

m-フェニレンジアミン=二塩酸塩の
ラット及びマウスを用いた
経口によるがん原性試験結果報告書

表 ・ 図

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表 1 試験計画と方法

表 1 試験の計画と方法

	急性毒性試験	2週間毒性試験	13週間毒性試験	がん原性試験
〔 動 物 〕				
使 用 動 物 種	ラット F344 マウス BDF ₁	同 左 同 左	同 左 同 左	同 左 同 左
供 給 業 者	日本チャールス・リバー	同 左	同 左	同 左
投与開始時までの期間	1週間	2週間	2週間	2週間
投与開始時の動物の週令	6週令	同 左	同 左	同 左
定 期 解 剖 時 の 週 令	8週令	8週間	19 ～20週令	110～111週令

	急性毒性試験	2週間毒性試験	13週間毒性試験	がん原性試験
〔試験計画〕				
投与方法	強制経口	経口 (飲水に混ぜ自由摂取)	同 左	同 左
群構成	雌雄各6群	同 左	同 左	雌雄各4群
使用動物数	雄60匹、雌60匹 10匹/群	同 左	同 左	雄200匹、雌200匹 50匹/群
投与濃度	ラット 800mg/kg/BW 471 277 163 96 0	ラット 22,000ppm 7,500 2,500 833 278 0	ラット 1,000ppm 500 250 125 62.5 0	ラット 400ppm 160 64 0
	マウス 345mg/kg/BW 230 153 102 68 0	マウス 9,000ppm 3,000 1,000 333 111 0	マウス 2,000ppm 667 222 74.1 24.4 0	マウス 180ppm 60 20 0

	急性毒性試験	2週間毒性試験	13週間毒性試験	がん原性試験
投 与 と 期 間	1 回	1 4日間連続	92～94日連続	104週間連続
観 察	一般状態の観察： 毎日体重測定 投与当日,1,2,3,4,7, 10,14	同 左 体重測定 投与開始日,1,2,4,7, 10,14	同 左 体重測定：毎週 摂餌量の測定：毎週 摂水量の測定：毎週 木曜日から月曜日の 間	同 左 体重測定：14週まで毎週、 それ以降は隔週 摂餌量の測定：14週まで 毎週それ以降は隔週 摂水量の測定：14週まで 毎週木曜日から月曜日の 間、それ以降は隔週の木 曜日から月曜日の間
解剖と病理学的検査	解剖：全動物 病理組織学的検査： 死亡動物 瀕死動物 各群より2例	同 左	解剖：全動物 病理組織学的検査： 全動物 血液・生化学的検査： 全動物	同 左

	急性毒性試験	2週間毒性試験	13週間毒性試験	がん原性試験
〔動物管理〕				
飼料	CRF-1固型 (放射線滅菌) オリエンタル酵母 給餌は自由摂取	同 左	同 左	同 左
飲料水	市水を紫外線滅菌して 使用 自動給水装置により 自由摂取	市水を紫外線滅菌して 使用 給水びんにより自由摂 取させる。	同 左	同 左
ケージ中の動物数	1匹	1匹	1匹	1匹
飼育室の環境	バリアシステム 温度 $24 \pm 1^{\circ}\text{C}$ 湿度 $50 \pm 5\%$ 照明時間12時間 換気回数15~17回/時	同 左	同 左	バリアシステム 温度 $24 \pm 1^{\circ}\text{C}$ 湿度 $50 \pm 5\%$ 照明時間12時間 換気回数15~17回/時

	急性毒性試験	2週間毒性試験	13週間毒性試験	がん原性試験
〔被験物質〕				
被験物質中の濃度 測定方法	紫外分光光度法	高速液クロ法	同 左	同 左
測定回数	1回	1回	1回／月	1回／3ヶ月

表 2 生存動物数（ラット・急性試験）

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0007

SEX	DOSE LEVEL (MG/KG)	ANIMALS INITIALLY IN STUDY	TIME AFTER ADMINISTRATION														SURVIVAL RATE *
			HOURS				DAYS										
			1	2	4	6	1	2	3	4	5	6	7	8	9	10	
MALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	96	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	163	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	277	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9/10
	471	10	10	10	10	10	8	8	1	1	1	1	1	1	1	1	1/10
	800	10	10	10	10	10	0	0	0	0	0	0	0	0	0	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	96	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	163	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9/10
	277	10	10	10	10	10	9	9	9	5	5	5	5	5	5	5	5/10
	471	10	10	10	10	10	3	1	0	0	0	0	0	0	0	0	0/10
	800	10	10	10	10	10	1	0	0	0	0	0	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0007

SEX	DOSE LEVEL (MG/KG)	ANIMALS INITIALLY IN STUDY	TIME AFTER ADMINISTRATION DAYS				SURVIVAL RATE *
			11	12	13	14	
MALE	CONTROL	10	10	10	10	10	10/10
	96	10	10	10	10	10	10/10
	163	10	10	10	10	10	10/10
	277	10	9	9	9	9	9/10
	471	10	1	1	1	1	1/10
	800	10	0	0	0	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10/10
	96	10	10	10	10	10	10/10
	163	10	9	9	9	9	9/10
	277	10	5	5	5	5	5/10
	471	10	0	0	0	0	0/10
	800	10	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表 3 体重値（ラット・急性試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0007

SEX	DOSE LEVEL (MG/KG)	DAYS AFTER ADMINISTRATION													
		0		1		2		3		4		7		10	
MALE	CONTROL	102 ±	3	116 ±	3	122 ±	3	127 ±	4	132 ±	5	148 ±	7	165 ±	8
	96	102 ±	3	109 ±	4***	116 ±	5**	120 ±	4***	126 ±	5*	141 ±	7*	158 ±	8
	163	102 ±	3	106 ±	5***	110 ±	5***	111 ±	6***	116 ±	6***	132 ±	7***	148 ±	9***
	277	103 ±	3	102 ±	5***	103 ±	6***	105 ±	8***	111 ±	7***	131 ±	8***	149 ±	9***
	471	103 ±	3	99 ±	4***	97 ±	4***	106 ±	0	110 ±	0	131 ±	0	151 ±	0
	800	103 ±	3												
FEMALE	CONTROL	87 ±	2	94 ±	8	99 ±	5	102 ±	4	105 ±	3	114 ±	4	123 ±	4
	96	87 ±	2	92 ±	4	94 ±	4*	95 ±	4***	100 ±	4**	110 ±	4	120 ±	4
	163	87 ±	2	87 ±	3*	88 ±	3***	88 ±	4***	92 ±	6***	106 ±	4***	115 ±	3***
	277	87 ±	2	83 ±	3**	83 ±	3***	82 ±	4***	87 ±	5***	101 ±	3***	114 ±	3***
	471	87 ±	2	80 ±	1***	80 ±	0								
	800	87 ±	2	83 ±	0										

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0007

SEX	DOSE LEVEL (MG/KG)	DAYS AFTER ADMINISTRATION 14	
MALE	CONTROL	188 ±	9
	96	178 ±	10*
	163	169 ±	11***
	277	173 ±	9**
	471	177 ±	0
	800		
FEMALE	CONTROL	134 ±	5
	96	129 ±	4*
	163	127 ±	4**
	277	126 ±	3**
	471		
	800		

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表 4 生存動物数（ラット・2週間試験）

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0026

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION DAYS														SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	
MALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	278	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	833	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	2500	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	7500	10	10	10	10	10	10	10	10	10	10	10	9	3	0	0	0/10
	22500	10	10	10	10	10	10	10	10	10	10	10	8	3	0	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	278	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	833	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	2500	10	10	10	10	10	10	10	9	8	8	6	4	2	2	1	1/10
	7500	10	10	10	10	10	10	10	9	8	5	3	0	0	0	0	0/10
	22500	10	10	10	10	10	10	10	10	9	2	1	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

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表 5 体重値（ラット・2 週間試験）

TABLE BODY WEIGHT CHANGES (G)

STUDY NO. : 0026

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (DAYS)
	0	1
		2
		4
		7
		10
		14

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (DAYS)					
		0	1	2	4	7	10
MALE	CONTROL	134 ± 4	139 ± 4	143 ± 4	153 ± 5	168 ± 6	183 ± 7
	278	134 ± 4	138 ± 4	143 ± 5	153 ± 5	169 ± 6	184 ± 7
	833	134 ± 4	128 ± 4	128 ± 4	138 ± 5	151 ± 6	163 ± 7
	2500	134 ± 4	124 ± 3	117 ± 3	108 ± 5	98 ± 8	88 ± 8
	7500	134 ± 4	123 ± 4	114 ± 4	101 ± 4	86 ± 4	72 ± 4
FEMALE	CONTROL	108 ± 4	112 ± 4	113 ± 4	118 ± 4	126 ± 5	134 ± 5
	278	108 ± 4	109 ± 3	111 ± 3	116 ± 4	124 ± 4	131 ± 4
	833	109 ± 4	101 ± 4	98 ± 4	99 ± 4	105 ± 5	111 ± 6
	2500	109 ± 4	99 ± 3	93 ± 3	83 ± 4	71 ± 6	63 ± 6
	7500	109 ± 4	98 ± 3	92 ± 3	81 ± 3	68 ± 2	57 ± 1
FEMALE CONTROL	22500	109 ± 4	99 ± 4	92 ± 4	81 ± 3	67 ± 4	60 ± 0

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (DAYS)
	0	1
		2
		4
		7
		10
		14

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表 6 生存動物数（ラット・13週間試験）

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0038

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	
MALE	0	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	62.5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	125	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	250	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	500	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	1000	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
FEMALE	0	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	62.5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	125	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	250	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	500	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	1000	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表7 体重値（ラット・13週間試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0038

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)													
		0		1		2		3		4		5		6	
MALE	0	135 ±	5	174 ±	7	208 ±	8	240 ±	10	264 ±	11	284 ±	13	300 ±	14
	62.5	135 ±	5	175 ±	7	209 ±	7	238 ±	9	261 ±	11	279 ±	11	295 ±	13
	125	135 ±	5	176 ±	7	207 ±	8	234 ±	8	258 ±	8	278 ±	9	293 ±	8
	250	135 ±	5	175 ±	6	206 ±	8	235 ±	8	259 ±	9	279 ±	9	296 ±	10
	500	135 ±	5	166 ±	6*	195 ±	10**	218 ±	13***	238 ±	14***	258 ±	15***	274 ±	15***
	1000	135 ±	5	148 ±	7***	171 ±	11***	191 ±	13***	207 ±	15***	220 ±	17***	233 ±	18***
FEMALE	0	103 ±	3	122 ±	4	136 ±	5	146 ±	6	157 ±	7	167 ±	7	175 ±	8
	62.5	103 ±	3	122 ±	3	136 ±	3	146 ±	3	158 ±	4	165 ±	4	173 ±	5
	125	103 ±	3	123 ±	5	137 ±	5	147 ±	5	158 ±	7	166 ±	9	174 ±	10
	250	103 ±	3	121 ±	4	135 ±	5	146 ±	5	156 ±	6	166 ±	8	171 ±	7
	500	103 ±	3	111 ±	5***	124 ±	6***	136 ±	6**	147 ±	8**	153 ±	8***	158 ±	8***
	1000	103 ±	3	88 ±	6***	100 ±	9***	113 ±	8***	121 ±	8***	126 ±	8***	129 ±	8***

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0038

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		7	8	9	10	11	12	13
MALE	0	316 ± 13	332 ± 15	345 ± 15	355 ± 15	365 ± 15	371 ± 15	380 ± 15
	62.5	311 ± 14	325 ± 14	336 ± 15	345 ± 14	355 ± 15	362 ± 14	371 ± 16
	125	309 ± 9	323 ± 9	334 ± 10	343 ± 12	351 ± 12*	359 ± 13	368 ± 13
	250	312 ± 10	326 ± 10	339 ± 11	348 ± 11	357 ± 13	365 ± 13	375 ± 14
	500	288 ± 15***	301 ± 17***	312 ± 17***	320 ± 17***	325 ± 19***	331 ± 18***	340 ± 19***
	1000	245 ± 19***	255 ± 21***	265 ± 21***	270 ± 23***	276 ± 23***	281 ± 24***	287 ± 24***
FEMALE	0	181 ± 8	188 ± 9	192 ± 10	198 ± 10	201 ± 11	202 ± 11	206 ± 11
	62.5	180 ± 6	186 ± 7	191 ± 7	196 ± 8	199 ± 8	200 ± 8	203 ± 6
	125	180 ± 9	186 ± 11	191 ± 11	196 ± 10	200 ± 10	199 ± 10	204 ± 9
	250	177 ± 9	183 ± 9	188 ± 11	191 ± 10	195 ± 10	194 ± 11	199 ± 11
	500	162 ± 10***	166 ± 10***	170 ± 11***	173 ± 13***	175 ± 11***	177 ± 10***	179 ± 11***
	1000	132 ± 7***	136 ± 7***	137 ± 7***	140 ± 8***	142 ± 9***	143 ± 8***	144 ± 8***

表 8 生存動物数（ラット・がん原性試験）

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			14	15	16	17	18	19	20	21	22	23	24	25	26	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			27	28	29	30	31	32	33	34	35	36	37	38	39	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

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TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			40	41	42	43	44	45	46	47	48	49	50	51	52	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

(C100)

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TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			53	54	55	56	57	58	59	60	61	62	63	64	65	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	160	50	50	50	50	49	49	49	49	49	49	49	49	49	49	49/50
	400	50	50	50	49	49	49	49	49	49	49	49	49	49	49	49/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	64	50	50	50	50	50	50	50	49	49	49	49	49	49	49	49/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

(C100)

BAIS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			66	67	68	69	70	71	72	73	74	75	76	77	78	
MALE	CONTROL	50	50	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	64	50	50	50	50	50	50	50	50	50	50	50	50	49	49	49/50
	160	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	400	50	49	49	49	49	49	49	49	49	49	49	49	49	48	48/50
FEMALE	CONTROL	50	50	50	49	49	49	49	49	49	49	49	49	49	49	49/50
	64	50	49	49	49	49	49	49	49	48	48	48	48	48	48	48/50
	160	50	50	50	50	50	50	50	50	50	50	50	50	49	49	49/50
	400	50	50	50	50	50	50	50	50	50	50	50	50	49	49	49/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

(C100)

BAIS

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			79	80	81	82	83	84	85	86	87	88	89	90	91	
MALE	CONTROL	50	48	48	48	48	48	48	47	46	45	45	45	45	44	44/50
	64	50	49	49	49	48	48	48	48	48	48	48	47	47	46	46/50
	160	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	400	50	48	48	47	47	47	46	46	45	45	44	43	42	42	42/50
FEMALE	CONTROL	50	49	49	49	49	47	47	47	46	46	46	46	46	46	46/50
	64	50	48	48	48	48	48	47	46	45	45	44	44	44	42	42/50
	160	50	49	49	49	49	49	49	49	49	49	49	49	48	48	48/50
	400	50	49	49	49	49	49	49	49	48	48	48	48	47	47	47/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			92	93	94	95	96	97	98	99	100	101	102	103	104	
MALE	CONTROL	50	44	44	44	44	43	43	43	43	43	42	42	42	41	41/50
	64	50	46	46	46	46	46	45	45	44	43	43	43	43	43	43/50
	160	50	49	49	49	49	49	48	48	47	46	45	44	42	42	42/50
	400	50	42	42	42	42	41	41	40	40	40	39	39	37	37	37/50
FEMALE	CONTROL	50	45	45	45	45	44	44	44	43	42	42	41	41	41	41/50
	64	50	42	41	41	41	41	40	40	40	40	39	39	39	39	39/50
	160	50	48	47	47	47	47	47	47	47	46	42	42	41	40	40/50
	400	50	47	47	47	47	47	47	47	47	47	47	47	46	42	42/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表 9 体重値（ラット・がん原性試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)									
		0	1	2	3	4	5	6			
MALE	CONTROL	131 ± 5	169 ± 7	203 ± 10	231 ± 10	251 ± 11	268 ± 11	284 ± 13			
	64	132 ± 5	169 ± 7	204 ± 10	232 ± 10	252 ± 10	270 ± 11	286 ± 11			
	160	131 ± 5	168 ± 6	202 ± 9	229 ± 9	249 ± 10	266 ± 10	282 ± 11			
	400	131 ± 5	163 ± 7***	196 ± 7***	224 ± 8***	243 ± 8***	261 ± 9***	276 ± 9**			
FEMALE	CONTROL	103 ± 3	122 ± 4	138 ± 5	150 ± 5	158 ± 5	167 ± 6	173 ± 7			
	64	103 ± 3	123 ± 4	139 ± 5	152 ± 4*	160 ± 5*	170 ± 6*	178 ± 6***			
	160	103 ± 3	122 ± 4	138 ± 5	150 ± 6	158 ± 6	167 ± 7	173 ± 8			
	400	103 ± 3	117 ± 4***	132 ± 5***	144 ± 6***	150 ± 6***	158 ± 7***	164 ± 7***			

(C200)

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TABLE BODY WEIGHT CHANGES (G) STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		8	9	10	11	12	13
		7							
MALE	CONTROL	297 ± 13		310 ± 14	320 ± 14	328 ± 14	336 ± 14	343 ± 14	349 ± 14
	64	299 ± 12		312 ± 13	323 ± 13	332 ± 13	341 ± 14	347 ± 14	354 ± 14
	160	295 ± 11		308 ± 12	319 ± 13	327 ± 13	335 ± 13	342 ± 14	348 ± 15
	400	288 ± 10***		300 ± 11***	311 ± 12**	319 ± 12**	327 ± 12**	333 ± 13**	340 ± 13**
FEMALE	CONTROL	179 ± 8		184 ± 9	190 ± 10	193 ± 10	198 ± 10	200 ± 11	203 ± 11
	64	184 ± 7***		189 ± 7**	194 ± 7*	198 ± 8**	203 ± 8**	206 ± 8**	209 ± 8**
	160	179 ± 9		184 ± 10	190 ± 10	193 ± 10	198 ± 10	202 ± 11	204 ± 11
	400	168 ± 8***		173 ± 9***	177 ± 9***	180 ± 10***	185 ± 10***	187 ± 10***	189 ± 10***

(C200)

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TABLE BODY WEIGHT CHANGES (G) STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)							
		14	16	18	20	22	24	26	
MALE	CONTROL	354 ± 14	364 ± 15	372 ± 16	380 ± 15	389 ± 17	397 ± 17	403 ± 18	
	64	359 ± 15	369 ± 16	378 ± 17	387 ± 17*	396 ± 18	403 ± 17	409 ± 18	
	160	352 ± 15	361 ± 17	370 ± 17	379 ± 18	388 ± 19	394 ± 20	401 ± 20	
	400	345 ± 13**	355 ± 14**	364 ± 14*	373 ± 15*	382 ± 16*	389 ± 16*	395 ± 17*	
FEMALE	CONTROL	205 ± 11	208 ± 12	212 ± 12	216 ± 12	220 ± 13	223 ± 14	226 ± 15	
	64	210 ± 8**	215 ± 9**	219 ± 9***	223 ± 9**	229 ± 9***	231 ± 10**	235 ± 11***	
	160	206 ± 10	210 ± 11	214 ± 11	217 ± 12	223 ± 12	225 ± 12	229 ± 12	
	400	192 ± 10***	196 ± 11***	200 ± 11***	203 ± 11***	207 ± 11***	209 ± 11***	212 ± 12***	

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		32	34	36	38	40
		28	30					
MALE	CONTROL	410 ± 18	416 ± 18	420 ± 18	426 ± 19	429 ± 20	433 ± 20	437 ± 23
	64	416 ± 18	422 ± 19	426 ± 18	431 ± 19	436 ± 19	439 ± 20	444 ± 20
	160	408 ± 21	414 ± 22	418 ± 22	423 ± 22	428 ± 23	431 ± 23	436 ± 24
	400	402 ± 17*	407 ± 18*	413 ± 17	418 ± 17*	422 ± 18	425 ± 19	431 ± 19
FEMALE	CONTROL	230 ± 15	233 ± 15	236 ± 18	238 ± 18	241 ± 18	243 ± 19	245 ± 18
	64	238 ± 11**	242 ± 12**	245 ± 11**	248 ± 12**	250 ± 12**	251 ± 13**	254 ± 14**
	160	231 ± 13	235 ± 14	239 ± 14	241 ± 14	244 ± 15	246 ± 16	248 ± 17
	400	215 ± 13***	217 ± 13***	221 ± 13***	223 ± 14***	226 ± 14***	227 ± 14***	230 ± 14***

