)	81	41/50	36.4 (38)	72	38/49
102	49.1 (34)	34/50	41.0 (40)	84	40/50	40.8 (39)	83	38/50	36.1 (36)	74	36/49
104	47.9 (33)	33/50	40.9 (38)	85	38/50	39.8 (37)	83	36/50	35.9 (36)	75	36/49

&lt; &gt;:No. of effective animals, ( ):No. of measured animals

Au.Wt.: g

TABLE 10 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES IN FEMALE MOUSE  
(TWO-YEAR STUDY)

Week on Study	Control		5 ppm		30 ppm		90 ppm				
	Au.Wt.	No. of Surviv. <50>	Au.Wt.	% of cont. <49>	No. of Surviv.	Au.Wt.	% of cont. <50>	No. of Surviv.	Au.Wt.	% of cont. <48>	No. of Surviv.
0	18.6 (50)	50/50	18.5 (49)	99	50/50	18.6 (50)	100	50/50	18.5 (48)	99	50/50
1	19.5 (50)	50/50	18.6 (49)	95	50/50	18.6 (49)	95	49/50	18.4 (48)	94	49/49
2	20.1 (50)	50/50	19.4 (49)	97	50/50	19.7 (49)	98	49/50	19.7 (48)	98	49/49
3	21.0 (50)	50/50	20.2 (49)	96	50/50	20.3 (49)	97	49/50	20.2 (48)	96	49/49
4	21.7 (50)	50/50	20.8 (49)	96	50/50	21.0 (49)	97	49/50	20.9 (48)	96	49/49
5	22.0 (50)	50/50	21.5 (49)	98	49/49	21.6 (49)	98	49/50	21.5 (48)	98	49/49
6	22.4 (50)	50/50	21.8 (49)	97	49/49	22.0 (49)	98	49/50	21.7 (48)	97	49/49
7	22.6 (50)	50/50	22.1 (49)	98	49/49	22.4 (49)	99	49/50	21.9 (48)	97	49/49
8	23.4 (50)	50/50	22.4 (49)	96	49/49	23.0 (49)	98	49/50	22.4 (48)	96	49/49
9	23.4 (50)	50/50	23.1 (49)	99	49/49	23.5 (49)	100	49/50	23.4 (48)	100	49/49
10	23.6 (50)	50/50	22.8 (49)	97	49/49	23.7 (49)	100	49/50	23.1 (48)	98	49/49
11	24.0 (50)	50/50	23.6 (49)	98	49/49	23.9 (49)	100	49/50	23.6 (48)	98	49/49
12	24.4 (50)	50/50	23.6 (49)	97	49/49	24.3 (49)	100	49/50	23.7 (48)	97	49/49
13	25.2 (50)	50/50	24.2 (49)	96	49/49	24.5 (49)	97	49/50	23.8 (48)	94	49/49
14	25.4 (50)	50/50	24.5 (49)	96	49/49	24.6 (49)	97	49/50	24.4 (48)	96	49/49
16	26.0 (50)	50/50	25.0 (49)	96	49/49	25.2 (49)	97	49/50	24.4 (48)	94	49/49
18	26.4 (50)	50/50	25.1 (49)	95	49/49	25.1 (49)	95	49/50	24.5 (48)	93	49/49
20	27.6 (50)	50/50	25.8 (49)	93	49/49	26.6 (49)	96	49/50	25.3 (48)	92	49/49
22	27.6 (50)	50/50	26.4 (49)	96	49/49	26.5 (49)	96	49/50	25.5 (48)	92	49/49
24	28.1 (50)	50/50	26.7 (49)	95	49/49	26.9 (49)	96	49/50	25.6 (48)	91	49/49
26	28.8 (50)	50/50	27.3 (49)	95	49/49	27.2 (49)	94	49/50	26.1 (48)	91	49/49
28	29.2 (50)	50/50	27.3 (49)	93	49/49	28.0 (49)	96	49/50	26.2 (48)	90	49/49
30	29.6 (50)	50/50	27.7 (49)	94	49/49	28.0 (49)	95	49/50	26.0 (48)	88	49/49
32	30.3 (50)	50/50	28.5 (49)	94	49/49	28.7 (49)	95	49/50	26.9 (48)	89	49/49
34	30.7 (50)	50/50	28.4 (49)	93	49/49	28.4 (49)	93	49/50	26.7 (48)	87	49/49
36	30.5 (50)	50/50	28.6 (49)	94	49/49	29.0 (49)	95	49/50	27.0 (47)	89	48/49