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		42	44	46	48	50	52	54
MALE	CONTROL	440 $\pm$ 21	445 $\pm$ 22	448 $\pm$ 22	453 $\pm$ 22	454 $\pm$ 23	457 $\pm$ 23	461 $\pm$ 22
	64	447 $\pm$ 20	452 $\pm$ 20	454 $\pm$ 20	459 $\pm$ 21	461 $\pm$ 20	464 $\pm$ 21	467 $\pm$ 22
	160	438 $\pm$ 24	443 $\pm$ 24	446 $\pm$ 24	451 $\pm$ 24	454 $\pm$ 24	457 $\pm$ 25	461 $\pm$ 33
	400	434 $\pm$ 19	438 $\pm$ 20	441 $\pm$ 20	445 $\pm$ 21	447 $\pm$ 21	448 $\pm$ 21*	449 $\pm$ 21*
FEMALE	CONTROL	248 $\pm$ 19	252 $\pm$ 19	255 $\pm$ 19	258 $\pm$ 20	261 $\pm$ 20	263 $\pm$ 21	266 $\pm$ 22
	64	257 $\pm$ 14**	261 $\pm$ 15*	264 $\pm$ 15**	268 $\pm$ 16**	270 $\pm$ 16*	273 $\pm$ 17*	276 $\pm$ 19*
	160	251 $\pm$ 17	254 $\pm$ 17	256 $\pm$ 17	260 $\pm$ 18	263 $\pm$ 19	266 $\pm$ 20	268 $\pm$ 20
	400	232 $\pm$ 14***	235 $\pm$ 15***	237 $\pm$ 15***	240 $\pm$ 15***	241 $\pm$ 15***	242 $\pm$ 16***	244 $\pm$ 16***

(C200)

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TABLE BODY WEIGHT CHANGES (G) STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		60	62	64	66	68
		56	58					
MALE	CONTROL	464 ± 24	469 ± 25	472 ± 27	476 ± 25	478 ± 26	482 ± 26	486 ± 26
	64	471 ± 22	477 ± 22	478 ± 21	482 ± 22	484 ± 22	486 ± 23	489 ± 22
	160	462 ± 26	466 ± 26	468 ± 26	470 ± 25	472 ± 25	474 ± 24	476 ± 25
	400	453 ± 22*	457 ± 22*	461 ± 23*	462 ± 24**	462 ± 24**	463 ± 23***	465 ± 24***
FEMALE	CONTROL	270 ± 23	276 ± 25	280 ± 26	286 ± 27	292 ± 28	295 ± 31	300 ± 38
	64	279 ± 22*	284 ± 26	290 ± 23*	296 ± 25	301 ± 25	305 ± 25	312 ± 26
	160	271 ± 22	278 ± 23	282 ± 24	287 ± 25	293 ± 25	297 ± 27	304 ± 27
	400	247 ± 17***	253 ± 17***	259 ± 18***	261 ± 19***	264 ± 20***	266 ± 21***	272 ± 22***

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		74	76	78	80	82
		70	72					
MALE	CONTROL	488 ± 26	490 ± 26	491 ± 26	493 ± 27	492 ± 28	493 ± 29	492 ± 28
	64	489 ± 23	492 ± 23	493 ± 23	493 ± 26	493 ± 26	491 ± 27	491 ± 26
	160	477 ± 25*	480 ± 26*	480 ± 25*	482 ± 25*	480 ± 25*	478 ± 25**	476 ± 26**
	400	464 ± 24***	464 ± 24***	464 ± 24***	462 ± 26***	460 ± 27***	453 ± 32***	448 ± 37***
FEMALE	CONTROL	308 ± 31	313 ± 31	317 ± 32	321 ± 33	324 ± 33	324 ± 32	326 ± 34
	64	316 ± 25	319 ± 28	323 ± 26	327 ± 25	329 ± 25	331 ± 26	331 ± 26
	160	308 ± 28	314 ± 28	317 ± 29	320 ± 32	324 ± 30	325 ± 31	328 ± 31
	400	274 ± 23***	278 ± 23***	280 ± 24***	282 ± 25***	286 ± 26***	287 ± 27***	287 ± 27***

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)			
		98	100	102	104
MALE	CONTROL	468 ± 32	457 ± 37	451 ± 44	440 ± 50
	64	465 ± 32	456 ± 40	448 ± 57	436 ± 73
	160	444 ± 26***	434 ± 29**	428 ± 38*	421 ± 35
	400	404 ± 39***	397 ± 39***	389 ± 41***	377 ± 44***
FEMALE	CONTROL	338 ± 36	340 ± 42	338 ± 45	335 ± 47
	64	331 ± 33	329 ± 36	327 ± 42	320 ± 46
	160	328 ± 42	323 ± 51	331 ± 38	328 ± 44
	400	275 ± 33***	268 ± 35***	258 ± 42***	258 ± 37***

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		88	90	92	94	96
		84	86					
MALE	CONTROL	489 ± 28	485 ± 28	483 ± 33	480 ± 36	481 ± 27	475 ± 36	474 ± 29
	64	490 ± 28	486 ± 30	483 ± 34	480 ± 39	482 ± 29	477 ± 30	468 ± 32
	160	473 ± 26**	470 ± 26**	468 ± 25*	464 ± 26*	461 ± 25***	455 ± 25**	448 ± 27***
	400	439 ± 50***	440 ± 43***	436 ± 44***	437 ± 27***	430 ± 29***	422 ± 34***	416 ± 29***
FEMALE	CONTROL	328 ± 34	330 ± 34	333 ± 35	333 ± 38	339 ± 31	340 ± 31	339 ± 34
	64	330 ± 29	332 ± 28	331 ± 31	327 ± 35	330 ± 37	331 ± 34	328 ± 39
	160	331 ± 32	331 ± 32	332 ± 34	333 ± 35	332 ± 39	334 ± 35	332 ± 37
	400	288 ± 28***	287 ± 27***	288 ± 28***	287 ± 28***	285 ± 30***	283 ± 30***	279 ± 31***

(C200)

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表 1 0 腫瘍性病変総数（良性／悪性）及び担癌動物数
（ラット・がん原性試験）

表 1 0 腫瘍性病変総数（良性／悪性）及び担癌動物数
（ラット・癌原性試験）

TABLE NO. OF TUMORS (BENIGN/MALIGNANT)
AND NO. OF ANIMALS WITH TUMORS (SINGLE/MULTIPLE)

STUDY NO. : 0059

SEX : MALE

SUMMARY OF TUMORS	SUMMARY			
	A	B	C	D
NO. OF BENIGN TUMORS	110	124	110	108
NO. OF MALIGNANT TUMORS	13	13	16	9
NO. OF TOTAL TUMORS	123	137	126	117
NO. OF ANIMALS WITH A SINGLE TUMOR	7	3	6	9
NO. OF ANIMALS WITH MULTIPLE TUMOR	43	47	44	40
NO. OF EXAMINED ANIMALS	50	50	50	50
A: 0 (PPM)	B: 64 (PPM)	C: 160 (PPM)	D: 400 (PPM)	

TABLE NO. OF TUMORS (BENIGN/MALIGNANT)
AND NO. OF ANIMALS WITH TUMORS (SINGLE/MULTIPLE)

STUDY NO. : 0059

SEX : FEMALE

SUMMARY OF TUMORS	SUMMARY			
	A	B	C	D
NO. OF BENIGN TUMORS	70	63	73	74
NO. OF MALIGNANT TUMORS	18	14	12	9
NO. OF TOTAL TUMORS	88	77	85	83
NO. OF ANIMALS WITH A SINGLE TUMOR	17	25	10	19
NO. OF ANIMALS WITH MULTIPLE TUMOR	29	22	31	27
NO. OF EXAMINED ANIMALS	50	50	50	50
A: 0 (PPM)	B: 64 (PPM)	C: 160 (PPM)	D: 400 (PPM)	

表 1 1 腫瘍性病変（発生頻度）－全動物・全期間－
（ラット・がん原性試験）

表 1 1 腫瘍性病変（発生頻度）－全動物・全期間－
（ラット・癌原性試験）

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS)

STUDY NO. : 0059

SEX : MALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPM) NO. OF EXAMINED ANIMALS	0	64	160	400
			50	50	50	50
BRAIN	GLIOMA		0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)
SPINAL CORD	GLIOMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
LUNG	+ALVEOLAR/BRONCHIOLAR ADENOMA		1 (2.0)	2 (4.0)	2 (4.0)	0 (0.0)
	+ALVEOLAR/BRONCHIOLAR CARCINOMA		0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)
THYROID	+ADENOMA		2 (4.0)	3 (6.0)	0 (0.0)	0 (0.0)
	+ADENOCARCINOMA		2 (4.0)	0 (0.0)	2 (4.0)	0 (0.0)
	+C-CELL ADENOMA		4 (8.0)	6 (12.0)	5 (10.0)	7 (14.0)
	+C-CELL CARCINOMA		0 (0.0)	1 (2.0)	1 (2.0)	2 (4.0)
LIVER	+ADENOMA		3 (6.0)	3 (6.0)	0 (0.0)	2 (4.0)
	+HEPATOCELLULAR CARCINOMA		0 (0.0)	0 (0.0)	1 (2.0)	1 (2.0)
COLON	+ALIGNANT SCHWANNOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
URINARY BLADDER	+PAPILLOMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
TESTIS	+INTERSTITIAL CELL TUMOR		47 (94.0)	47 (94.0)	47 (94.0)	47 (94.0)
SPLEEN	+LEUKEMIA		5 (10.0)	8 (16.0)	5 (10.0)	1 (2.0)
	+HEMANGIOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
	+ANGIOSARCOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
LYMPH NODES	+SARCOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
PANCREATIC ISLET	+ADENOMA		4 (8.0)	4 (8.0)	9 (18.0)	6 (12.0)
	+ADENOCARCINOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
EXOCRINE PANCREAS	+ADENOMA		1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)
MAMMARY GLAND	+ADENOMA		2 (4.0)	1 (2.0)	0 (0.0)	0 (0.0)
	+FIBROADENOMA		0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)
SKIN	+PAPILLOMA		1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
	+ADENOMA		2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)
	+TRICHOEPITHELIOMA		1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
+ : BENIGN * : MALIGNANT						

STUDY NO. : 0059

SEX : MALE

ORGAN_____	TYPE OF TUMOR____	DOSE LEVEL (PPM)							
		NO. OF EXAMINED ANIMALS	50	0	64	160	400		

SKIN	+KERATOACANTHOMA		1 (2.0)		6 (12.0)		5 (10.0)		3 (6.0)
SUBCUTANEOUS TISSUE	*SARCOMA		0 (0.0)		0 (0.0)		1 (2.0)		0 (0.0)
	+FIBRINOMA		4 (8.0)		3 (6.0)		2 (4.0)		2 (4.0)
	+LIPOMA		0 (0.0)		0 (0.0)		2 (4.0)		1 (2.0)
	+HEMANGIOMA		1 (2.0)		1 (2.0)		2 (4.0)		0 (0.0)
	*ALIGNANT SCHWANNOMA		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)
PITUITARY	+ADENOMA		27 (54.0)		30 (60.0)		23 (46.0)		26 (52.0)
ADRENAL	+ADENOMA		0 (0.0)		0 (0.0)		0 (0.0)		2 (4.0)
	+PHEOCHROMOCYTOMA		8 (16.0)		11 (22.0)		9 (18.0)		9 (18.0)
	*ALIGNANT PHEOCHROMOCYTOMA		3 (6.0)		2 (4.0)		0 (0.0)		0 (0.0)
BONE	*OSTEOGENIC SARCOMA		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)
PERITONEUM	*MESOTHELIOMA		2 (4.0)		0 (0.0)		0 (0.0)		2 (4.0)
	*ALIGNANT SCHWANNOMA		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)
PREPUTIAL GLAND									
	+ADENOMA		1 (2.0)		4 (8.0)		4 (8.0)		0 (0.0)
ZYMBAI GLAND									
	+PAPILLOMA		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)

+ : BENIGN	* : MALIGNANT								

STUDY NO. : 0059

SEX : FEMALE

ORGAN_____	TYPE OF TUMOR____	DOSE LEVEL (PPM)		NO. OF EXAMINED ANIMALS			
		50	0	50	64	160	400
LUNG	+ALVEOLAR/BRONCHIOALAR ADENOMA	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	
	*ALVEOLAR/BRONCHIOALAR CARCINOMA	0 (0.0)	1 (2.0)	0 (0.0)			
THYROID	+ADENOMA	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)		
	+C-CELL ADENOMA	6 (12.0)	3 (6.0)	2 (4.0)	2 (4.0)		
	*C-CELL CARCINOMA	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)		
LIVER	+ADENOMA	1 (2.0)	0 (0.0)	1 (2.0)	1 (2.0)		
	*SARCOMA	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
KIDNEY	+ADENOMA	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)		
	*NEPHROBLASTOMA	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
COLON	+EPIDERMAL CYST	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
LARGE INTESTINE							
	*LEIOMYOSARCOMA	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)		
URINARY BLADDER							
	+PAPILLOMA	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
UTERUS	+PAPILLOMA	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)		
	+POLYP	10 (20.0)	8 (16.0)	11 (22.0)	12 (24.0)		
	*ADENOCARCINOMA	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)		
	*SARCOMA	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)		
SPLEEN	*LEUKEMIA	5 (10.0)	8 (16.0)	9 (18.0)	5 (10.0)		
	*ANGIOSARCOMA	0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)		
PANCREATIC ISLET							
	+ADENOMA	2 (4.0)	3 (6.0)	0 (0.0)	1 (2.0)		
	*ADENOCARCINOMA	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)		
MAMMARY GLAND							
	+ADENOMA	7 (14.0)	5 (10.0)	8 (16.0)	11 (22.0)		
	*ADENOCARCINOMA	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)		
	+FIBROADENOMA	3 (6.0)	0 (0.0)	0 (0.0)	2 (4.0)		
SKIN	+PAPILLOMA	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)		
	*KERATOCANTHOMA	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)		
SUBCUTANEOUS TISSUE							
	*SARCOMA	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
+ : BENIGN	* : MALIGNANT						

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS)

STUDY NO. : 0059

SEX : FEMALE

ORGAN_____	TYPE OF TUMOR___	DOSE LEVEL (PPM) NO. OF EXAMINED ANIMALS	0	64	160	400
			50	50	50	50
SUBCUTANEOUS TISSUE						
	+FIBROMA		0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)
MUSCLE	+OSTEOGENIC SARCOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
PITUITARY	+ADENOMA		27 (54.0)	31 (62.0)	34 (68.0)	32 (64.0)
ADRENAL	+ADENOMA		4 (8.0)	5 (10.0)	5 (10.0)	2 (4.0)
	+PHEOCHROMOCYTOMA		5 (10.0)	3 (6.0)	7 (14.0)	7 (14.0)
	+GANGLIONEUROMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
	+MALIGNANT PHEOCHROMOCYTOMA		2 (4.0)	1 (2.0)	0 (0.0)	1 (2.0)
OVARY	+MALIGN. GRANULOSA-THECA CELL TUMOR		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
TOOTH	+AMELOBLASTOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
BONE	+OSTEOGENIC SARCOMA		1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
CLITORAL GLAND						
	+ADENOMA		3 (6.0)	2 (4.0)	0 (0.0)	2 (4.0)
ZYMBAL GLAND						
	+SQUAMOUS CELL CARCINOMA		3 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)
+ : BENIGN - : MALIGNANT						

表 1 2 生存動物数（マウス・急性試験）

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0008

SEX	DOSE LEVEL (MG/KG)	ANIMALS INITIALLY IN STUDY	TIME AFTER ADMINISTRATION														SURVIVAL RATE *
			HOURS				DAYS										
			1	2	4	6	1	2	3	4	5	6	7	8	9	10	
MALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	68	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	102	10	10	10	10	10	10	10	9	8	8	8	8	8	8	8	8/10
	153	10	10	10	10	10	10	8	5	5	5	4	3	3	3	3	3/10
	230	10	10	10	10	9	8	2	1	1	0	0	0	0	0	0	0/10
	345	10	10	10	10	8	2	1	0	0	0	0	0	0	0	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	68	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	102	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9/10
	153	10	10	10	10	10	10	7	4	4	4	4	4	4	4	4	4/10
	230	10	10	10	10	10	8	4	1	1	1	1	1	1	1	1	1/10
	345	10	10	10	10	7	1	0	0	0	0	0	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0008

SEX	DOSE LEVEL (MG/KG)	ANIMALS INITIALLY IN STUDY	TIME AFTER ADMINISTRATION				SURVIVAL RATE *
			DAYS				
			11	12	13	14	
MALE	CONTROL	10	10	10	10	10	10/10
	68	10	10	10	10	10	10/10
	102	10	8	8	8	8	8/10
	153	10	3	3	3	3	3/10
	230	10	0	0	0	0	0/10
	345	10	0	0	0	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10/10
	68	10	10	10	10	10	10/10
	102	10	9	9	9	9	9/10
	153	10	4	4	4	4	4/10
	230	10	1	1	1	1	1/10
	345	10	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表 13 体重値（マウス・急性試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0008

SEX	DOSE LEVEL (MG/KG)	DAYS AFTER ADMINISTRATION						
		0	1	2	3	4	7	10
MALE	CONTROL	20.8 ± 0.7	24.1 ± 0.8	24.5 ± 0.9	25.0 ± 1.2	24.8 ± 1.5	25.5 ± 1.6	25.9 ± 1.5
	68	20.8 ± 0.7	20.8 ± 0.9***	21.7 ± 0.6***	22.7 ± 0.6***	23.7 ± 0.7*	24.6 ± 0.7	25.1 ± 0.7
	102	20.8 ± 0.7	20.4 ± 0.8***	20.3 ± 1.1***	21.2 ± 1.0***	22.5 ± 1.0**	23.6 ± 1.5*	24.6 ± 1.4
	153	20.8 ± 0.7	20.0 ± 0.7***	19.2 ± 1.2***	18.9 ± 2.3***	19.7 ± 2.7***	23.1 ± 0.4*	23.6 ± 0.5*
	230	20.8 ± 0.7	20.3 ± 0.8***	19.7 ± 0.3***	18.9 ± 0.0	18.1 ± 0.0		
	345	20.8 ± 0.7	20.1 ± 0.4***	19.0 ± 0.0				
FEMALE	CONTROL	15.7 ± 0.8	18.2 ± 1.2	18.5 ± 1.2	18.9 ± 1.2	18.7 ± 1.4	18.5 ± 1.0	18.6 ± 1.0
	68	15.7 ± 0.8	14.8 ± 0.8***	14.8 ± 1.4***	15.6 ± 1.2***	16.9 ± 1.1**	17.5 ± 0.9*	18.4 ± 0.9
	102	15.7 ± 0.8	14.9 ± 0.9***	14.4 ± 1.2***	14.7 ± 1.6***	15.7 ± 1.7***	17.6 ± 1.0	18.5 ± 1.0
	153	15.7 ± 0.8	14.7 ± 0.9***	14.0 ± 0.9***	14.9 ± 0.8***	15.7 ± 1.0**	18.7 ± 0.3	18.8 ± 0.4
	230	15.7 ± 0.8	15.0 ± 0.8***	14.3 ± 0.9***	16.2 ± 0.0	17.3 ± 0.0	17.7 ± 0.0	19.5 ± 0.0
	345	15.7 ± 0.8	14.6 ± 0.0					

TABLE BODY WEIGHT CHANGES (G)

STUDY NO. : 0008

SEX	DOSE LEVEL (MG/KG)	DAYS AFTER ADMINISTRATION 14
MALE	CONTROL	26.7 $\pm$ 1.4
	68	25.7 $\pm$ 0.7
	102	25.4 $\pm$ 1.8
	153	24.7 $\pm$ 0.7*
	230	
	345	
FEMALE	CONTROL	19.3 $\pm$ 1.2
	68	19.2 $\pm$ 1.0
	102	19.2 $\pm$ 1.1
	153	19.9 $\pm$ 0.5
	230	20.3 $\pm$ 0.0
	345	

表 1 4 生存動物数（マウス・2週間試験）

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0027

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION DAYS														SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	
MALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	111	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	333	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	1000	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	3000	10	10	10	10	10	10	10	10	10	9	9	8	8	8	6	6/10
	9000	10	10	10	10	10	10	9	9	8	7	6	3	2	1	0	0/10
FEMALE	CONTROL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	111	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	333	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	1000	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	3000	10	10	10	10	10	10	10	9	9	6	5	4	3	0	0	0/10
	9000	10	10	10	10	10	10	10	9	8	2	1	0	0	0	0	0/10

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表 1 5 体重値（マウス・2週間試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0027

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (DAYS)						
		0	1	2	4	7	10	14
MALE	CONTROL	25.1 ± 0.8	25.1 ± 0.8	25.5 ± 0.8	26.0 ± 0.8	26.7 ± 0.7	27.1 ± 1.2	27.1 ± 1.1
	111	25.1 ± 0.8	25.0 ± 0.9	25.3 ± 0.7	25.8 ± 0.6	26.5 ± 0.6	26.9 ± 0.8	27.0 ± 0.6
	333	25.1 ± 0.8	24.2 ± 0.6*	24.2 ± 0.7**	24.9 ± 0.7**	25.8 ± 0.6**	26.3 ± 0.7	26.5 ± 0.8
	1000	25.1 ± 0.8	22.5 ± 0.8***	21.6 ± 0.8***	20.6 ± 1.2***	20.0 ± 1.7***	20.6 ± 1.8***	21.6 ± 2.0***
	3000	25.1 ± 0.8	22.1 ± 0.7***	20.9 ± 0.8***	19.1 ± 0.8***	16.6 ± 0.9***	15.3 ± 0.8***	13.5 ± 0.6***
	9000	25.1 ± 0.8	22.0 ± 0.8***	20.8 ± 0.9***	18.5 ± 1.0***	15.8 ± 0.7***	14.2 ± 0.7***	
FEMALE	CONTROL	19.5 ± 0.7	19.1 ± 0.7	19.3 ± 0.9	19.9 ± 1.2	20.2 ± 0.9	20.7 ± 0.9	20.8 ± 0.8
	111	19.5 ± 0.7	19.0 ± 0.8	19.1 ± 0.8	19.8 ± 0.9	20.1 ± 0.7	21.0 ± 0.7	21.0 ± 0.7
	333	19.5 ± 0.7	18.2 ± 0.9*	18.0 ± 1.3*	18.9 ± 1.3	19.6 ± 1.7	20.3 ± 0.8	20.5 ± 1.0
	1000	19.5 ± 0.7	17.3 ± 0.7***	16.6 ± 0.8***	15.9 ± 0.8***	15.8 ± 0.9***	16.5 ± 1.3***	18.0 ± 1.6***
	3000	19.5 ± 0.7	17.2 ± 0.8***	15.8 ± 0.8***	13.8 ± 0.8***	12.2 ± 0.8***	11.4 ± 0.3***	
	9000	19.5 ± 0.7	17.4 ± 0.7***	16.0 ± 0.6***	13.9 ± 0.6***	11.7 ± 0.5***	10.9 ± 0.0	

表 1 6 生存動物数（マウス・13週間試験）

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0039

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	
MALE	0	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	24.7	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	74.1	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	222	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	667	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	2000	10	10	10	10	7	6	6	6	6	6	6	6	6	6	6/10
FEMALE	0	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	24.7	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	74.1	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	222	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	667	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10/10
	2000	10	10	8	4	4	4	4	4	4	2	2	2	2	2	2/ 8

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

表 1 7 体重値（マウス・13週間試験）

BODY WEIGHT CHANGES (G)

STUDY NO. : 0039

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		0	1	2	3	4	5	6
MALE	0	24.8 ± 0.7	26.1 ± 0.9	27.3 ± 0.7	28.0 ± 0.9	28.9 ± 0.9	30.0 ± 1.1	31.1 ± 1.3
	24.7	24.8 ± 0.7	26.5 ± 1.0	27.2 ± 1.2	28.5 ± 1.3	29.7 ± 1.7	30.8 ± 1.9	31.7 ± 2.2
	74.1	24.8 ± 0.7	26.1 ± 0.7	27.0 ± 0.7	28.2 ± 0.9	29.4 ± 1.1	31.0 ± 1.4	32.1 ± 1.5
	222	24.8 ± 0.7	25.9 ± 1.4	26.4 ± 1.4	27.7 ± 1.5	28.9 ± 2.1	30.4 ± 2.2	31.3 ± 2.6
	667	24.8 ± 0.7	22.7 ± 1.4***	24.1 ± 1.2***	25.8 ± 1.1***	26.3 ± 0.9***	27.2 ± 1.2***	27.9 ± 1.3***
	2000	24.8 ± 0.7	17.8 ± 0.7***	15.7 ± 0.8***	15.9 ± 2.6***	19.3 ± 3.8***	22.1 ± 4.1**	22.9 ± 4.5**
FEMALE	0	19.0 ± 0.6	20.0 ± 0.9	20.4 ± 0.7	21.4 ± 0.8	22.0 ± 1.1	22.3 ± 0.8	22.5 ± 1.0
	24.7	19.0 ± 0.6	20.1 ± 1.0	20.6 ± 0.7	21.2 ± 0.8	21.8 ± 0.7	22.7 ± 1.2	22.8 ± 0.8
	74.1	19.0 ± 0.7	19.5 ± 1.0	20.2 ± 0.5	20.9 ± 0.5	21.4 ± 0.8	21.9 ± 0.8	22.0 ± 0.8
	222	19.0 ± 0.7	19.1 ± 0.7*	19.5 ± 0.6**	20.3 ± 0.6**	20.7 ± 0.7**	21.3 ± 0.6**	21.5 ± 0.6*
	667	19.0 ± 0.7	17.2 ± 0.7***	19.0 ± 0.4***	19.7 ± 0.5***	20.0 ± 0.4***	20.6 ± 0.4***	20.8 ± 0.7***
	2000	19.0 ± 0.7	12.6 ± 0.7***	10.9 ± 0.7***	11.7 ± 1.3***	16.0 ± 3.0***	17.7 ± 1.8***	18.8 ± 1.4***
(C200)		BAIS						

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0039

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		7	8	9	10	11	12	13
MALE	0	32.2 ± 1.4	33.6 ± 1.4	34.3 ± 1.6	35.0 ± 1.9	35.9 ± 1.6	37.2 ± 1.9	38.0 ± 2.1
	24.7	32.9 ± 2.3	33.8 ± 2.4	34.8 ± 2.5	35.6 ± 2.7	36.4 ± 2.9	37.6 ± 3.1	38.4 ± 3.2
	74.1	33.3 ± 1.6	34.4 ± 1.7	35.3 ± 2.0	36.0 ± 2.0	36.7 ± 2.1	38.1 ± 2.6	38.4 ± 2.7
	222	32.5 ± 2.7	33.6 ± 3.0	34.4 ± 3.2	35.1 ± 3.6	34.7 ± 4.4	36.0 ± 4.0	37.4 ± 3.8
	667	28.9 ± 1.2***	29.6 ± 1.5***	29.9 ± 1.4***	30.6 ± 1.3***	30.7 ± 1.6***	31.9 ± 1.4***	32.5 ± 1.3***
	2000	23.9 ± 3.9**	24.9 ± 2.7***	25.3 ± 2.3***	25.8 ± 2.1***	25.9 ± 1.9***	26.2 ± 2.0***	26.6 ± 1.8***
FEMALE	0	23.1 ± 1.0	23.5 ± 1.2	23.3 ± 1.0	24.1 ± 0.9	24.6 ± 1.7	25.1 ± 1.1	24.5 ± 2.5
	24.7	23.4 ± 0.9	23.5 ± 0.9	23.8 ± 1.0	24.5 ± 1.6	24.7 ± 1.0	25.4 ± 1.2	25.9 ± 2.3
	74.1	22.1 ± 0.8*	22.8 ± 1.0	23.3 ± 1.2	23.8 ± 1.6	23.9 ± 1.1	24.5 ± 1.3	24.7 ± 1.3
	222	22.2 ± 0.7	22.4 ± 1.1	22.4 ± 0.8*	23.0 ± 0.8*	23.4 ± 0.9	23.2 ± 1.3**	23.7 ± 1.9
	667	21.3 ± 0.7***	21.4 ± 0.4***	21.7 ± 0.6***	21.4 ± 1.4***	22.4 ± 0.6**	22.6 ± 0.5***	22.9 ± 0.5
	2000	19.7 ± 1.2***	20.7 ± 1.0**	19.1 ± 1.2***	19.7 ± 1.3***	20.0 ± 2.1**	20.3 ± 1.2***	20.4 ± 1.7

表 18 生存動物数（マウス・がん原性試験）

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			1	2	3	4	5	6	7	8	9	10	11	12	13	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	20	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	60	50	50	50	50	50	50	50	50	50	49	49	49	49	49	49/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	20	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	60	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			14	15	16	17	18	19	20	21	22	23	24	25	26	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	20	50	50	50	50	50	50	49	49	49	49	49	49	49	49	49/50
	60	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	20	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	60	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			27	28	29	30	31	32	33	34	35	36	37	38	39	
MALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	49	49/50
	20	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	60	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
FEMALE	CONTROL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	20	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	60	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			40	41	42	43	44	45	46	47	48	49	50	51	52	
MALE	CONTROL	50	49	49	48	48	48	48	48	48	48	48	48	48	48	48/50
	20	50	49	49	49	49	49	49	49	49	49	49	48	48	48	48/50
	60	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	180	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
FEMALE	CONTROL	50	50	50	49	49	49	49	49	49	49	49	49	49	49	49/50
	20	50	50	50	50	50	50	50	50	50	50	50	49	49	49	49/50
	60	50	50	50	50	49	49	49	49	49	49	49	49	49	49	49/50
	180	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			53	54	55	56	57	58	59	60	61	62	63	64	65	
MALE	CONTROL	50	48	48	48	48	48	48	48	48	48	48	48	48	48	48/50
	20	50	48	48	48	48	48	47	46	46	46	45	45	45	45	45/50
	60	50	49	49	49	49	49	49	49	49	49	49	49	49	49	49/50
	180	50	49	49	49	48	48	48	48	48	48	48	48	48	48	48/50
FEMALE	CONTROL	50	49	49	49	49	49	49	49	49	49	49	49	49	48	48/50
	20	50	49	49	48	48	47	47	47	47	47	47	47	47	47	47/50
	60	50	49	48	48	48	48	48	48	48	48	48	48	48	48	48/50
	180	50	50	50	50	50	50	50	50	50	50	49	49	49	49	49/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE

SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			66	67	68	69	70	71	72	73	74	75	76	77	78	
MALE	CONTROL	50	48	47	46	46	46	45	45	45	45	45	44	43	43	43/50
	20	50	45	45	44	44	44	44	43	43	43	43	43	43	43	43/50
	60	50	48	48	48	48	48	48	47	47	47	47	47	47	47	47/50
	180	50	48	48	48	48	48	48	47	46	45	45	45	45	45	45/50
FEMALE	CONTROL	50	48	47	47	47	47	47	46	46	46	46	46	45	45	45/50
	20	50	47	47	47	46	45	45	44	44	44	43	42	42	42	42/49
	60	50	48	48	48	48	47	47	47	47	47	47	47	47	47	47/50
	180	50	49	48	48	48	48	48	48	47	47	47	47	47	47	47/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			79	80	81	82	83	84	85	86	87	88	89	90	91	
MALE	CONTROL	50	43	43	43	43	42	42	42	41	40	40	40	39	39	39/50
	20	50	43	42	42	41	40	39	39	39	39	38	38	38	37	37/50
	60	50	46	45	45	45	44	43	43	43	42	41	40	39	39	39/50
	180	50	45	45	44	43	42	42	42	41	40	40	39	38	38	38/50
FEMALE	CONTROL	50	45	45	44	44	44	43	42	42	41	41	40	39	36	36/50
	20	50	42	41	41	40	39	39	39	39	37	36	35	32	32	32/49
	60	50	47	46	46	46	45	45	44	44	43	42	42	39	36	36/50
	180	50	47	46	45	45	45	45	45	45	45	45	45	45	44	44/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

(C100)

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TABLE SURVIVAL ANIMAL NUMBERS

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS)-----													SURVIVAL RATE *
			92	93	94	95	96	97	98	99	100	101	102	103	104	
MALE	CONTROL	50	39	38	38	37	36	35	35	34	34	34	33	33	33	33/50
	20	50	36	36	36	34	34	34	34	33	32	30	30	30	30	30/50
	60	50	39	39	39	37	37	36	33	32	29	28	28	27	26	26/47
	180	50	38	38	37	37	36	36	35	35	32	29	29	29	29	29/50
FEMALE	CONTROL	50	35	35	35	34	33	33	32	32	31	29	28	26	21	21/50
	20	50	32	30	30	29	29	27	26	25	25	25	23	22	20	20/49
	60	50	36	35	34	32	32	32	31	31	30	29	29	28	26	26/50
	180	50	43	41	39	38	37	35	35	35	34	34	34	33	31	31/50

* NUMBER OF SURVIVAL / NUMBER OF EFFECTIVE ANIMALS

(C100)

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表 19 体重値（マウス・がん原性試験）

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		0	1	2	3	4	5	6
MALE	CONTROL	24.1 ± 0.9	25.7 ± 1.1	26.6 ± 1.1	28.0 ± 1.2	28.8 ± 1.4	29.3 ± 1.4	30.6 ± 1.6
	20	24.1 ± 0.9	25.6 ± 1.1	26.3 ± 1.3	27.8 ± 1.4	28.1 ± 1.5*	29.0 ± 1.7	30.1 ± 2.0
	60	24.1 ± 0.9	25.5 ± 1.0	26.2 ± 1.5	27.7 ± 1.9	28.3 ± 1.8	28.9 ± 2.3	30.1 ± 2.3
	180	24.1 ± 0.9	25.4 ± 1.0	26.0 ± 1.1*	27.4 ± 1.4*	27.8 ± 1.5**	28.7 ± 1.6	29.4 ± 1.9***
FEMALE	CONTROL	19.7 ± 0.7	20.3 ± 1.0	21.3 ± 0.8	22.1 ± 1.1	23.4 ± 1.0	23.5 ± 1.2	24.1 ± 1.3
	20	19.7 ± 0.7	20.5 ± 0.8	21.2 ± 0.8	22.2 ± 1.1	22.9 ± 1.3*	23.3 ± 1.4	23.9 ± 1.4
	60	19.7 ± 0.7	20.0 ± 0.7	20.8 ± 0.8**	21.7 ± 0.8*	22.6 ± 1.0***	22.9 ± 1.0**	23.8 ± 1.1
	180	19.7 ± 0.7	19.7 ± 0.9**	20.4 ± 0.9***	21.4 ± 1.0***	22.1 ± 1.0***	22.5 ± 1.1***	23.4 ± 1.1**

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		7	8	9	10	11	12	13
MALE	CONTROL	31.2 ± 1.6	32.2 ± 1.9	32.7 ± 2.0	33.9 ± 2.1	34.5 ± 2.2	35.5 ± 2.4	35.8 ± 2.5
	20	31.0 ± 2.1	31.5 ± 2.1	32.4 ± 2.2	33.6 ± 2.5	34.4 ± 2.7	35.1 ± 2.8	35.9 ± 2.9
	60	30.9 ± 2.5	31.5 ± 2.8	32.5 ± 2.4	33.5 ± 2.8	34.2 ± 2.9	34.9 ± 3.1	35.9 ± 3.3
	180	30.4 ± 2.0*	31.0 ± 2.1**	32.0 ± 2.3	32.9 ± 2.5*	33.6 ± 2.6	34.6 ± 2.7	35.7 ± 2.8
FEMALE	CONTROL	24.2 ± 1.2	25.1 ± 1.5	25.6 ± 1.3	26.4 ± 1.4	26.0 ± 1.8	27.0 ± 1.8	27.3 ± 1.7
	20	24.3 ± 1.6	24.9 ± 1.6	25.3 ± 1.8	26.3 ± 2.0	26.3 ± 2.1	26.8 ± 2.2	27.3 ± 2.3
	60	24.0 ± 1.1	24.7 ± 1.3	25.3 ± 1.3	25.8 ± 1.4*	25.9 ± 1.6	26.7 ± 1.9	27.2 ± 2.0
	180	23.6 ± 1.3*	24.0 ± 1.5***	25.1 ± 1.5	25.3 ± 1.9**	25.7 ± 2.0	26.0 ± 2.1*	26.3 ± 1.9**

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		14	16	18	20	22	24	26
MALE	CONTROL	37.2 ± 2.5	38.7 ± 2.8	40.3 ± 3.0	41.8 ± 3.2	43.6 ± 3.2	44.5 ± 3.4	46.1 ± 3.4
	20	36.6 ± 3.0	37.9 ± 3.6	39.1 ± 4.0	40.8 ± 3.9	42.6 ± 4.0	43.4 ± 4.1	44.8 ± 4.1
	60	36.7 ± 3.5	38.1 ± 3.8	39.4 ± 4.0	40.7 ± 4.3	42.2 ± 4.4	42.9 ± 4.5	44.2 ± 4.4*
	180	36.3 ± 2.9	37.7 ± 3.3	39.2 ± 3.6	40.6 ± 3.8	42.2 ± 3.9	43.3 ± 4.0	44.2 ± 4.2*
FEMALE	CONTROL	27.9 ± 2.1	28.7 ± 2.4	29.5 ± 2.2	30.5 ± 2.8	31.4 ± 2.8	32.5 ± 3.0	32.2 ± 3.1
	20	27.8 ± 2.6	28.5 ± 2.8	29.6 ± 2.7	30.4 ± 3.0	31.2 ± 3.0	32.1 ± 3.3	32.7 ± 3.3
	60	27.6 ± 2.1	28.0 ± 2.2	29.2 ± 2.3	30.0 ± 2.5	30.8 ± 2.8	31.7 ± 2.4	32.3 ± 3.0
	180	27.0 ± 2.1*	27.3 ± 2.5**	28.2 ± 2.6**	29.7 ± 3.0	30.5 ± 3.2	30.4 ± 2.9***	31.4 ± 3.3

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		28	30	32	34	36	38	40
MALE	CONTROL	47.0 $\pm$ 3.3	47.0 $\pm$ 3.2	47.5 $\pm$ 3.2	47.6 $\pm$ 3.8	48.7 $\pm$ 4.7	48.3 $\pm$ 4.3	49.4 $\pm$ 3.0
	20	46.0 $\pm$ 3.9	45.9 $\pm$ 3.9	46.2 $\pm$ 4.0	46.6 $\pm$ 3.7	48.1 $\pm$ 3.9	47.7 $\pm$ 3.7	48.2 $\pm$ 3.7
	60	45.4 $\pm$ 4.4*	45.7 $\pm$ 4.3	46.2 $\pm$ 4.2	46.8 $\pm$ 4.0	47.8 $\pm$ 4.1	47.6 $\pm$ 3.9	48.1 $\pm$ 3.7
	180	45.7 $\pm$ 4.4	45.8 $\pm$ 4.6	46.1 $\pm$ 4.9	46.8 $\pm$ 5.1	47.7 $\pm$ 5.4	47.6 $\pm$ 5.0	48.6 $\pm$ 3.6
FEMALE	CONTROL	33.7 $\pm$ 3.1	33.6 $\pm$ 3.1	33.5 $\pm$ 3.2	34.2 $\pm$ 3.2	34.4 $\pm$ 3.5	34.6 $\pm$ 3.5	34.5 $\pm$ 3.9
	20	34.5 $\pm$ 3.4	33.7 $\pm$ 3.6	33.5 $\pm$ 3.6	34.4 $\pm$ 3.7	34.6 $\pm$ 4.1	35.0 $\pm$ 3.9	34.9 $\pm$ 4.0
	60	33.7 $\pm$ 3.2	33.4 $\pm$ 3.5	33.6 $\pm$ 2.9	34.0 $\pm$ 3.0	34.4 $\pm$ 3.6	34.6 $\pm$ 3.1	34.8 $\pm$ 3.1
	180	32.8 $\pm$ 3.3	32.7 $\pm$ 3.3	33.0 $\pm$ 3.1	33.4 $\pm$ 3.1	33.9 $\pm$ 3.6	33.9 $\pm$ 3.5	34.0 $\pm$ 3.4