38	31.3 (50)	50/50	29.4 (49)	94	49/49	29.1 (49)	93	49/50	27.1 (47)	87	48/49
40	30.9 (50)	50/50	29.0 (49)	94	49/49	29.3 (49)	95	49/50	27.2 (47)	88	48/49
42	31.8 (50)	50/50	29.7 (49)	93	49/49	29.2 (49)	92	49/50	27.6 (47)	87	48/49
44	31.6 (50)	50/50	29.9 (49)	95	49/49	29.6 (49)	94	49/50	27.7 (47)	88	48/49
46	32.6 (49)	49/50	30.7 (49)	94	49/49	30.9 (49)	95	49/50	28.2 (47)	87	48/49
48	32.8 (49)	49/50	30.7 (49)	94	49/49	30.4 (49)	93	49/50	28.3 (47)	86	48/49
50	33.5 (49)	49/50	31.0 (49)	93	49/49	30.8 (49)	92	49/50	28.5 (47)	85	48/49
52	33.3 (48)	48/50	30.9 (49)	93	49/49	30.9 (47)	93	47/50	28.5 (45)	86	46/49
54	33.8 (47)	47/50	31.4 (49)	93	49/49	30.8 (47)	91	47/50	28.4 (45)	84	45/48
56	34.6 (47)	47/50	32.4 (49)	94	49/49	31.5 (46)	91	46/50	29.0 (44)	84	44/48
58	34.7 (47)	47/50	32.5 (49)	94	49/49	31.4 (46)	90	46/50	28.7 (44)	83	44/48
60	34.7 (47)	47/50	32.7 (49)	94	49/49	31.7 (46)	91	46/50	29.0 (44)	84	44/48
62	35.7 (46)	46/50	33.4 (49)	94	49/49	32.6 (46)	91	46/50	29.4 (44)	82	44/48
64	35.6 (46)	46/50	33.2 (49)	93	49/49	31.4 (45)	88	45/50	29.2 (44)	82	44/48
66	35.5 (45)	45/50	33.6 (49)	95	49/49	31.8 (45)	90	45/50	29.4 (42)	83	42/48
68	35.3 (45)	45/50	33.8 (49)	96	49/49	32.5 (44)	92	44/50	29.4 (42)	83	42/48
70	36.2 (43)	43/50	34.2 (48)	94	48/49	33.1 (42)	91	42/50	29.9 (42)	83	42/48
72	36.1 (43)	43/50	33.8 (48)	94	48/49	33.0 (41)	91	41/50	29.9 (41)	83	40/48
74	36.9 (43)	43/50	35.1 (48)	95	48/49	33.3 (40)	90	40/50	29.5 (40)	80	40/48
76	37.0 (43)	43/50	34.9 (48)	94	48/49	33.3 (40)	90	40/50	29.4 (39)	79	39/48
78	37.7 (43)	43/50	35.1 (48)	93	48/49	33.5 (40)	89	40/50	29.1 (38)	77	38/48
80	36.8 (43)	43/50	34.9 (48)	95	47/49	33.3 (40)	90	40/50	29.5 (38)	80	38/48
82	36.9 (41)	41/50	34.7 (46)	94	46/49	33.6 (39)	91	39/50	29.2 (37)	79	37/48
84	36.7 (41)	41/50	35.7 (46)	97	46/49	33.0 (36)	90	36/50	29.5 (37)	80	37/48
86	37.2 (40)	40/50	35.3 (46)	95	46/49	33.0 (35)	89	35/50	29.8 (35)	80	35/48
88	35.9 (39)	39/50	35.1 (46)	98	46/49	32.7 (35)	91	35/50	29.6 (35)	82	35/48
90	36.2 (39)	39/50	34.6 (46)	96	45/49	33.3 (35)	92	35/50	29.8 (34)	82	34/48
92	36.2 (39)	39/50	34.9 (44)	96	44/49	33.2 (35)	92	35/50	29.8 (34)	82	34/48
94	36.6 (38)	38/50	34.5 (42)	94	42/49	33.5 (35)	92	35/50	29.2 (32)	80	32/48
96	36.2 (38)	38/50	35.0 (41)	97	41/49	34.0 (34)	94	33/50	30.1 (31)	83	31/48
98	36.0 (35)	35/50	34.9 (39)	97	38/49	33.1 (31)	92	31/50	29.8 (28)	83	27/48
100	35.2 (30)	30/50	34.6 (38)	98	38/49	33.3 (29)	95	29/50	29.5 (27)	84	27/48
102	34.9 (29)	29/50	33.4 (36)	96	36/49	33.0 (28)	95	28/50	29.5 (27)	85	27/48
104	33.7 (29)	29/50	33.5 (36)	99	36/49	33.8 (26)	100	25/50	30.2 (24)	90	24/48

&lt; &gt;:No. of effective animals, ( ):No. of measured animals

Au.Wt.: g

TABLE 11 INCIDENCE AND TIME OF MASS OCCURRENCE (CLINICAL OBSERVATION) :MOUSE :MALE

Time of mass occurrence	Dosing week								
	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
The kind of mass	No. of animals with mass (No. of dead and moribund animals with mass)								
Internal mass									
Control	1	5	6	4	5	11	10	10	21 (11)
5 ppm	1	1	2	1	0	0	1	5	8 (5)
30 ppm	1	3	1	0	5	4	3	6	13 (7)
90 ppm	3	2	0	0	0	1	3	5	11 (4)
External mass									
Control	0	0	0	0	1	1	4	6	6 (2)
5 ppm	0	0	0	0	0	0	0	2	2 (0)
30 ppm	0	0	0	0	1	2	5	7	8 (1)
90 ppm	0	0	0	0	0	0	3	1	3 (0)

TABLE 12 INCIDENCE AND TIME OF MASS OCCURRENCE (CLINICAL OBSERVATION) :MOUSE :FEMALE

Time of mass occurrence	Dosing week								
	0~13	14~26	27~39	40~52	53~65	66~78	79~91	92~104	0~104
The kind of mass	No. of animals with mass (No. of dead and moribund animals with mass)								
Internal mass									
Control	0	2	0	1	5	5	3	5	12 (9)
5 ppm	0	0	0	1	2	3	4	5	8 (5)
30 ppm	4	2	0	3	3	3	3	7	16 (10)
90 ppm	3	4	2	2	7	5	2	4	19 (13)
External mass									
Control	0	0	1	1	1	1	1	2	2 (0)
5 ppm	0	0	0	0	0	2	3	7	8 (3)
30 ppm	0	0	1	1	1	3	2	4	7 (6)
90 ppm	0	0	0	0	0	0	2	2	2 (2)

(Study No. 0115, 0116)

TABLE 13 FOOD CONSUMPTION IN MALE MOUSE (TWO-YEAR STUDY)