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		42	44	46	48	50	52	54
MALE	CONTROL	49.4 ± 2.7	50.2 ± 2.8	50.3 ± 2.8	50.3 ± 2.9	50.6 ± 3.0	50.9 ± 3.1	51.8 ± 3.2
	20	48.9 ± 3.7	49.7 ± 3.5	49.5 ± 3.4	49.7 ± 3.5	49.7 ± 3.3	50.3 ± 3.2	50.8 ± 4.0
	60	48.6 ± 3.7	49.4 ± 3.6	49.0 ± 3.4*	49.5 ± 3.4	49.8 ± 3.5	50.2 ± 3.6	51.2 ± 3.3
	180	49.0 ± 3.8	49.6 ± 3.9	49.5 ± 4.3	49.5 ± 4.5	49.6 ± 4.7	50.2 ± 4.6	51.0 ± 3.8
FEMALE	CONTROL	35.7 ± 3.8	35.4 ± 3.9	36.0 ± 3.6	35.8 ± 3.9	36.2 ± 3.7	36.1 ± 4.2	36.7 ± 3.7
	20	35.3 ± 3.9	35.6 ± 4.0	35.3 ± 4.0	35.9 ± 3.9	36.3 ± 3.7	35.7 ± 3.9	37.0 ± 3.9
	60	35.2 ± 3.1	35.2 ± 3.3	35.4 ± 2.9	35.5 ± 3.2	35.6 ± 3.3	35.7 ± 3.4	36.4 ± 3.8
	180	34.4 ± 3.5	34.6 ± 3.9	34.5 ± 3.8*	34.8 ± 3.8	34.7 ± 3.7	34.6 ± 3.9	35.5 ± 3.8

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)						
		56	58	60	62	64	66	68
MALE	CONTROL	52.1 ± 3.2	52.3 ± 3.1	52.3 ± 3.5	52.2 ± 3.4	52.8 ± 3.4	52.4 ± 4.7	53.3 ± 4.1
	20	50.5 ± 4.7	51.5 ± 3.7	51.6 ± 3.6	51.5 ± 3.6	52.1 ± 3.7	52.2 ± 3.5	52.5 ± 3.7
	60	51.6 ± 3.5	52.0 ± 3.4	52.0 ± 3.1	51.9 ± 3.3	52.4 ± 3.3	52.7 ± 3.1	53.5 ± 3.3
	180	51.5 ± 3.7	52.2 ± 3.6	52.3 ± 3.6	52.1 ± 3.6	52.8 ± 3.9	53.0 ± 3.9	53.6 ± 4.1
FEMALE	CONTROL	36.4 ± 3.9	37.6 ± 3.9	37.9 ± 4.1	38.2 ± 3.9	39.2 ± 4.3	39.4 ± 4.1	39.7 ± 4.2
	20	36.4 ± 4.3	37.4 ± 4.3	37.8 ± 4.8	38.1 ± 4.7	38.7 ± 5.0	38.8 ± 5.0	39.0 ± 5.2
	60	36.5 ± 3.4	37.3 ± 3.9	37.3 ± 4.0	38.2 ± 4.0	38.9 ± 4.1	39.0 ± 4.2	39.5 ± 4.4
	180	35.7 ± 4.0	36.6 ± 4.0	36.5 ± 4.3	36.5 ± 4.2*	36.8 ± 4.9*	36.9 ± 4.9**	37.3 ± 4.7*

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		74	76	78	80	82
		70	72					
MALE	CONTROL	53.0 ± 4.9	53.4 ± 5.0	53.7 ± 5.2	53.7 ± 5.5	54.5 ± 4.2	54.4 ± 5.0	54.0 ± 6.0
	20	53.1 ± 3.8	53.0 ± 4.2	53.4 ± 4.0	53.6 ± 4.1	53.6 ± 4.4	53.8 ± 4.8	53.3 ± 4.9
	60	53.7 ± 3.4	53.9 ± 3.4	54.5 ± 3.5	54.6 ± 3.7	54.4 ± 4.0	54.3 ± 5.1	54.3 ± 4.9
	180	53.6 ± 4.4	53.3 ± 5.4	54.7 ± 4.8	54.4 ± 5.2	54.4 ± 5.7	54.4 ± 6.2	54.0 ± 6.3
FEMALE	CONTROL	40.0 ± 4.3	40.3 ± 4.6	40.3 ± 4.8	40.2 ± 5.3	40.2 ± 5.5	40.5 ± 5.5	40.0 ± 4.9
	20	39.8 ± 5.1	40.0 ± 5.4	40.7 ± 5.2	40.6 ± 5.5	40.5 ± 5.8	40.7 ± 5.3	40.3 ± 5.7
	60	40.0 ± 4.4	40.2 ± 4.2	40.8 ± 4.5	40.9 ± 4.3	41.1 ± 4.6	41.4 ± 4.7	41.4 ± 4.7
	180	37.7 ± 5.1*	37.5 ± 5.3**	38.7 ± 4.4	38.9 ± 4.3	39.0 ± 4.5	39.0 ± 4.7	38.8 ± 4.6

(C200)

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TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)		88	90	92	94	96
		84	86					
MALE	CONTROL	54.0 ± 6.9	54.6 ± 5.8	54.2 ± 6.7	54.1 ± 6.0	53.5 ± 7.0	53.7 ± 6.7	53.6 ± 7.3
	20	53.6 ± 5.4	53.1 ± 5.9	52.5 ± 6.6	52.0 ± 7.5	52.2 ± 6.9	51.4 ± 8.8	52.1 ± 7.8
	60	55.2 ± 3.7	54.6 ± 3.9	53.9 ± 5.1	53.9 ± 5.1	53.1 ± 5.9	52.5 ± 7.2	51.9 ± 7.1
	180	54.1 ± 6.9	53.7 ± 7.3	53.1 ± 7.8	53.5 ± 6.6	52.3 ± 7.5	51.7 ± 8.3	51.2 ± 7.9
FEMALE	CONTROL	40.7 ± 5.6	40.5 ± 5.4	40.3 ± 5.8	39.4 ± 5.7	40.3 ± 5.1	40.1 ± 5.6	40.5 ± 4.8
	20	40.7 ± 4.3	40.9 ± 4.5	40.0 ± 5.3	40.9 ± 4.8	42.1 ± 7.8	40.1 ± 5.8	39.6 ± 4.9
	60	41.3 ± 4.7	41.4 ± 4.8	40.9 ± 5.6	40.4 ± 5.6	39.8 ± 5.9	39.8 ± 5.6	39.1 ± 5.9
	180	38.6 ± 4.9	38.7 ± 4.7	38.3 ± 4.9	37.3 ± 5.3	37.4 ± 5.6*	38.1 ± 4.8	37.7 ± 4.6*

TABLE

BODY WEIGHT CHANGES (G)

STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS)			
		98	100	102	104
MALE	CONTROL	51.8 ± 7.9	52.0 ± 7.0	52.1 ± 7.2	51.1 ± 7.7
	20	51.4 ± 7.3	51.0 ± 7.8	51.7 ± 6.7	50.7 ± 6.8
	60	51.0 ± 6.6	50.7 ± 5.2	49.2 ± 6.5	48.4 ± 6.9
	180	49.7 ± 8.5	49.3 ± 9.0	49.7 ± 8.2	48.4 ± 8.4
FEMALE	CONTROL	39.9 ± 4.7	39.6 ± 5.9	39.1 ± 6.1	39.7 ± 5.7
	20	40.1 ± 4.2	39.4 ± 4.3	38.8 ± 5.8	39.0 ± 5.0
	60	38.7 ± 5.1	39.0 ± 5.6	39.3 ± 5.4	38.8 ± 5.3
	180	37.4 ± 4.3*	37.3 ± 4.6	37.1 ± 4.8	37.1 ± 5.3

(C200)

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表 20 腫瘍性病変総数（良性／悪性）および担癌動物数
（マウス・がん原性試験）

表 2 0 腫瘍性病変総数（良性／悪性）および担癌動物数
（マウス・癌原性試験）

TABLE NO. OF TUMORS (BENIGN/MALIGNANT)
AND NO. OF ANIMALS WITH TUMORS (SINGLE/MULTIPLE)

STUDY NO. : 0060

SEX : MALE

SUMMARY OF TUMORS	SUMMARY			
	A	B	C	D
NO. OF BENIGN TUMORS	40	35	27	35
NO. OF MALIGNANT TUMORS	36	30	43	41
NO. OF TOTAL TUMORS	76	65	70	76
NO. OF ANIMALS WITH A SINGLE TUMOR	17	24	17	25
NO. OF ANIMALS WITH MULTIPLE TUMOR	24	18	21	21
NO. OF EXAMINED ANIMALS	50	50	47	50
A: 0 (PPM)	B: 20 (PPM)	C: 60 (PPM)	D: 180 (PPM)	

TABLE NO. OF TUMORS (BENIGN/MALIGNANT)
AND NO. OF ANIMALS WITH TUMORS (SINGLE/MULTIPLE)

STUDY NO. : 0060

SEX : FEMALE

SUMMARY OF TUMORS	SUMMARY			
	A	B	C	D
NO. OF BENIGN TUMORS	23	29	31	36
NO. OF MALIGNANT TUMORS	40	29	33	44
NO. OF TOTAL TUMORS	63	58	64	80
NO. OF ANIMALS WITH A SINGLE TUMOR	29	20	25	23
NO. OF ANIMALS WITH MULTIPLE TUMOR	16	16	18	24
NO. OF EXAMINED ANIMALS	50	50	50	50
A: 0 (PPM)	B: 20 (PPM)	C: 60 (PPM)	D: 180 (PPM)	

表 2 1 腫瘍性病変（発生頻度）－全動物・全期間－
（マウス・がん原性試験）

表 2 1 腫瘍性病変（発生頻度）－全動物・全期間－
（マウス・癌原性試験）

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS)

STUDY NO. : 0060

SEX : MALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPM)		0		20		60		180	
		NO. OF EXAMINED ANIMALS		50		50		47		50	
BRAIN	glioblastoma			1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)	
LUNG	+ALVEOLAR/BRONCHIOAL ADENOMA			4 (8.0)		3 (6.0)		1 (2.1)		2 (4.0)	
	ALVEOLAR/BRONCHIOAL CARCINOMA			10 (20.0)		3 (6.0)		9 (19.1)		8 (16.0)	
LIVER	+ADENOMA			14 (28.0)		13 (26.0)		11 (23.4)		18 (36.0)	
	hepatocellular carcinoma			4 (8.0)		2 (4.0)		1 (2.1)		5 (10.0)	
	hepatocellular carcinoma			13 (26.0)		10 (20.0)		14 (29.8)		14 (28.0)	
	hepatocellular carcinoma			0 (0.0)		1 (2.0)		1 (2.1)		0 (0.0)	
	hepatocellular carcinoma			0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)	
URTER	+POLYP			0 (0.0)		0 (0.0)		2 (4.3)		0 (0.0)	
STOMACH	adenocarcinoma			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)	
	keratinocarcinoma			1 (2.0)		1 (2.0)		0 (0.0)		0 (0.0)	
	leiomyosarcoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
LARGE INTESTINE	adenocarcinoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
	adenocarcinoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
TESTIS	+INTERSTITIAL CELL TUMOR			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
EPIDIDYMS	+XANTHOMA			1 (2.0)		1 (2.0)		1 (2.1)		0 (0.0)	
SEMINAL VESICLE	leiomyosarcoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
	leiomyosarcoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
PROSTATE	+ADENOMA			0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)	
	adenocarcinoma			0 (0.0)		0 (0.0)		1 (2.1)		0 (0.0)	
SPLEEN	benign lymphoma			5 (10.0)		2 (4.0)		1 (2.1)		2 (4.0)	
	adenocarcinoma			5 (10.0)		1 (2.0)		6 (12.8)		3 (6.0)	
LYMPH NODES	benign lymphoma			3 (6.0)		9 (18.0)		13 (27.7)		9 (18.0)	
	adenocarcinoma			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)	
PANCREATIC ISLET	+ADENOMA			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)	
MAMMARY GLAND	+ADENOMA			1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)	

+ : BENIGN * : MALIGNANT

STUDY NO. : 0060

SEX : MALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPM)		NO. OF EXAMINED ANIMALS		50		0		20		47		60		140	
SKIN	+EPIDERMAL CYST			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)			
SUBCUTANEOUS TISSUE	+HEMANGIOMA			1 (2.0)		1 (2.0)		0 (0.0)		0 (0.0)		1 (2.0)					
	+HEMANGIOENDOTHELIOMA			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)					
	+MALIGNANT FIBROUS HISTIOCYTOMA			1 (2.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)					
MUSCLE	+HEMANGIOSARCOMA			1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)					
PERIPHERAL NERVES																	
	+MALIGNANT SCHWANNOMA			0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)					
PITUITARY	+ADENOMA			6 (12.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)					
ADRENAL	+ADENOMA			4 (8.0)		4 (8.0)		0 (0.0)		0 (0.0)		2 (4.0)					
	+PHEOCHROMOCYTOMA			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)		2 (4.0)					
PARATHYROID GLAND																	
	+ADENOMA			1 (2.0)		3 (6.0)		3 (6.4)		4 (8.0)							
TOOTH	+TUMOR/BENIGN			2 (4.0)		2 (4.0)		1 (2.1)		2 (4.0)							
BONE MARROW																	
	+LEUKEMIA			0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)							
PERITONEUM																	
	+HEMANGIOENDOTHELIOMA			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)					
	+RHABDOMYOSARCOMA			0 (0.0)		1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)					

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS)

STUDY NO. : 0060

SEX : FEMALE

ORGAN_____	TYPE OF TUMOR____	DOSE LEVEL (PPM) NO. OF EXAMINED ANIMALS	0				20				60				180			
			50	0	50	20	50	60	50	180	50	60	50	180	50	60	50	180
LUNG	+ALVEOLAR/BRONCHIOULAR ADENOMA		2 (4.0)	0 (0.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)
	#ALVEOLAR/BRONCHIOULAR CARCINOMA		3 (6.0)	2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)
THYROID	+C-CELL ADENOMA		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)
LIVER	+ADENOMA		5 (10.0)	6 (12.0)		7 (14.0)		8 (16.0)		8 (16.0)		8 (16.0)		8 (16.0)		8 (16.0)		8 (16.0)
	#SARCOMA		2 (4.0)	0 (0.0)		4 (8.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
	#HEPATOCELLULAR CARCINOMA		1 (2.0)	1 (2.0)		2 (4.0)		1 (2.0)		1 (2.0)		2 (4.0)		1 (2.0)		1 (2.0)		1 (2.0)
	#HEMANGIOSARCOMA		0 (0.0)	0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.0)		1 (2.0)		1 (2.0)
URETER	+POLYP		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)
URINARY BLADDER																		
	+PAPILLOMA		1 (2.0)	1 (2.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
UTERUS	+POLYP		2 (4.0)	1 (2.0)		2 (4.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
	#SARCOMA		11 (22.0)	7 (14.0)		7 (14.0)		11 (22.0)		11 (22.0)		11 (22.0)		11 (22.0)		11 (22.0)		11 (22.0)
	+HEMANGIOMA		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)
SPLEEN	#MALIGNANT LYMPHOMA		2 (4.0)	6 (12.0)		3 (6.0)		3 (6.0)		3 (6.0)		3 (6.0)		3 (6.0)		3 (6.0)		3 (6.0)
	+HEMANGIOMA		1 (2.0)	0 (0.0)		0 (0.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)
	#ANGIOSARCOMA		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)
LYMPH NODES																		
	#MALIGNANT LYMPHOMA		20 (40.0)	11 (22.0)		12 (24.0)		19 (38.0)		19 (38.0)		19 (38.0)		19 (38.0)		19 (38.0)		19 (38.0)
	#MASTOCYTOMA		0 (0.0)	0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
PANCREATIC ISLET																		
	+ADENOMA		0 (0.0)	0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
MAMMARY GLAND																		
	#ADENOCARCINOMA		0 (0.0)	1 (2.0)		1 (2.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)		2 (4.0)
SUBCUTANEOUS TISSUE																		
	#MASTOCYTOMA		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)
MUSCLE	+HEMANGIOENDOTHELIOMA		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)
PERIPHERAL NERVES																		
	#MALIGNANT SCHWANNOMA		0 (0.0)	0 (0.0)		0 (0.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)		1 (2.0)
PITUITARY																		
	+ADENOMA		8 (16.0)	17 (34.0)		15 (30.0)		20 (40.0)		20 (40.0)		20 (40.0)		20 (40.0)		20 (40.0)		20 (40.0)
	#ADENOCARCINOMA		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)

+ : BENIGN # : MALIGNANT

TABLE NEOPLASTIC FINDINGS - INCIDENCE (%) (ALL ANIMALS)

STUDY NO. : 0060

SEX : FEMALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPM)		0		20		60		180	
		NO. OF EXAMINED ANIMALS		50	0	50	20	50	60	50	180
ADRENAL	+ADENOMA	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)
OVARY	+CYSTADENOMA	3 (6.0)	2 (4.0)	2 (4.0)	2 (4.0)	2 (4.0)	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)
HARDERIAN GLAND	+ADENOMA	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	4 (8.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	+ADENOCARCINOMA	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
BONE	+OSTEOGENIC SARCOMA	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)
PERITONEUM	+HEMANGIOMA	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)	0 (0.0)
	+HANGIOSARCOMA	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)
	+MASTOCYTOMA	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)