Week on Study	Control		5 ppm		30 ppm		90 ppm				
	Au.F.C.	No. of Surviv. <50>	Au.F.C.	% of cont. <50>	No. of Surviv.	Au.F.C.	% of cont. <50>	No. of Surviv.	Au.F.C.	% of cont. <40>	No. of Surviv.
1	3.7 (50)	50/50	3.3 (50)	89	50/50	3.3 (50)	89	50/50	3.3 (47)	89	50/50
2	3.7 (50)	50/50	3.4 (50)	92	50/50	3.6 (50)	97	50/50	3.7 (49)	100	50/50
3	3.6 (50)	50/50	3.2 (50)	89	49/50	3.1 (50)	86	50/50	3.2 (49)	89	50/50
4	3.6 (50)	50/50	3.4 (49)	94	49/50	3.4 (50)	94	50/50	3.4 (49)	94	50/50
5	3.7 (50)	50/50	3.4 (48)	92	49/50	3.3 (50)	89	50/50	3.3 (48)	89	49/50
6	3.8 (50)	50/50	3.5 (49)	92	49/50	3.5 (50)	92	50/50	3.5 (48)	92	49/50
7	3.7 (50)	50/50	3.5 (49)	95	49/50	3.6 (50)	97	50/50	3.4 (48)	92	49/50
8	4.0 (50)	50/50	3.7 (49)	93	49/50	3.7 (50)	93	50/50	3.7 (48)	93	49/50
9	3.9 (50)	50/50	3.7 (49)	95	49/50	3.8 (50)	97	50/50	3.9 (48)	100	49/50
10	4.0 (50)	50/50	3.6 (49)	90	49/50	3.6 (50)	90	50/50	3.6 (48)	90	49/50
11	3.9 (50)	50/50	3.7 (49)	95	49/50	3.5 (50)	90	50/50	3.7 (48)	95	49/50
12	4.1 (50)	50/50	3.8 (49)	93	49/50	3.7 (50)	90	50/50	3.8 (48)	93	49/50
13	4.1 (50)	50/50	3.8 (49)	93	49/50	3.8 (50)	93	50/50	3.9 (45)	95	49/50
14	4.0 (50)	50/50	3.8 (49)	95	49/50	3.7 (50)	93	50/50	3.8 (48)	95	49/50
18	4.3 (50)	50/50	3.8 (49)	88	49/50	3.9 (44)	91	50/50	3.9 (45)	91	46/50
22	4.3 (50)	50/50	3.9 (49)	91	49/50	4.0 (50)	93	50/50	4.1 (45)	95	45/49
26	4.3 (50)	50/50	4.1 (49)	95	49/50	4.0 (50)	93	50/50	4.2 (45)	98	45/49
30	4.4 (50)	50/50	4.1 (49)	93	49/50	4.1 (50)	93	50/50	4.4 (45)	100	45/49
34	4.4 (50)	50/50	4.1 (49)	93	49/50	4.2 (50)	95	50/50	4.3 (45)	98	45/49
38	4.5 (49)	49/50	4.1 (49)	91	49/50	4.1 (49)	91	48/50	4.4 (45)	98	45/49
42	4.5 (49)	49/50	4.1 (49)	91	49/50	4.2 (48)	93	48/50	4.4 (45)	98	45/49
46	4.6 (49)	49/50	4.3 (49)	93	49/50	4.3 (48)	93	48/50	4.4 (44)	96	44/49
50	4.5 (49)	49/50	4.2 (49)	93	49/50	4.2 (48)	93	48/50	4.5 (44)	100	44/49
52	4.7 (49)	49/50	4.3 (49)	91	49/50	4.2 (48)	89	48/50	4.4 (44)	94	44/49
54	4.7 (49)	49/50	4.3 (48)	91	48/50	4.4 (48)	94	48/50	4.5 (44)	96	44/49
58	4.7 (49)	49/50	4.3 (48)	91	48/50	4.4 (48)	94	48/50	4.6 (44)	98	44/49
62	4.9 (49)	49/50	4.6 (48)	94	48/50	4.5 (48)	92	48/50	4.8 (44)	98	44/49
66	4.9 (49)	49/50	4.6 (48)	94	48/50	4.6 (48)	94	48/50	4.8 (44)	98	44/49
70	4.9 (49)	49/50	4.6 (48)	94	47/50	4.8 (47)	98	46/50	5.0 (44)	102	44/49
74	5.1 (49)	49/50	4.7 (47)	92	47/50	4.6 (46)	90	46/50	4.8 (44)	94	44/49
78	4.9 (49)	49/50	4.6 (46)	94	46/50	4.5 (44)	92	44/50	4.7 (44)	96	44/49
82	4.8 (49)	49/50	4.2 (46)	88	46/50	4.4 (44)	92	44/50	4.6 (44)	96	44/49
86	4.8 (46)	46/50	4.4 (46)	92	46/50	4.5 (44)	94	43/50	4.7 (44)	98	43/49
90	4.9 (44)	44/50	4.5 (46)	92	45/50	4.7 (43)	96	43/50	4.9 (43)	100	42/49
94	4.9 (43)	43/50	4.6 (43)	94	43/50	4.6 (42)	94	42/50	4.9 (41)	100	41/49
98	4.8 (39)	39/50	4.4 (43)	92	43/50	4.4 (41)	92	41/50	4.5 (39)	94	39/49
102	4.5 (34)	34/50	4.1 (40)	91	40/50	4.4 (39)	98	38/50	4.5 (37)	100	36/49
104	4.6 (34)	33/50	4.3 (39)	93	38/50	4.3 (38)	93	36/50	4.6 (36)	100	36/49