0059 生存動物数

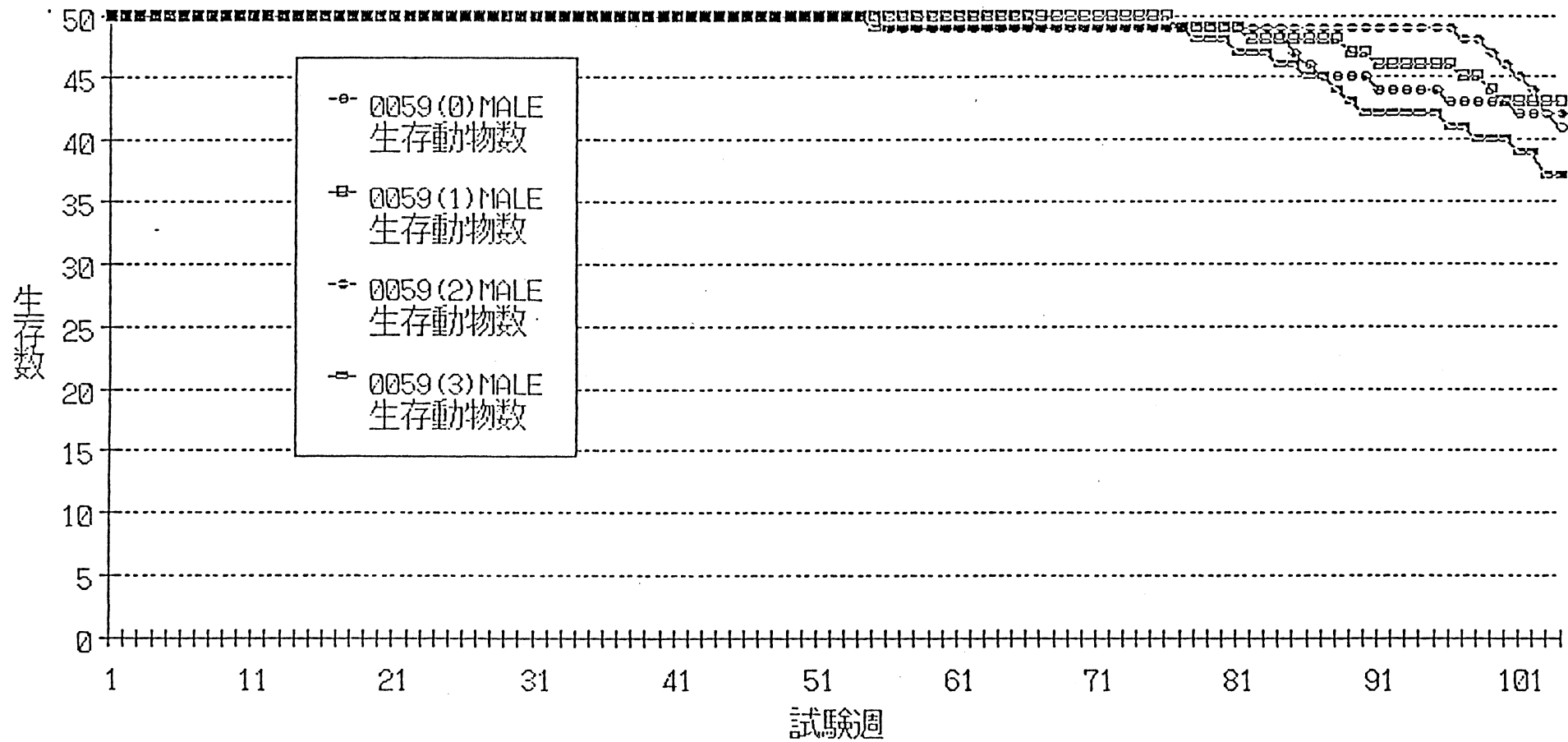


図 1

生存動物数（ラット・雄・がん原性試験）

0059 生存動物数

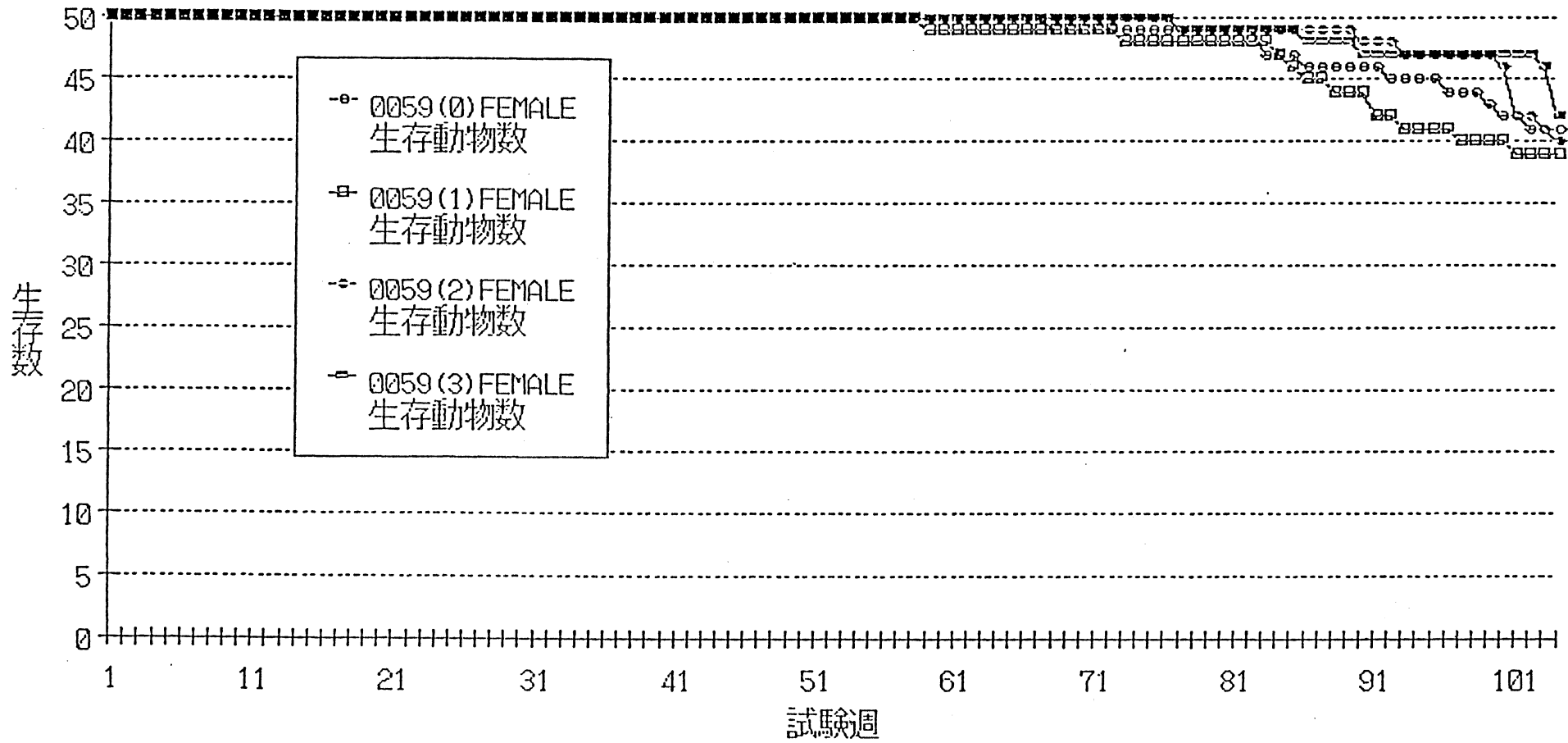
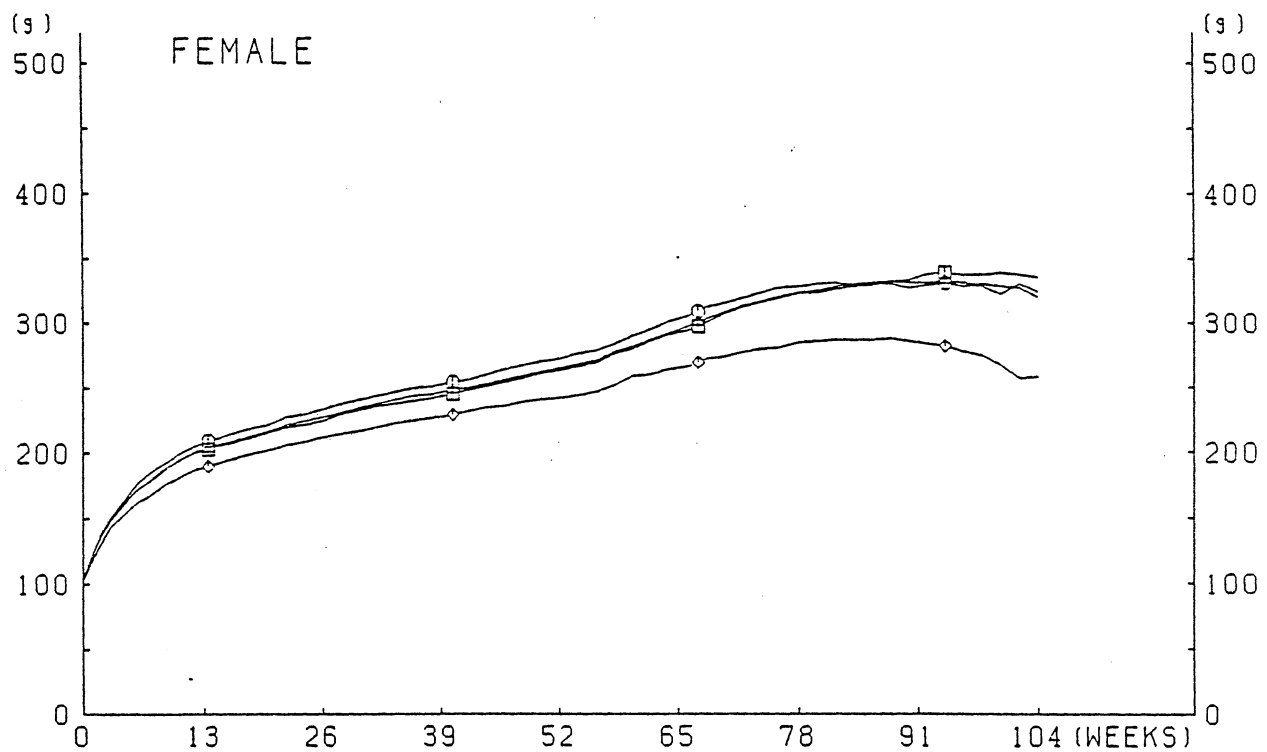
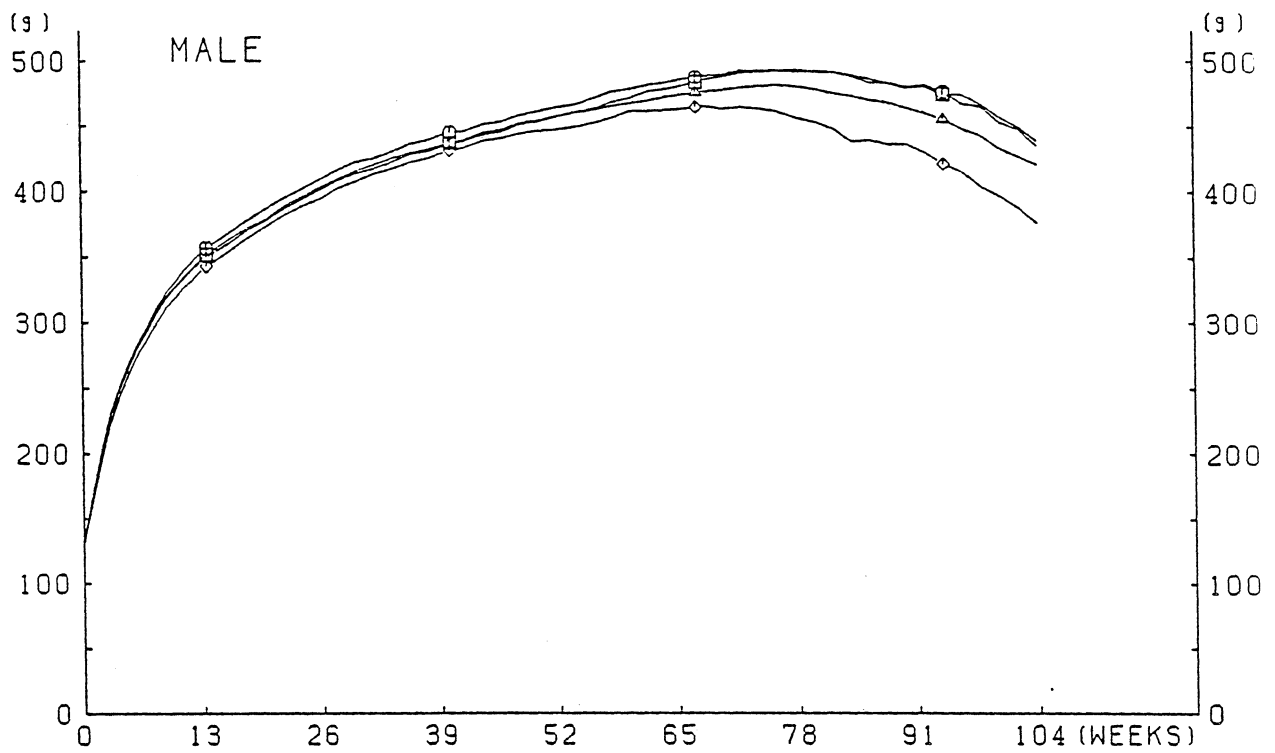


図 2

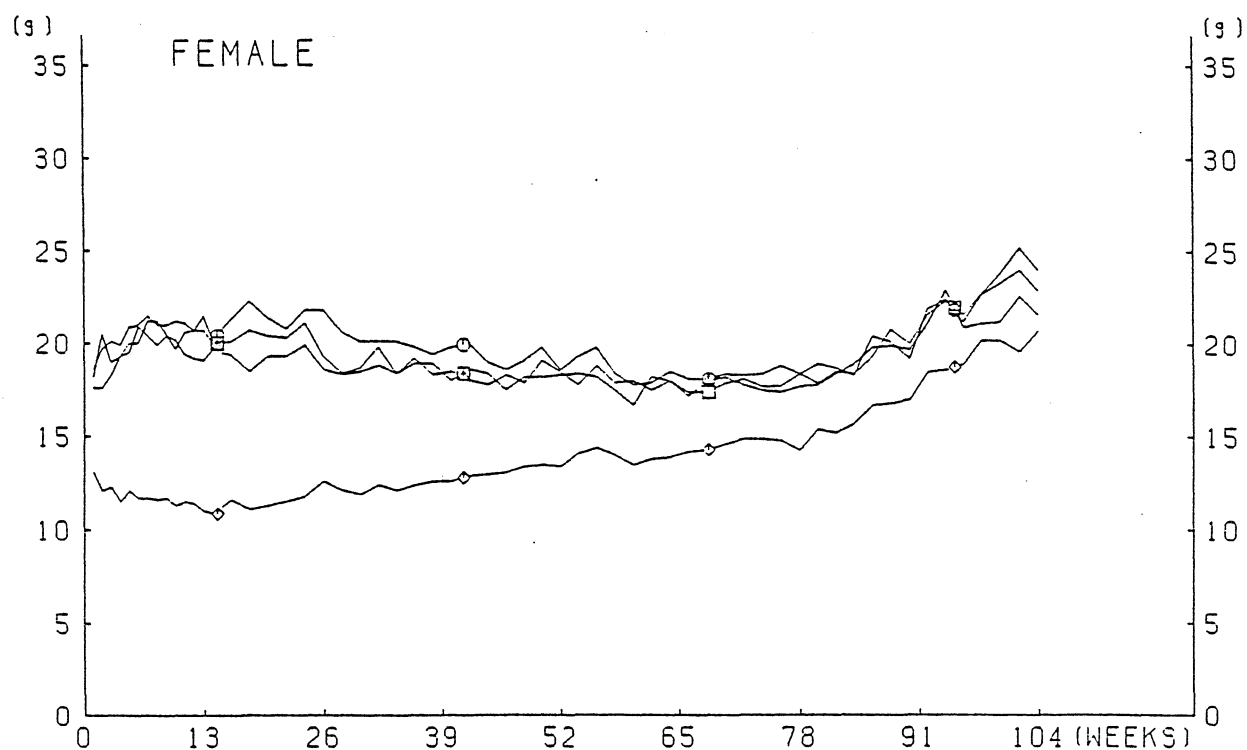
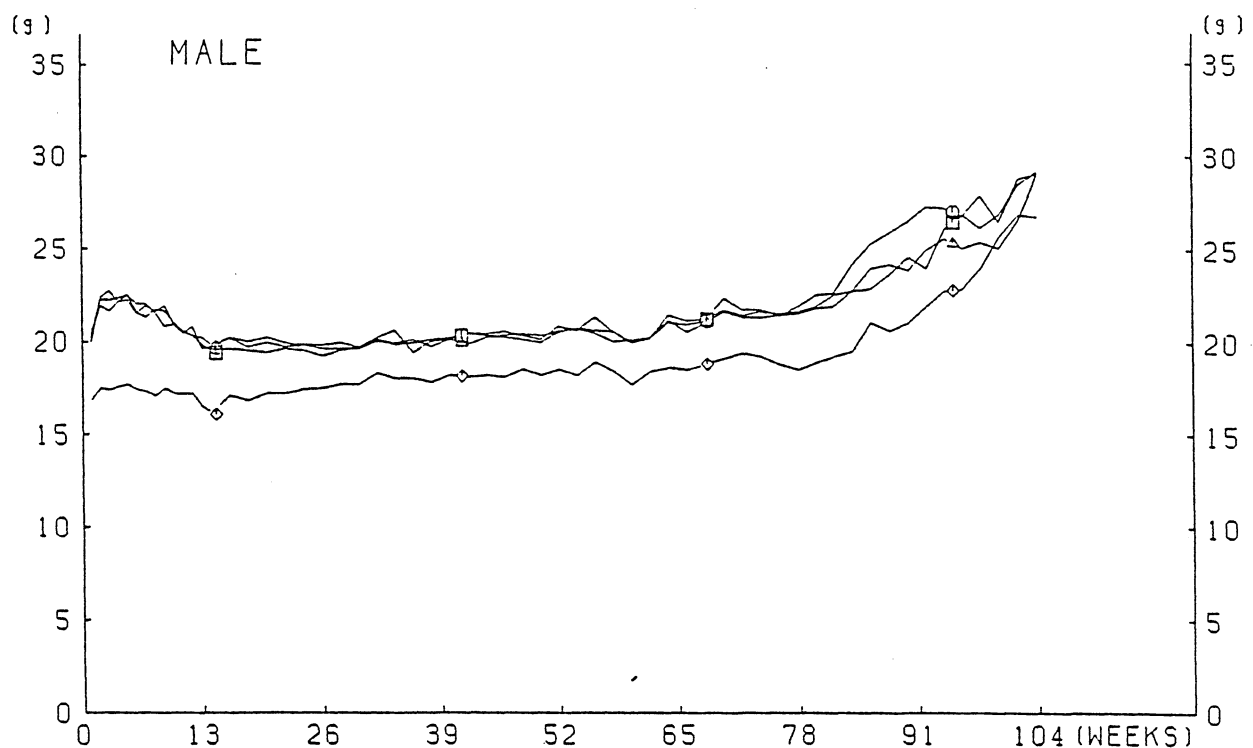
生存動物数（ラット・雌・がん原性試験）



STUDY NO. 0059
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)
 —□— CONTROL
 —○— 64
 —△— 160
 —◇— 400

BODY WEIGHT



STUDY NO. 0059
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)

—□— CONTROL

—○— 64

—△— 160

—◇— 400

WATER CONSUMPTION

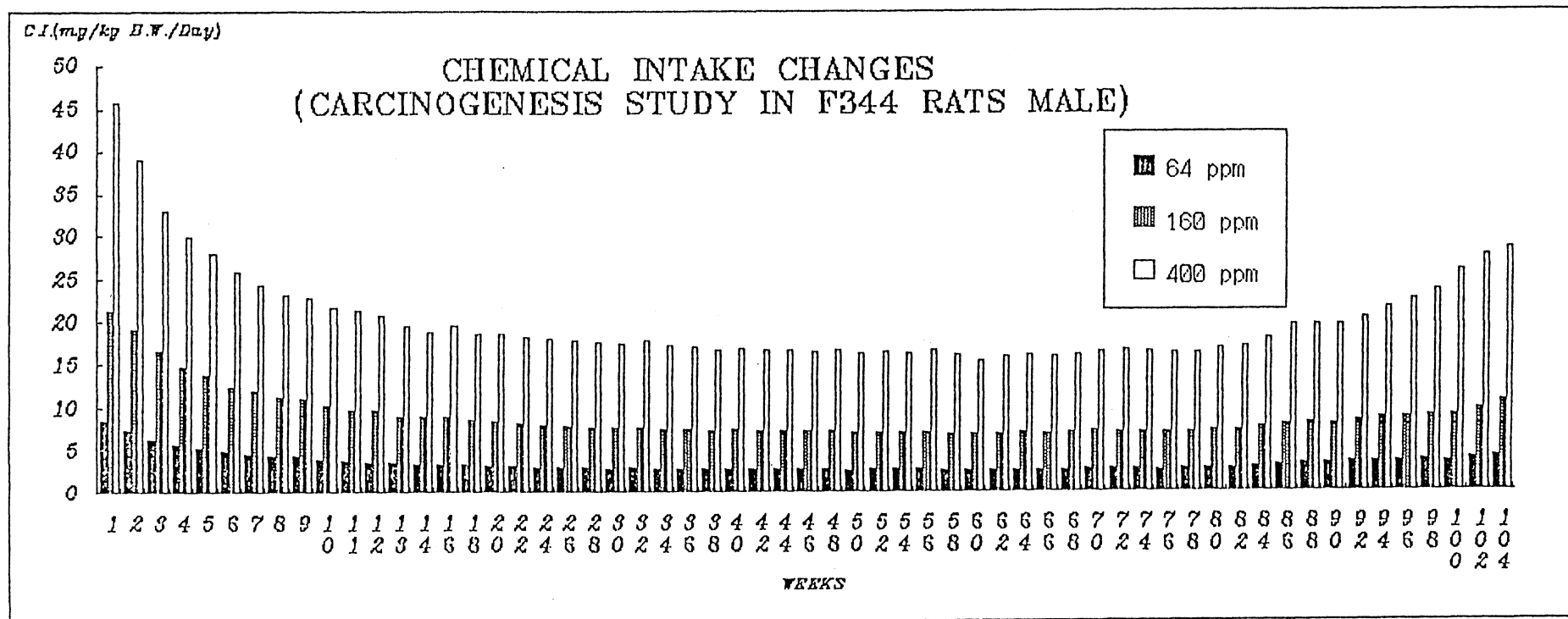


図 5

被験物質摂取量（ラット・雄・がん原性試験）

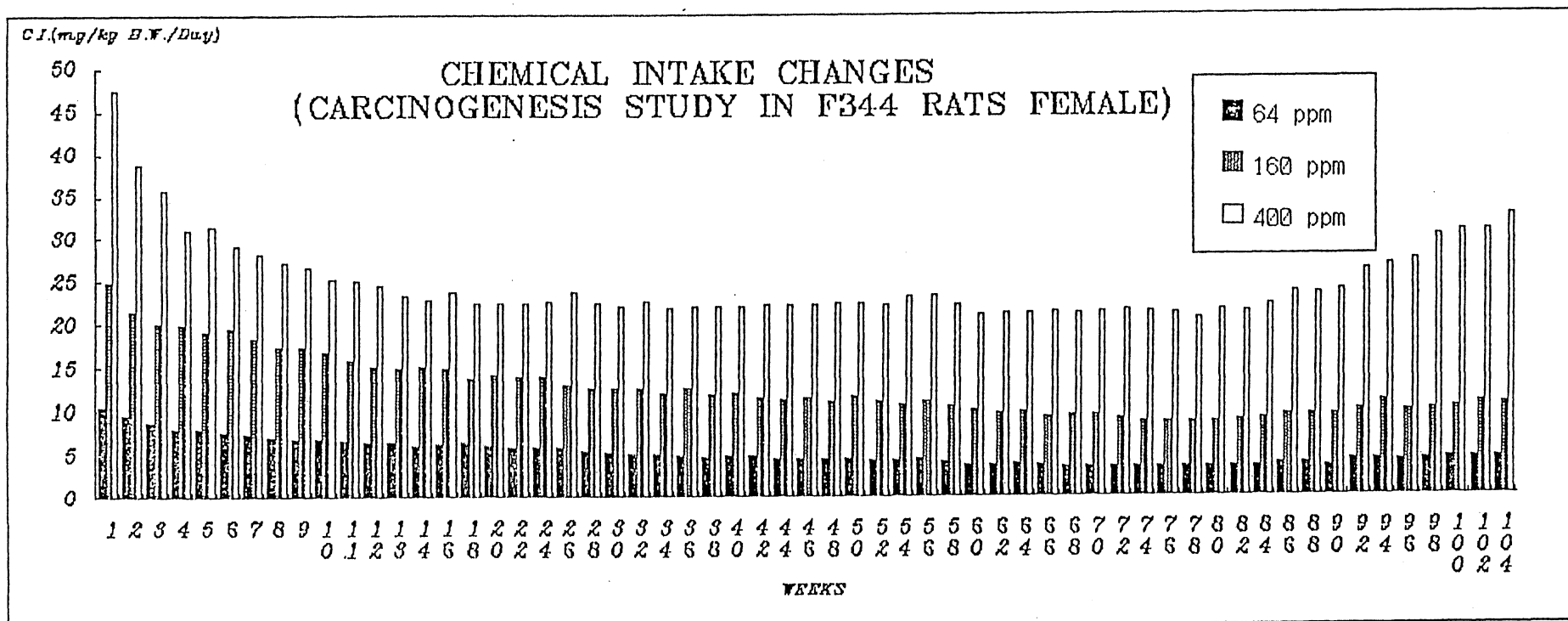


図 6

被験物質摂取量（ラット・雌・がん原性試験）

0060 生存動物数

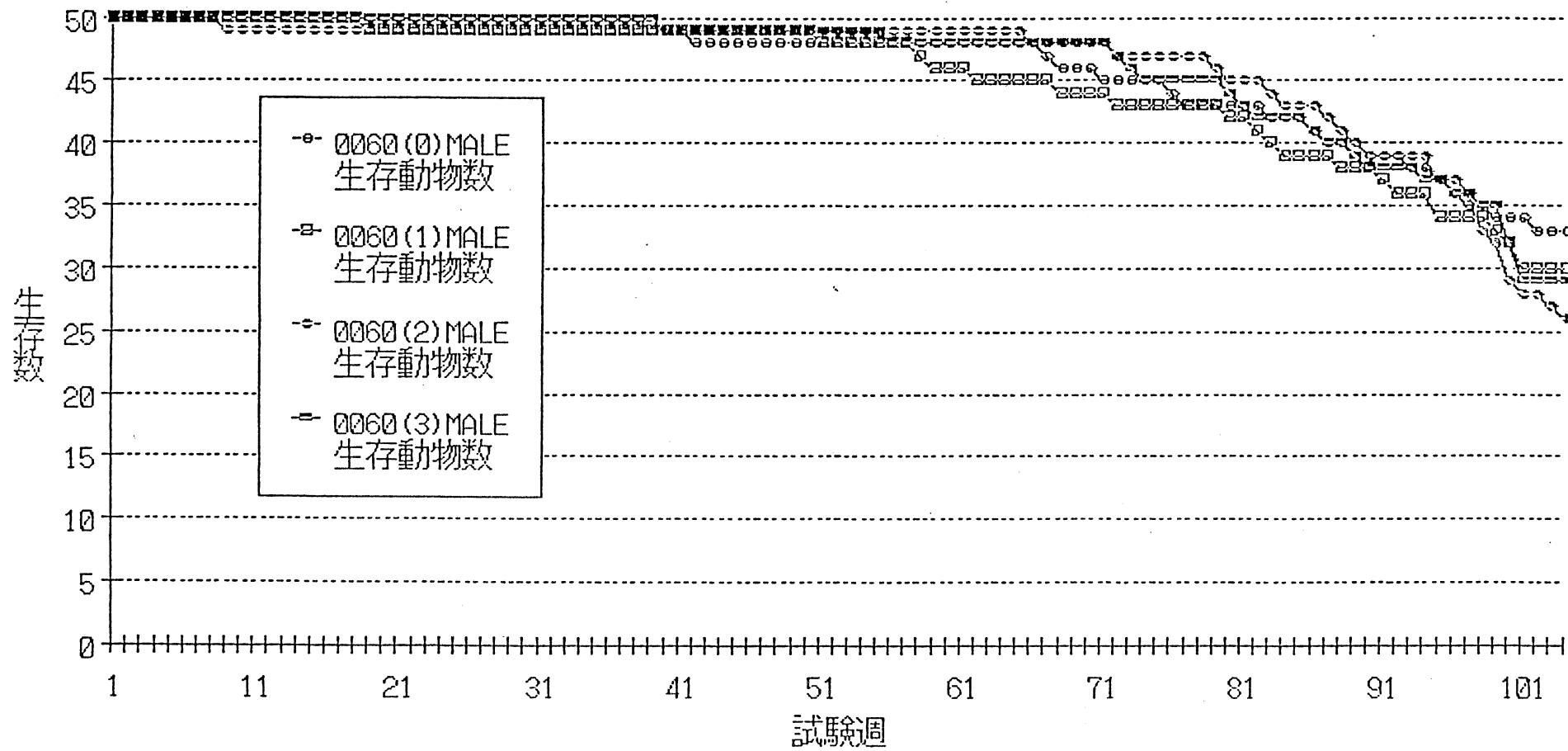


図 7

生存動物数（マウス・雄・がん原性試験）

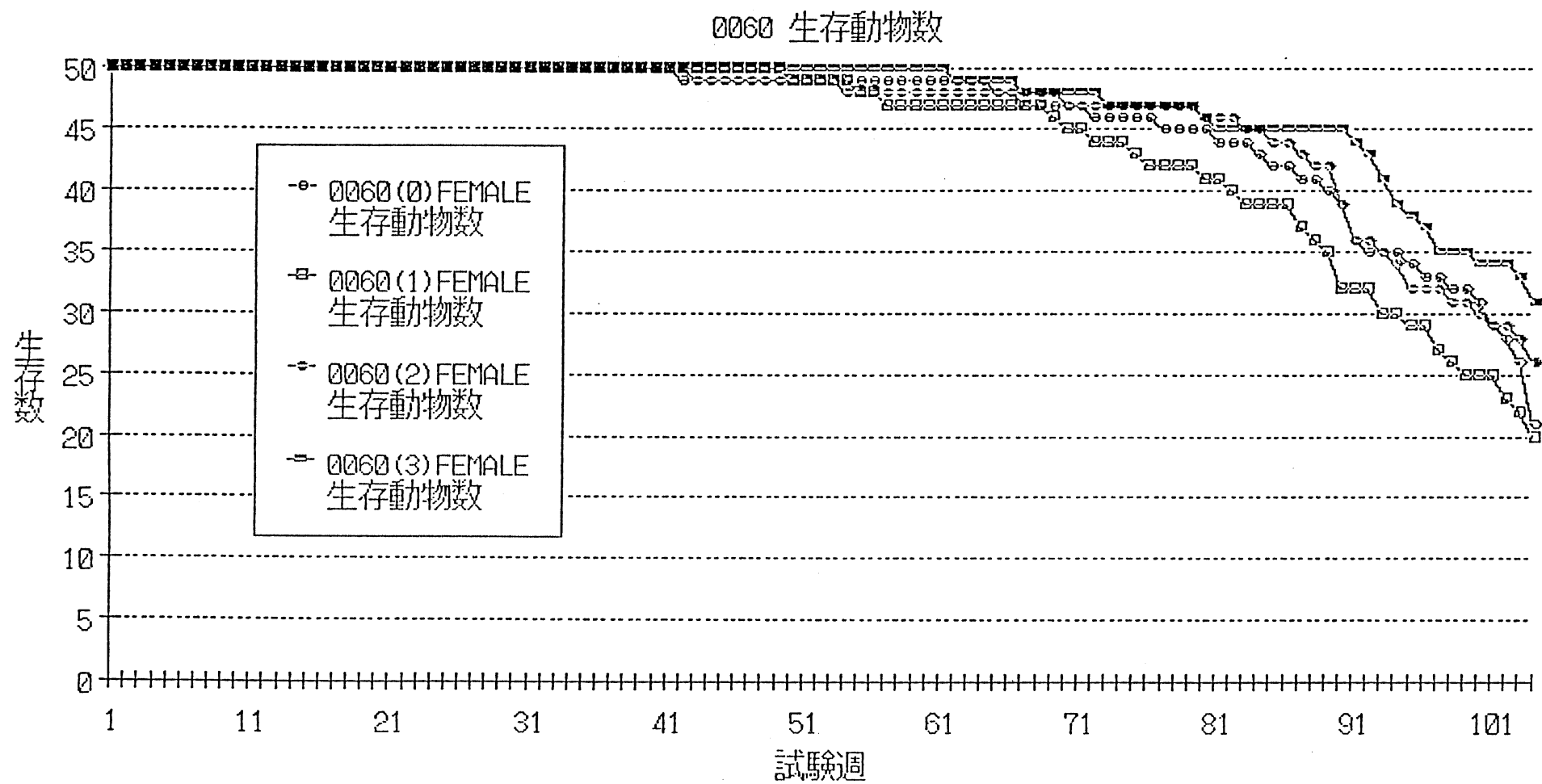
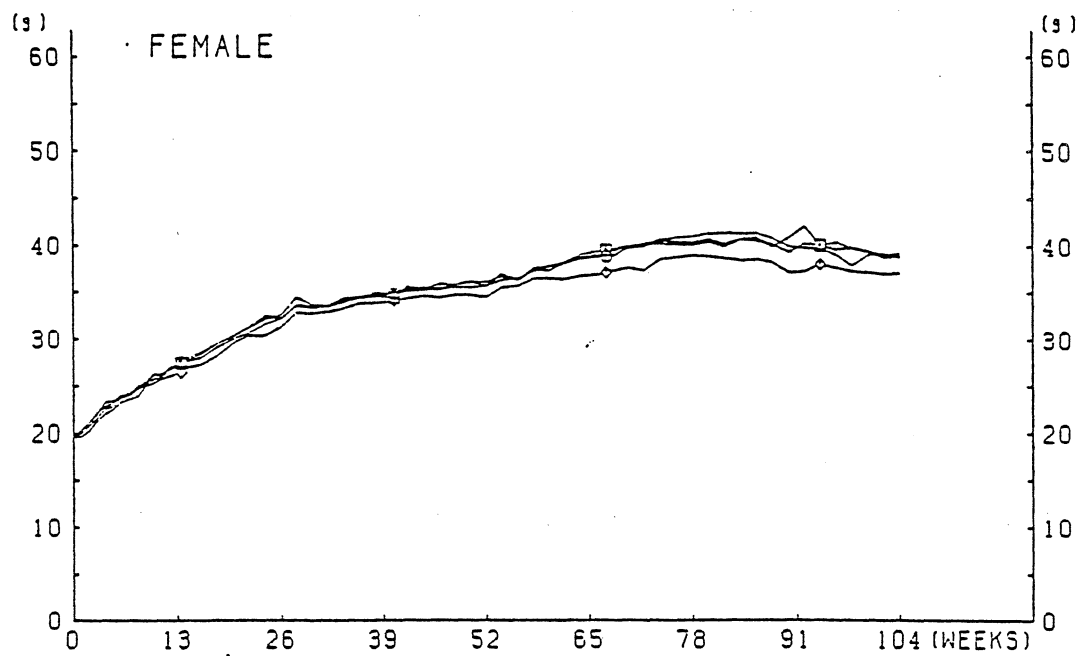
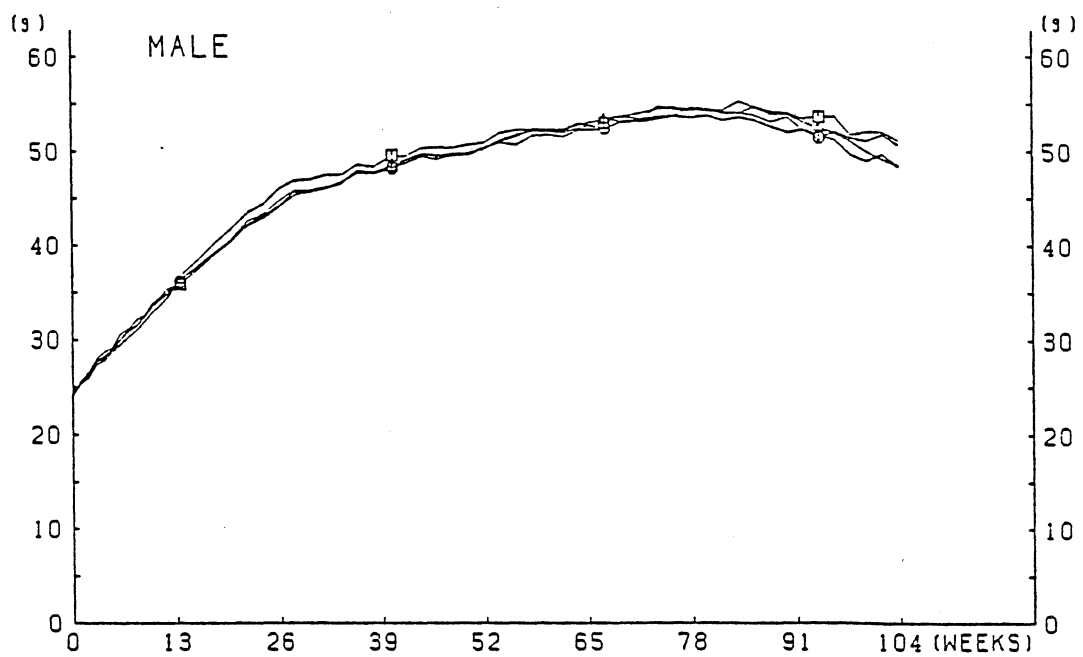


図 8

生存動物数 (マウス・雌・がん原性試験)



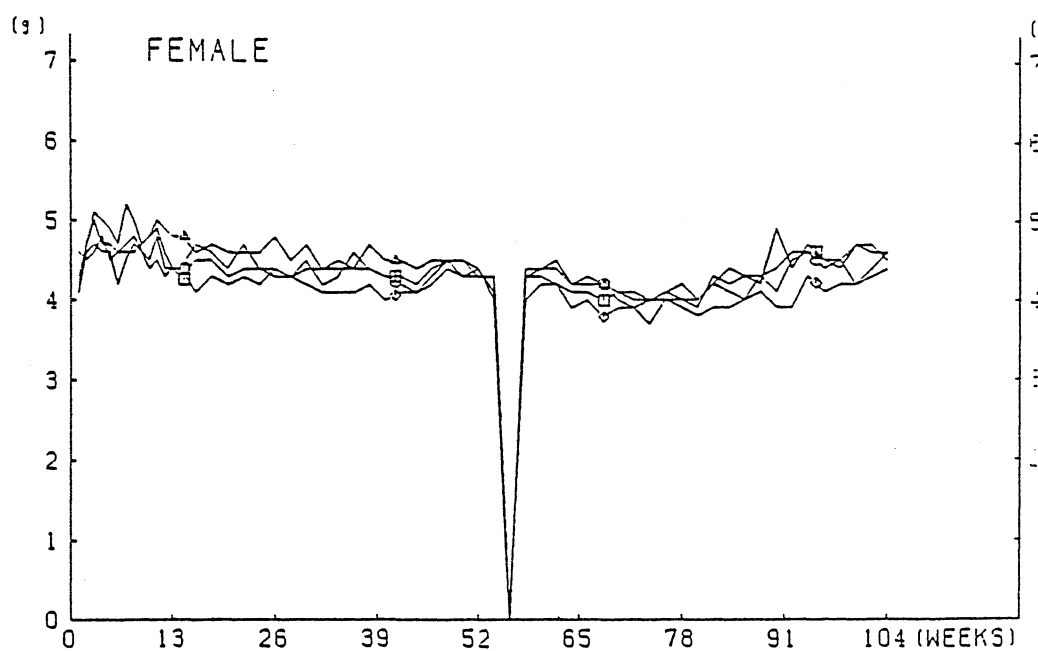
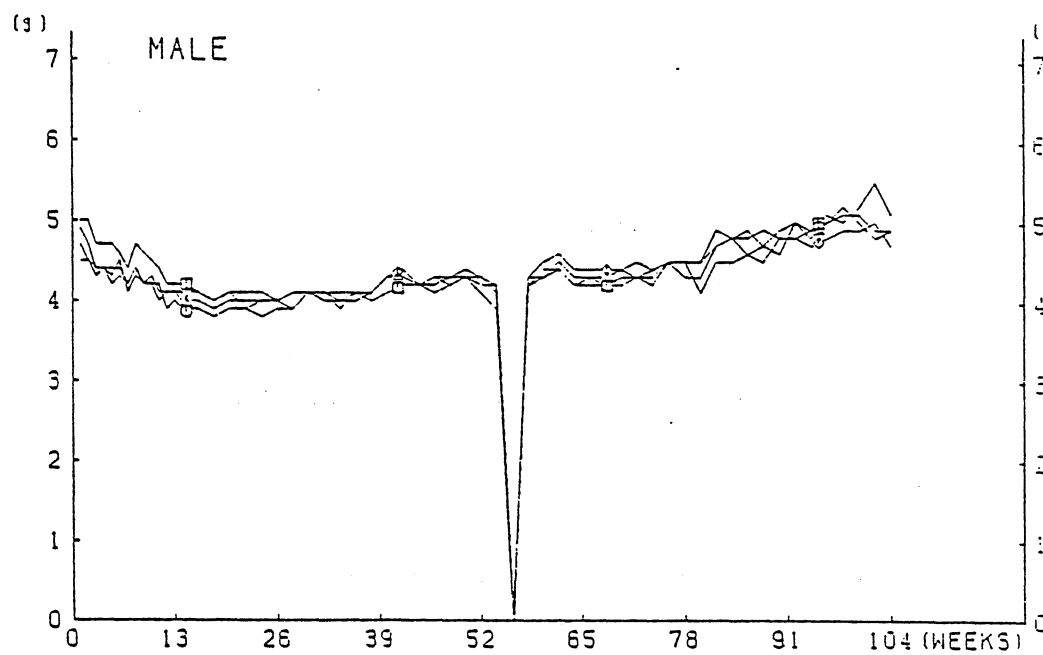
STUDY NO. 0060
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

DOSE LEVEL (PPM)
 —□— CONTROL
 —○— 20
 —△— 60
 —◇— 180

BODY WEIGHT

図 9

体重値 (マウス・がん原性試験)



STUDY NO. 0060
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

DOSE LEVEL (PPM)

—□— CONTROL
—○— 20
—△— 60
—◇— 130

WATER CONSUMPTION

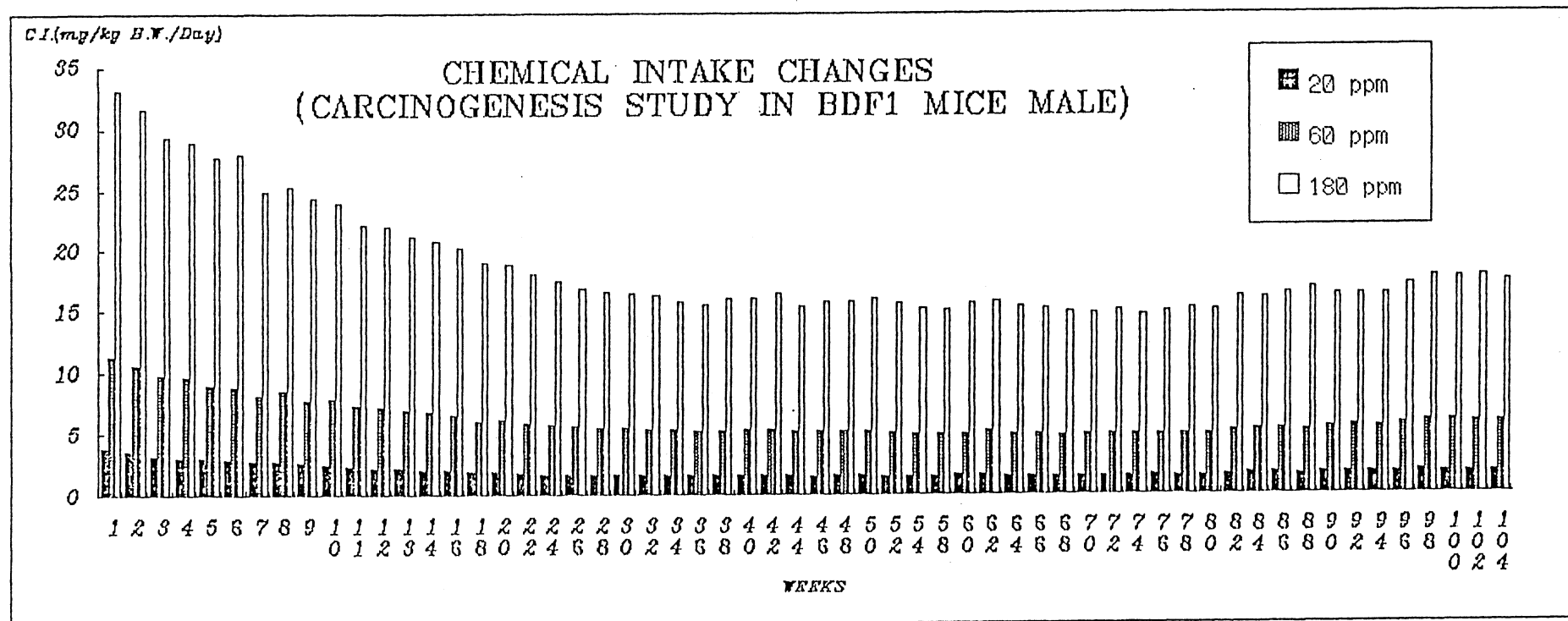


図 1 1

被験物質摂取量 (マウス・雄・がん原性試験)