< >:No. of effective animals, ( ):No. of measured animals Au.F.C.: g

(Study No. 0115, 0116)

TABLE 14 FOOD CONSUMPTION IN FEMALE MOUSE (TWO-YEAR STUDY)

Week on Study	Control		5 ppm		30 ppm		90 ppm				
	Au.F.C. (50)	No. of Surviv. (50)	Au.F.C. (49)	% of cont. (49)	No. of Surviv. (49)	Au.F.C. (50)	% of cont. (50)	No. of Surviv. (48)	Au.F.C. (48)	% of cont. (48)	No. of Surviv. (48)
1	3.1	50/50	2.8	90	50/50	2.8	90	49/50	2.8	90	49/49
2	3.1	50/50	2.9	94	50/50	3.0	97	49/50	3.1	100	49/49
3	3.3	50/50	3.0	91	50/50	2.9	88	49/50	2.9	88	49/49
4	3.4	50/50	3.1	91	50/50	3.2	94	49/50	3.1	91	49/49
5	3.5	50/50	3.3	94	49/49	3.4	97	49/50	3.2	91	49/49
6	3.6	50/50	3.5	97	49/49	3.5	97	49/50	3.4	94	49/49
7	3.7	50/50	3.5	95	49/49	3.6	97	49/50	3.3	89	49/49
8	3.9	50/50	3.7	95	49/49	3.8	97	49/50	3.7	95	49/49
9	3.7	50/50	3.7	100	49/49	3.9	105	49/50	3.8	103	49/49
10	3.8	50/50	3.7	97	49/49	3.8	100	49/50	3.7	97	49/49
11	3.8	50/50	3.7	97	49/49	3.8	100	49/50	3.9	103	49/49
12	3.9	50/50	3.9	100	49/49	3.9	100	49/50	3.9	100	49/49
13	4.0	50/50	3.9	98	49/49	4.0	100	49/50	3.9	98	49/49
14	3.8	50/50	3.8	100	49/49	3.8	100	49/50	3.9	103	49/49
18	4.1	50/50	4.2	102	49/49	4.1	100	49/50	4.1	100	49/49
22	4.1	50/50	4.1	100	49/49	4.2	102	49/50	4.3	105	49/49
26	4.3	50/50	4.1	95	49/49	4.3	100	49/50	4.5	105	49/49
30	4.3	50/50	4.3	100	49/49	4.5	105	49/50	4.6	107	49/49
34	4.4	50/50	4.3	98	49/49	4.4	100	49/50	4.7	107	49/49
38	4.4	50/50	4.5	102	49/49	4.5	102	49/50	4.6	105	48/49
42	4.5	50/50	4.5	100	49/49	4.5	100	49/50	4.6	102	48/49
46	4.3	49/50	4.5	105	49/49	4.8	112	49/50	4.6	107	48/49
50	4.3	49/50	4.4	102	49/49	4.5	105	49/50	4.7	109	48/49
52	4.3	48/50	4.5	105	49/49	4.5	105	47/50	4.6	107	46/49
54	4.5	47/50	4.5	100	49/49	4.8	107	47/50	4.6	102	45/48
58	4.5	47/50	4.6	102	49/49	4.6	102	46/50	4.7	104	44/48
62	4.8	46/50	5.0	104	49/49	5.0	104	46/50	4.9	102	44/48
66	4.5	45/50	4.6	102	49/49	4.7	104	45/50	4.7	104	42/48
70	4.9	43/50	5.0	102	48/49	4.9	100	42/50	4.9	100	42/48
74	4.6	43/50	4.8	104	48/49	4.7	102	40/50	4.6	100	40/48
78	4.5	43/50	4.5	100	48/49	4.5	100	40/50	4.4	98	38/48
82	4.4	41/50	4.2	95	46/49	4.4	100	39/50	4.3	98	37/48
86	4.4	40/50	4.4	100	46/49	4.4	100	35/50	4.5	102	35/48
90	4.3	39/50	4.4	102	45/49	4.6	107	35/50	4.6	107	34/48
94	4.5	38/50	4.5	100	42/49	4.6	102	35/50	4.4	98	32/48
98	4.2	35/50	4.4	105	38/49	4.5	107	31/50	4.3	102	27/48
102	4.0	29/50	4.1	103	36/49	4.4	110	28/50	4.2	105	27/48
104	4.0	29/50	4.3	108	36/49	4.7	118	25/50	4.4	110	24/48