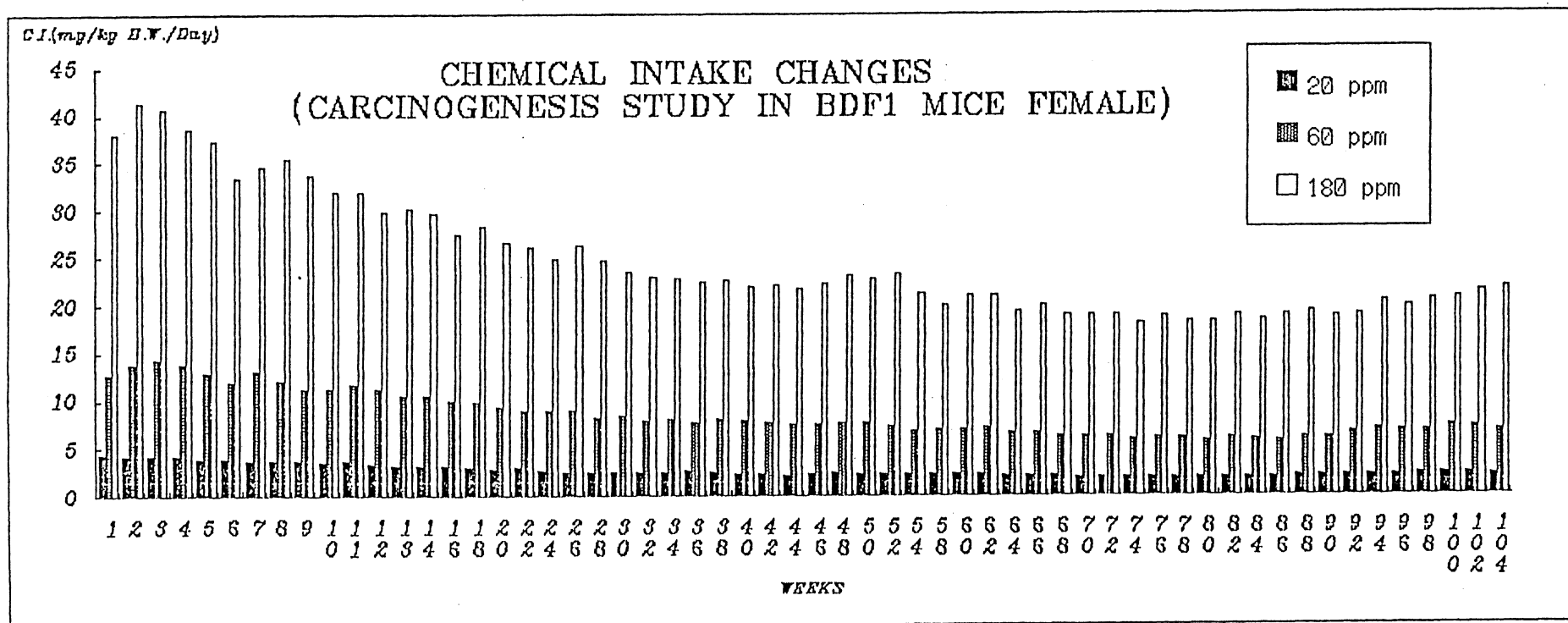
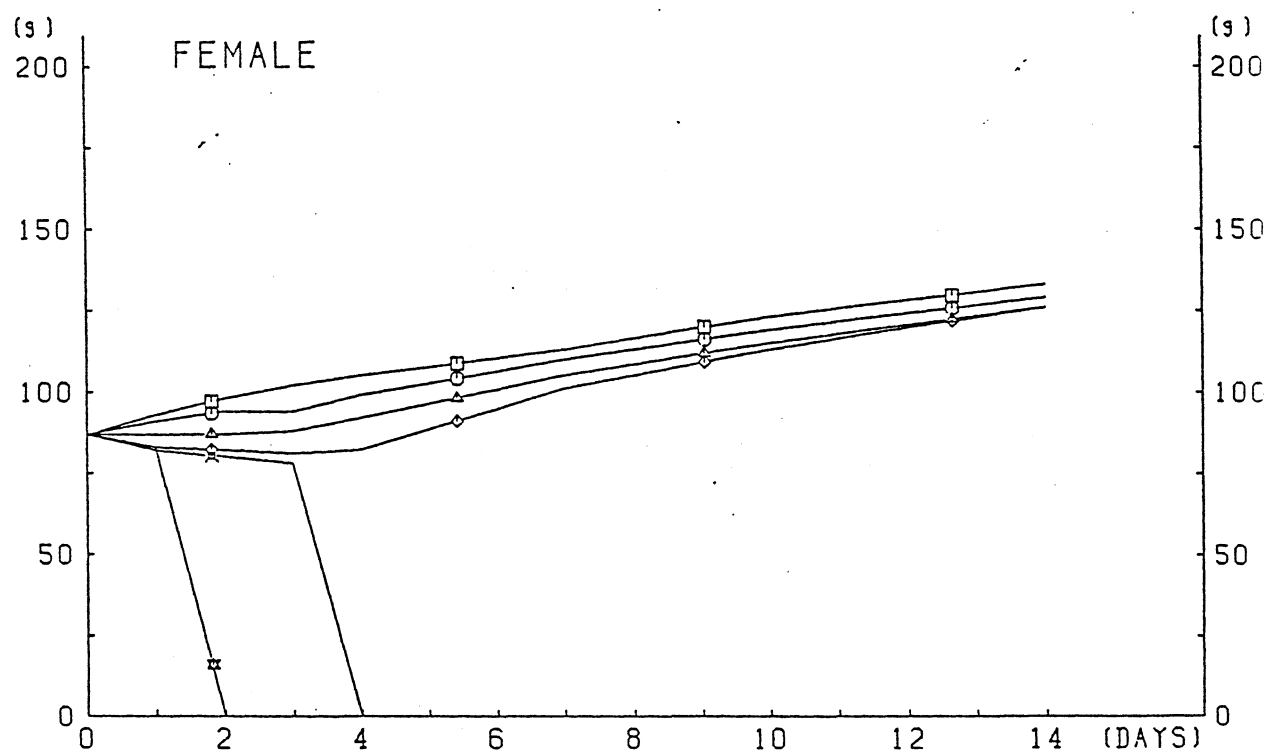
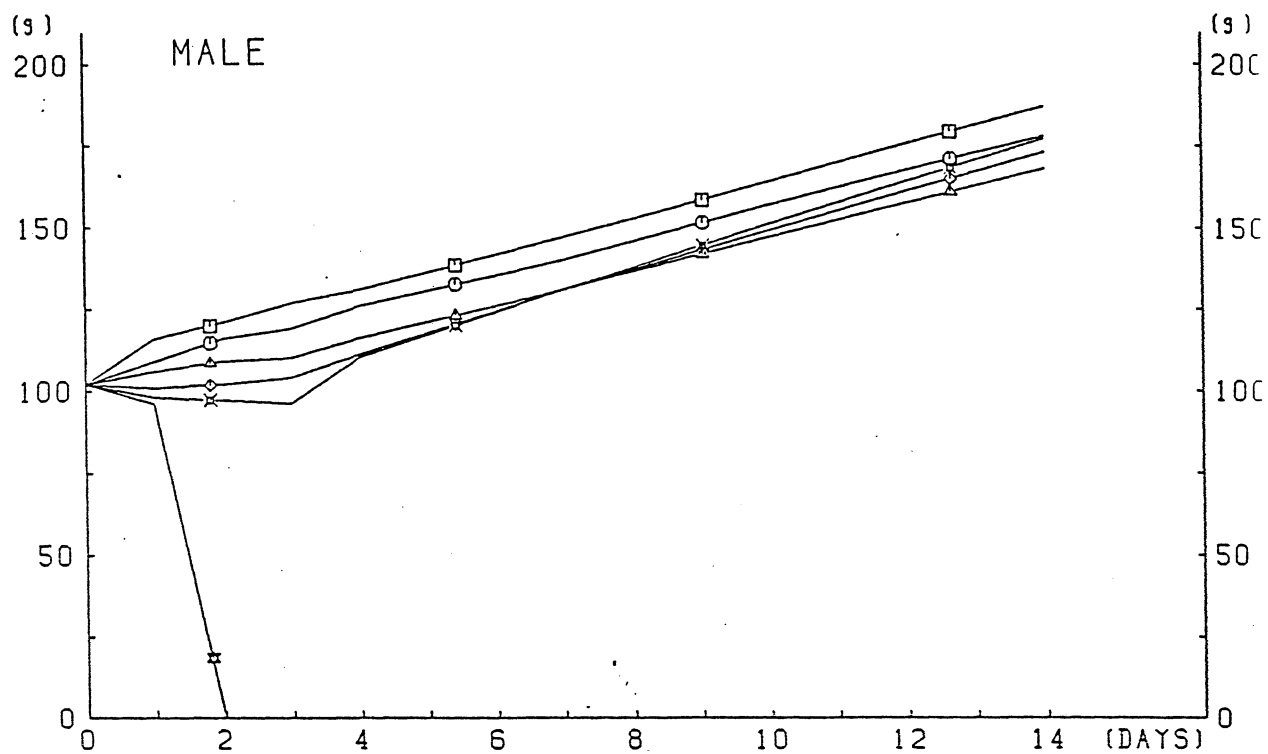


図 1 2

被験物質摂取量（マウス・雌・がん原性試験）

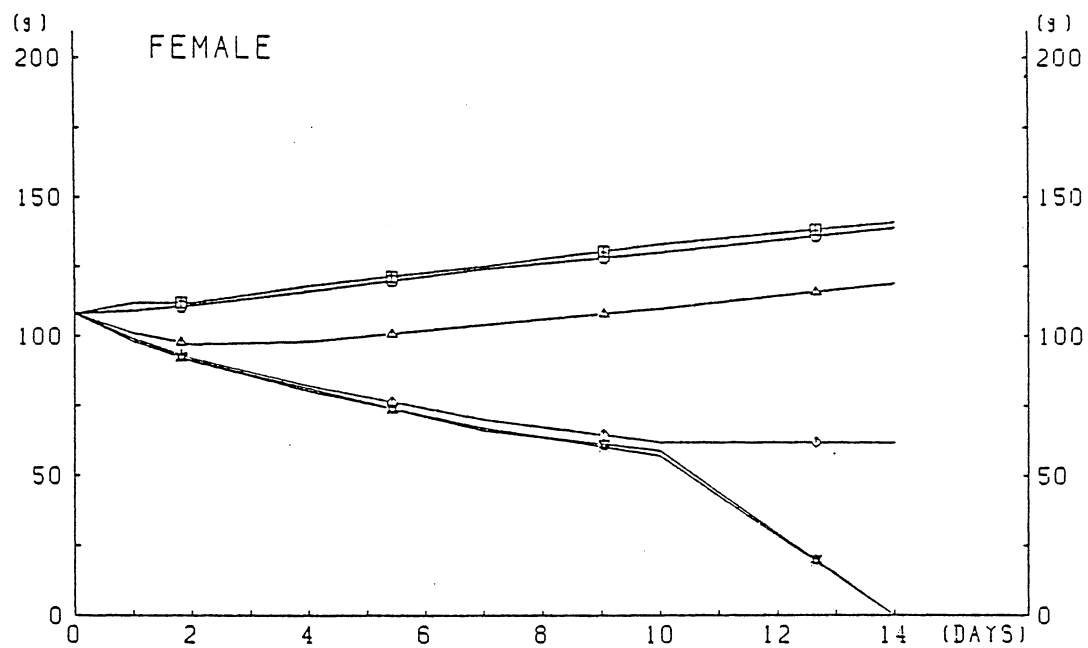
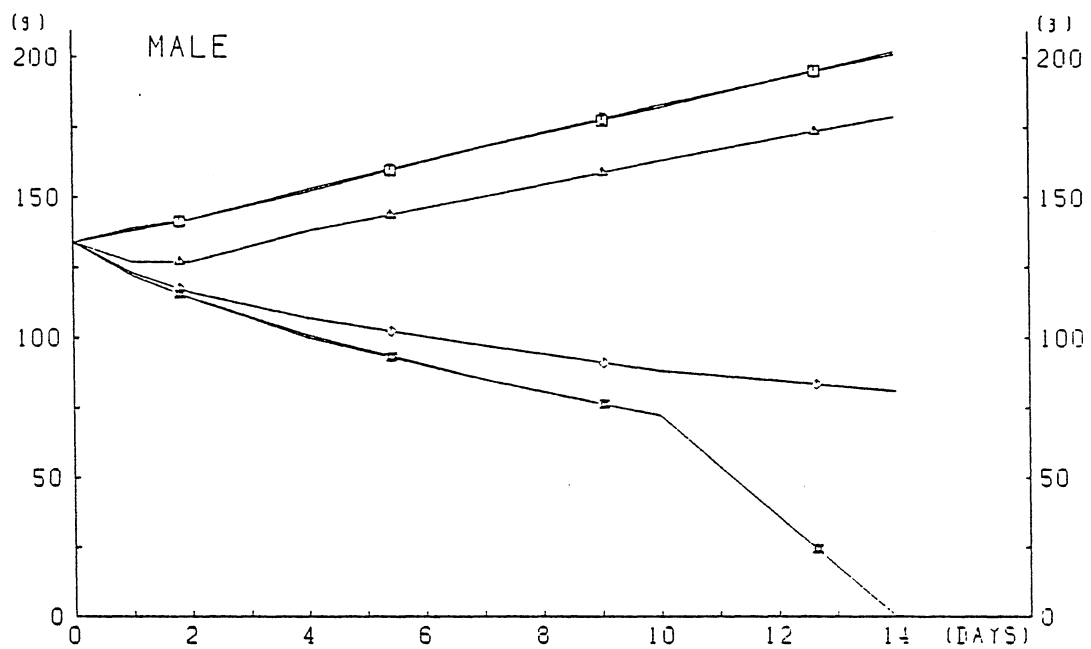


STUDY NO. 0007
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (MG/KG)

—□—	CONTROL
—○—	96
—△—	163
—◇—	277
—×—	471
—※—	800

BODY WEIGHT



STUDY NO. 0026
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

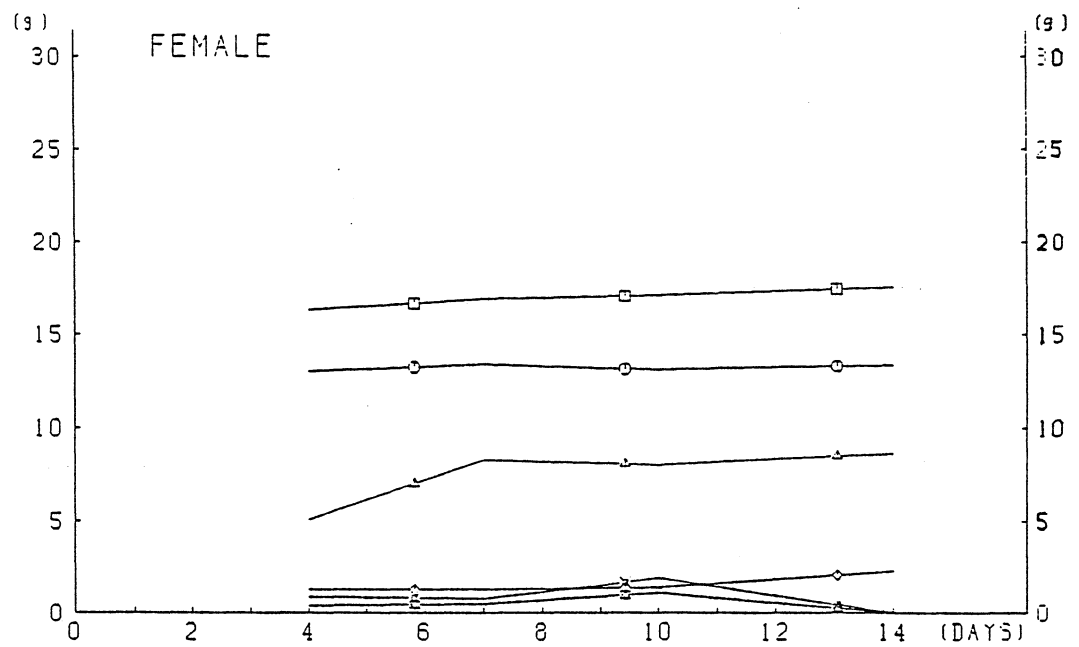
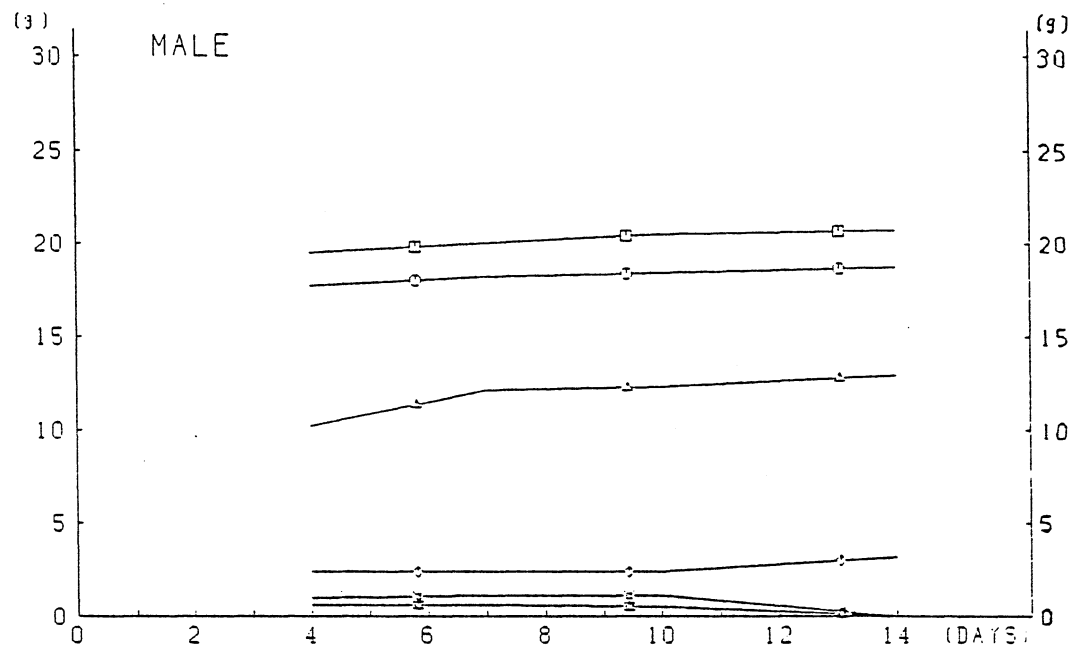
DOSE LEVEL (PPM)

- CONTROL
- 278
- △— 833
- ◇— 2500
- ×— 7500
- *— 22500

BODY WEIGHT

付録図 2

体重値 (ラット・2週間試験)