< >:No. of effective animals, ( ):No. of measured animals Au.F.C.: g

(Study No. 0115, 0116)

TABLE 15 NEOPLASTIC LESIONS (KIDNEY) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE : MALE

Group Name	Control	5 ppm	30 ppm	90 ppm
SITE : kidney				
TUMOUR : renal cell carcinoma				
Overall Rates(a)	0/50 ( 0.0)	1/50 ( 2.0)	4/50 ( 8.0)	11/48 (22.9)
Adjusted Rates(b)	0.0	2.50	11.11	27.78
Terminal Rates(c)	0/33 ( 0.0)	0/38 ( 0.0)	4/36 (11.1)	9/35 (25.7)
Standard Rates(d)	P= ----			
Prevalence Rates(d)	P<0.0001**			
Combind analysis(d)	P= ----			
Cochran-Armitage Test(e)	P<0.0001**			
Fisher Exact Test(e)		P=0.4950	P=0.0688	P=0.0007**
SITE : kidney				
TUMOUR : renal cell adenoma, renal cell carcinoma				
Overall Rates(a)	0/50 ( 0.0)	1/50 ( 2.0)	7/50 (14.0)	12/48 (25.0)
Adjusted Rates(b)	0.0	2.50	19.44	30.56
Terminal Rates(c)	0/33 ( 0.0)	0/38 ( 0.0)	7/36 (19.4)	10/35 (28.6)
Standard Rates(d)	P= ----			
Prevalence Rates(d)	P<0.0001**			
Combind analysis(d)	P= ----			
Cochran-Armitage Test(e)	P<0.0001**			
Fisher Exact Test(e)		P=0.4950	P=0.0101*	P=0.0004**

(a): Number of tumor-bearing animals/number of animals examined at the site.

(b): Kaplan-Meire estimate tumor incidence at the end of 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

Combind analysis : Death analysis + Incidental tumor test

(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value beyond the estimated P-value.

-----: There is no data which should be statistical analysis.

TABLE 16 NUMBER OF MOUSE WITH SELECTED KIDNEY LESIONS

Group	Male				Female			
	Control	5ppm	30ppm	90ppm	Control	5ppm	30ppm	90ppm
Number of examined	50	50	50	48	50	49	50	48
Hemorrhage	1	0	0	0	0	0	0	0
Infarct	1	0	2	1	0	0	0	0
Anisonucleosis	0	3	43	42	0	0	0	4
Hyaline droplet	2	1	0	0	9	2	12	12
Basophilic change	40	41	46	43	0	4	3	7
Deposit of amyloid	0	0	0	1	0	1	0	0
Inflammatory infiltration	0	0	0	1	0	0	0	2
Lymphocytic infiltration	14	7	16	11	15	11	9	4
Osseous metaplasia	0	0	0	1	0	0	0	0
Inflammatory polyp	1	1	0	1	1	2	3	4
Leukemic cell infiltration	1	1	2	2	9	8	9	6
Metastasis:uterus tumor	0	0	0	0	6	1	5	3
Metastasis:mammary gland tumor	0	0	0	1	0	0	0	0
Metastasis:lung tumor	0	0	0	1	0	0	1	0
Arteritis	0	0	1	0	0	0	0	0
Vacuolization of proximal tubule	41	0	0	0	0	0	0	0
Hydronephrosis	5	1	1	1	1	2	4	4
Retention cyst	4	0	7	13	1	0	0	0
Mineralization:papilla	0	0	0	1	0	0	0	0
Mineralization:cortex	0	0	1	1	0	0	0	0
Dilatation:tubular lumen	0	0	0	1	1	0	0	0
Glomerulosclerosis	1	0	0	0	0	0	0	0
Tubular necrosis:proximal tubule	0	0	1	2	1	0	0	0
Tubular cell hyperplasia:cystic	0	0	11	13	0	0	0	0
Tubular cell hyperplasia:solid	0	0	0	1	0	0	0	0
Renal cell adenoma	0	0	3	1	0	0	0	0
Renal cell carcinoma	0	1	4	11	0	0	0	0

TABLE 17 NEOPLASTIC LESIONS (LIVER) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE : MALE

Group Name	Control	5 ppm	30 ppm	90 ppm
SITE : liver				
TUMOUR : hepatocellular carcinoma				
Overall Rates (a)	10/50 (20.0)	0/50 ( 0.0)	7/50 (14.0)	10/48 (20.8)
Adjusted Rates (b)	21.21	0.0	15.00	23.68
Terminal Rates (c)	7/33 (21.2)	0/38 ( 0.0)	5/36 (13.9)	7/35 (20.0)
Standard Rates (d)	P=0.4773			
Prevalence Rates (d)	P=0.0319*			
Combind analysis (d)	P=0.0461*			
Cochran-Armitage Test (e)	P=0.0993			
Fisher Exact Test (e)		P=0.0016**	P=0.3417	P=0.4361
SITE : liver				
TUMOUR : hepatocellular adenoma, hepatocellular carcinoma				
Overall Rates (a)	14/50 (28.0)	7/50 (14.0)	12/50 (24.0)	17/48 (35.4)
Adjusted Rates (b)	28.95	17.50	23.08	42.11
Terminal Rates (c)	9/33 (27.3)	6/38 (15.8)	7/36 (19.4)	14/35 (40.0)
Standard Rates (d)	P=0.6219			
Prevalence Rates (d)	P=0.0133*			
Combind analysis (d)	P=0.0292*			
Cochran-Armitage Test (e)	P=0.0704			
Fisher Exact Test (e)		P=0.1246	P=0.4489	P=0.3587

(a): Number of tumor-bearing animals/number of animals examined at the site.

(b): Kaplan-Meire estimate tumor incidence at the end of 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

Combind analysis : Death analysis + Incidental tumor test

(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

TABLE 18 NEOPLASTIC LESIONS (LIVER) INCIDENCE AND STATISTICAL ANALYSIS : MOUSE : FEMALE

Group Name	Control	5 ppm	30 ppm	90 ppm
SITE : liver				
TUMOUR : hepatocellular carcinoma				
Overall Rates (a)	1/50 ( 2.0)	1/49 ( 2.0)	0/50 ( 0.0)	3/48 ( 6.3)
Adjusted Rates (b)	0.0	2.78	0.0	8.82
Terminal Rates (c)	0/29 ( 0.0)	1/36 ( 2.8)	0/25 ( 0.0)	1/24 ( 4.2)
Standard Rates (d)	P=1.0000 ?			
Prevalence Rates (d)	P=0.0177*			
Combind analysis (d)	P=0.0596			
Cochran-Armitage Test (e)	P=0.1224			
Fisher Exact Test (e)		P=0.2525	P=0.4950	P=0.3087
SITE : liver				
TUMOUR : hepatocellular adenoma, hepatocellular carcinoma				
Overall Rates (a)	2/50 ( 4.0)	2/49 ( 4.1)	4/50 ( 8.0)	6/48 (12.5)
Adjusted Rates (b)	3.45	5.56	13.33	17.65
Terminal Rates (c)	1/29 ( 3.4)	2/36 ( 5.6)	3/25 (12.0)	4/24 (16.7)
Standard Rates (d)	P=1.0000 ?			
Prevalence Rates (d)	P=0.0096**			
Combind analysis (d)	P=0.0208*			
Cochran-Armitage Test (e)	P=0.0620			
Fisher Exact Test (e)		P=0.3162	P=0.3574	P=0.1475

(a): Number of tumor-bearing animals/number of animals examined at the site.

(b): Kaplan-Meire estimate tumor incidence at the end of 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

Combind analysis : Death analysis + Incidental tumor test

(e): The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates.

? : The conditional probabilities of the largest and smallest possible outcomes can not be estimated or this P-value beyond the estimated P-value.

TABLE 19 NUMBER OF MOUSE WITH SELECTED LIVER LESIONS

Group	Male				Female			
	Control	5ppm	30ppm	90ppm	Control	5ppm	30ppm	90ppm
Number of examined	50	50	50	48	50	49	50	48
Congestion	0	0	0	0	0	0	0	1
Angiectasis	2	0	3	2	4	4	4	8
Peliosis-like lesion	0	0	1	0	1	0	0	0
Necrosis:central	0	0	0	3	1	0	1	2
Necrosis:focal	1	2	6	2	0	0	2	3
Fatty change	4	2	6	24	0	0	0	1
Cyst	1	0	0	1	3	3	0	0
Deposit of amyloid	1	0	0	0	0	0	0	0
Inflammatory infiltration	0	0	0	1	0	1	1	2
Lymphocytic infiltration	1	0	0	0	0	0	0	1
Granulation	28	30	26	20	26	27	17	15
Leukemic cell infiltration	2	3	5	2	9	13	9	8
Metastasis:subcutis tumor	1	0	0	0	7	2	7	12
Metastasis:epididymis tumor	0	1	0	1	1	0	1	1
Clear cell focus	6	0	0	3	0	1	0	3
Basophilic cell focus	3	1	1	1	0	0	1	2
Mixed cell focus	1	0	0	1	0	0	1	1
Vacuolic change:central	0	0	0	0	0	0	0	5
Hemangioma	0	0	1	0	0	0	0	0
Hepatocellular adenoma	5	7	6	8	1	1	4	3
Histiocytic sarcoma	2	0	0	0	0	0	1	0
Hemangiosarcoma	3	0	2	1	2	0	0	1
Hepatocellular carcinoma	10	0	7	10	1	1	0	3