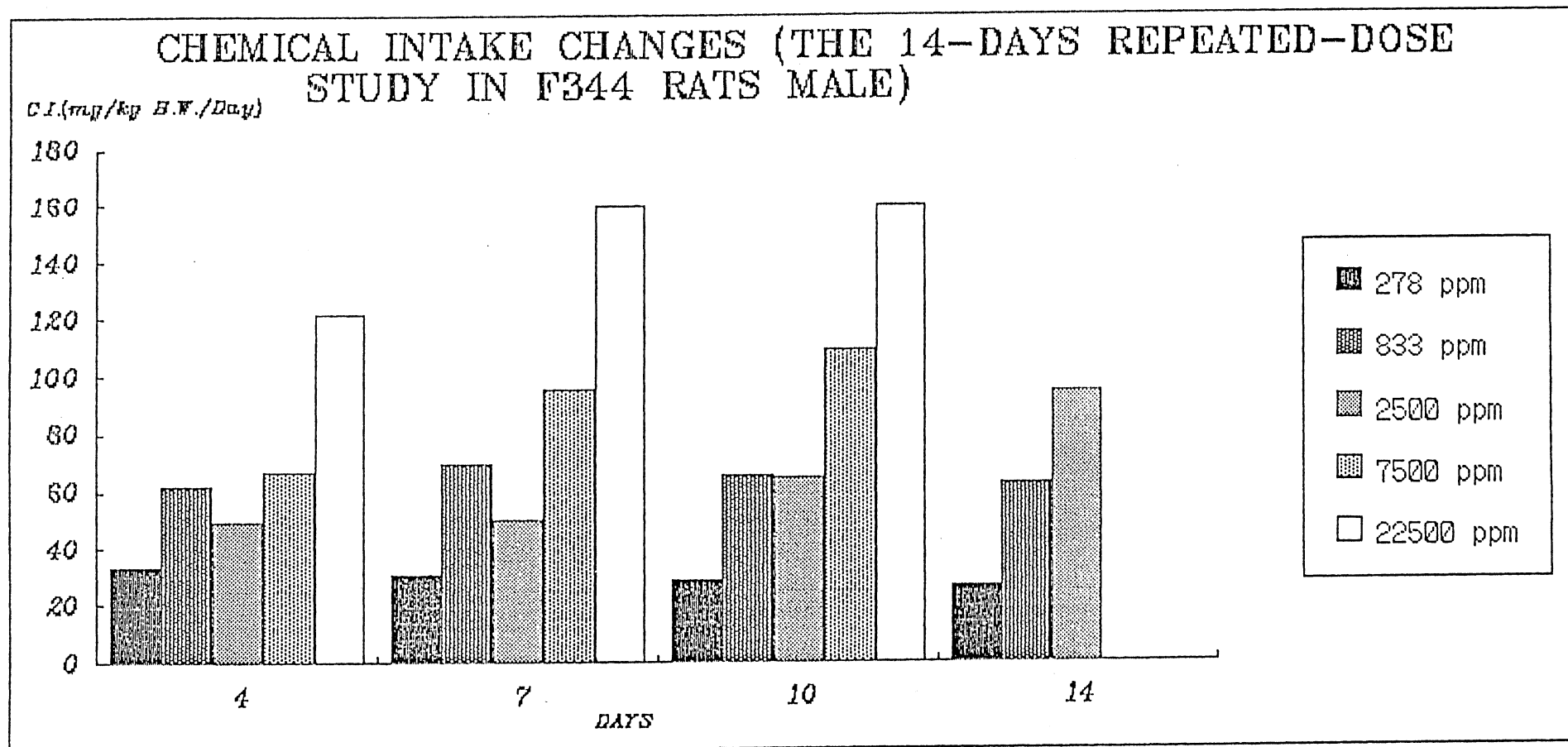


STUDY NO. 0026
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)

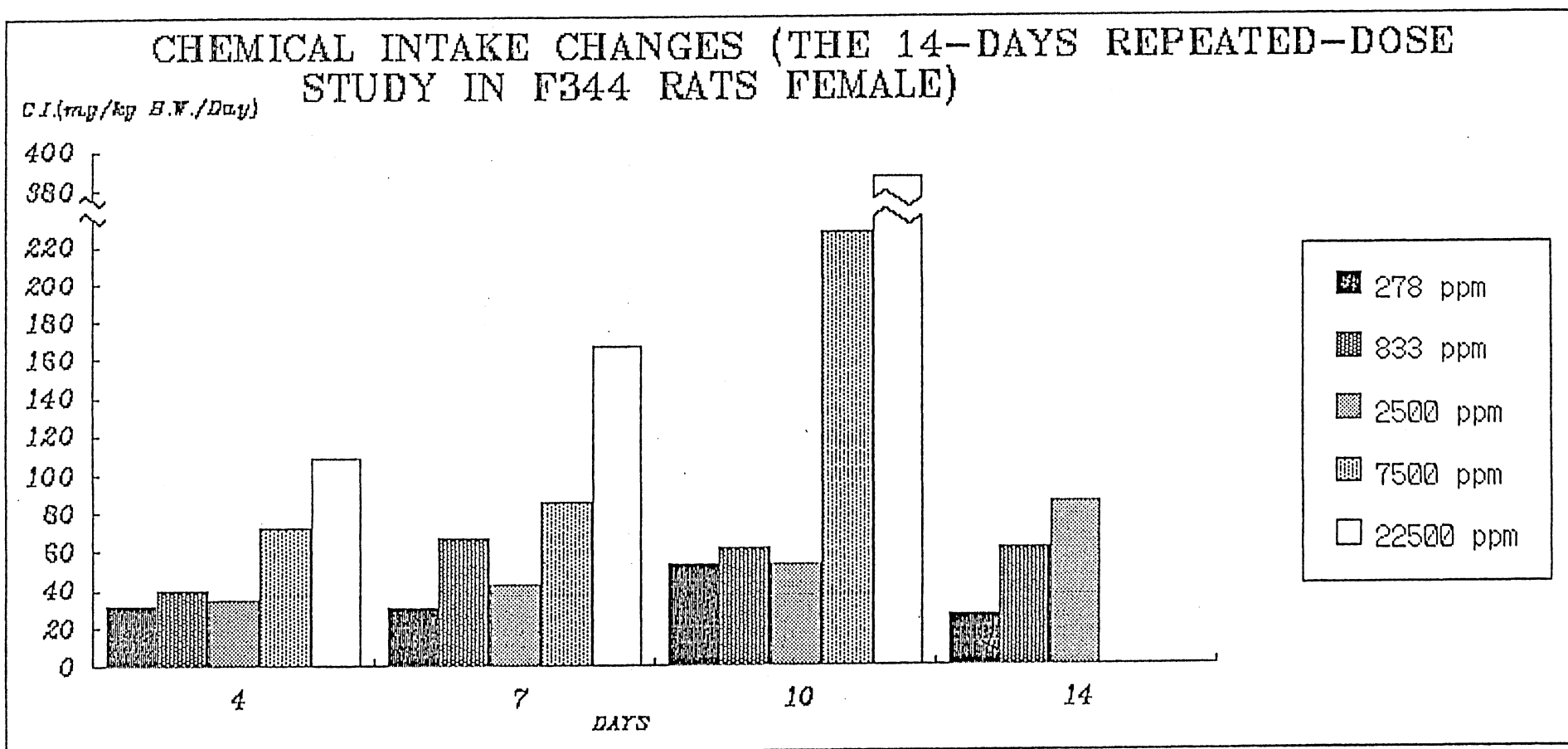
—□— CONTROL
 —○— 273
 —△— 833
 —◇— 2500
 —×— 7500
 —+— 22500

WATER CONSUMPTION



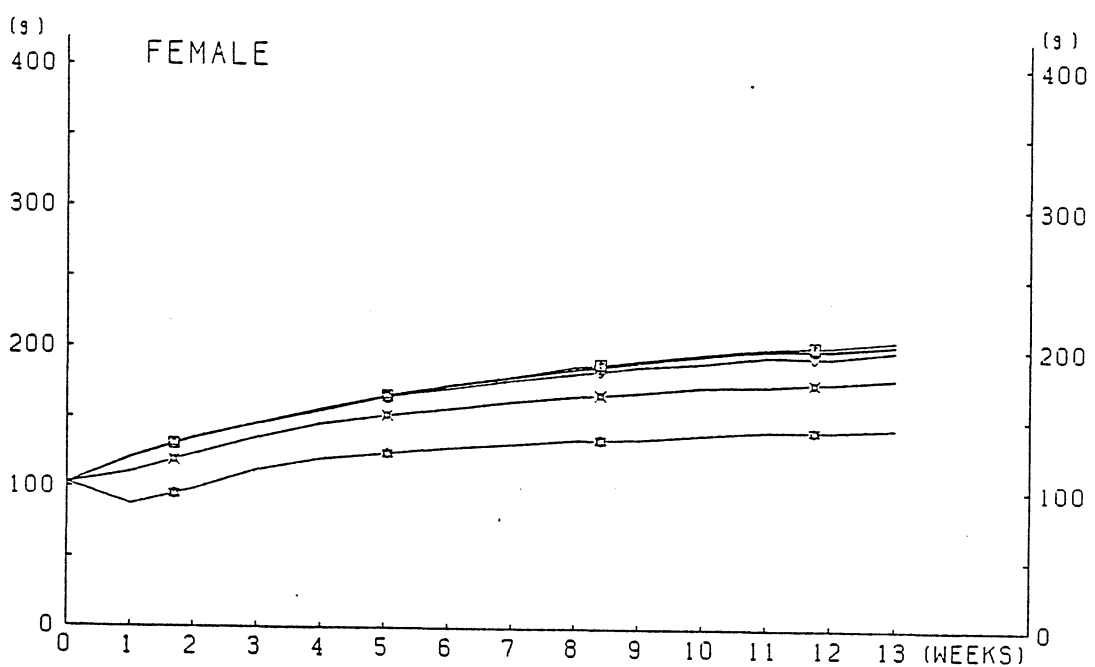
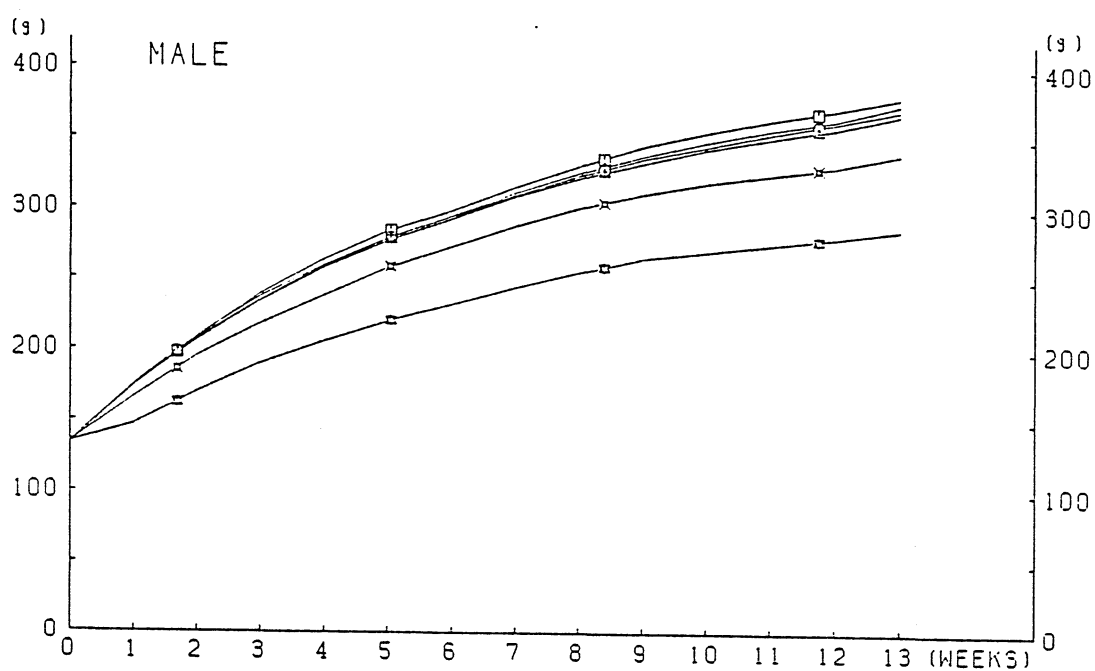
付録図 4

被験物質摂取量（ラット・2週間試験）



付録図 4

被験物質摂取量（ラット・2週間試験）

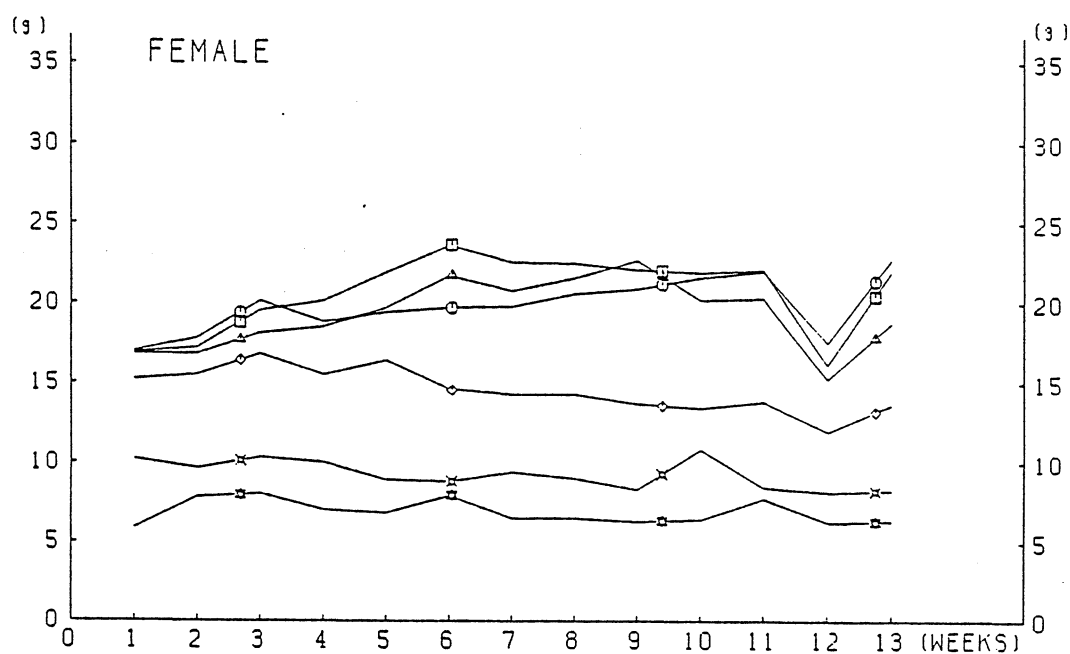
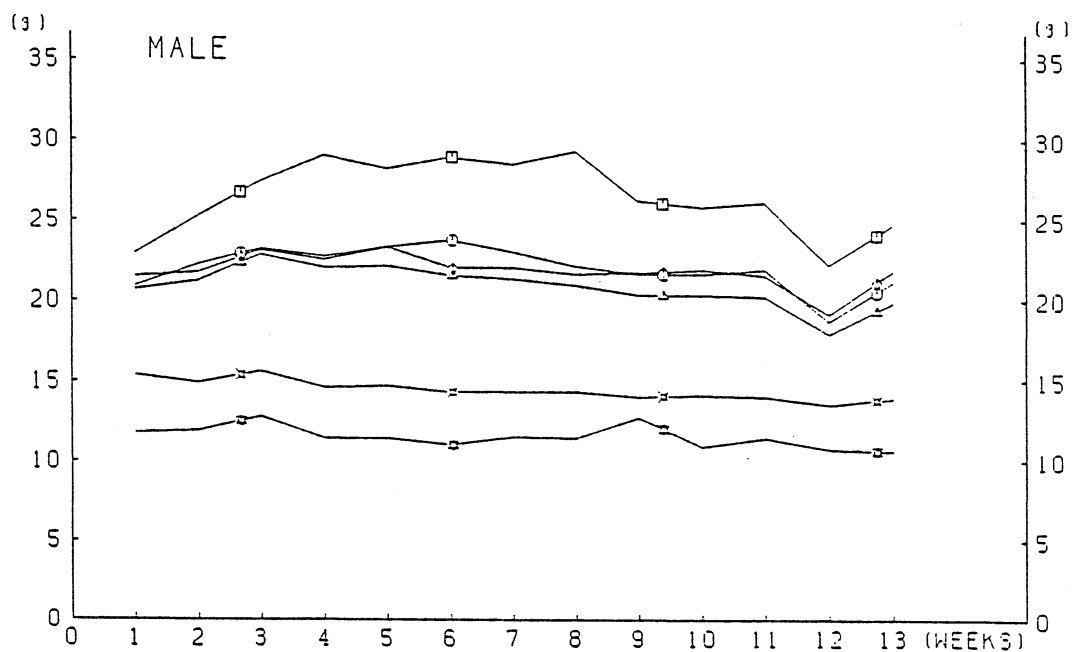


STUDY NO. 0038
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)

—□— 0
 —○— 62.5
 —△— 125
 —◇— 250
 —×— 500
 —■— 1000

BODY WEIGHT

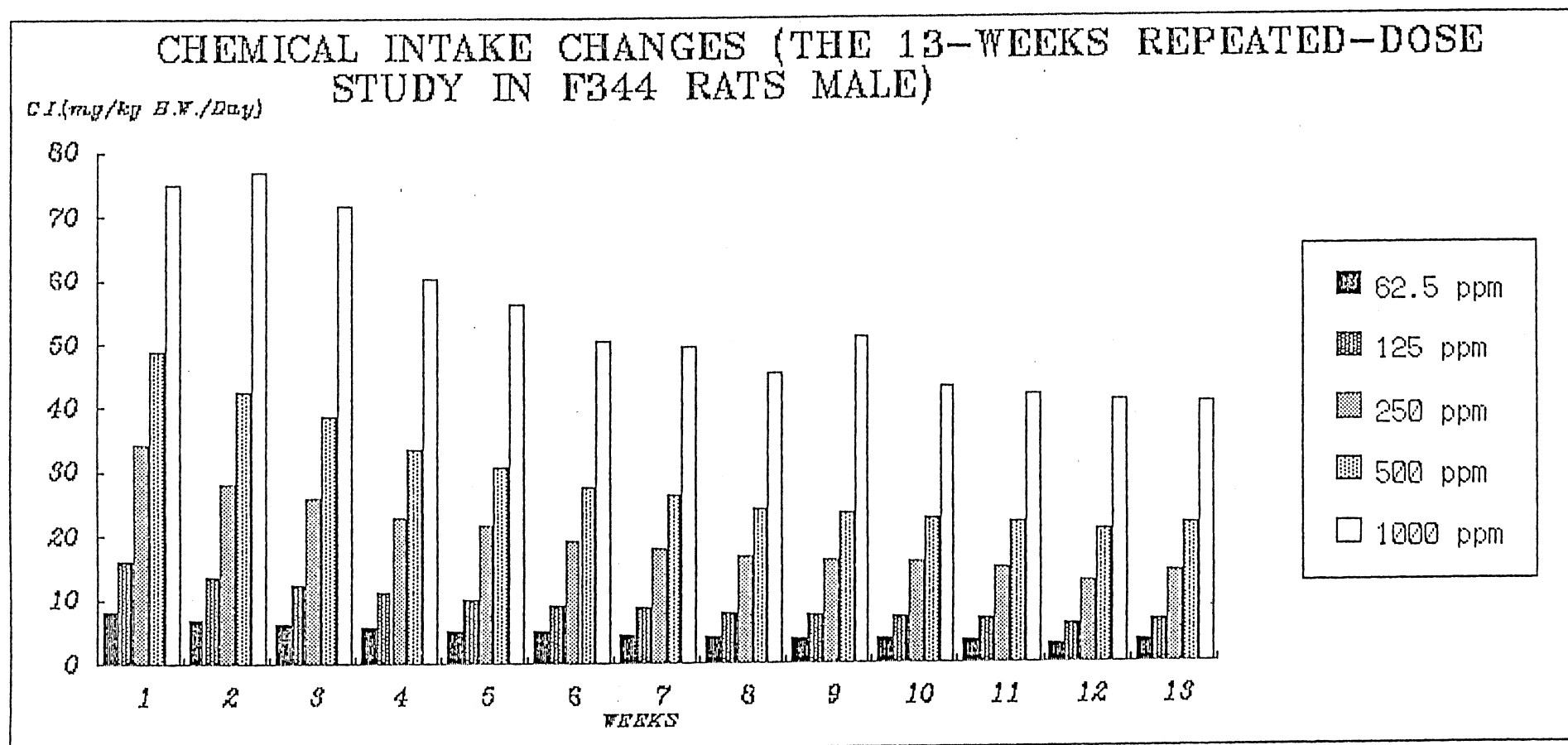


STUDY NO. 0038
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)

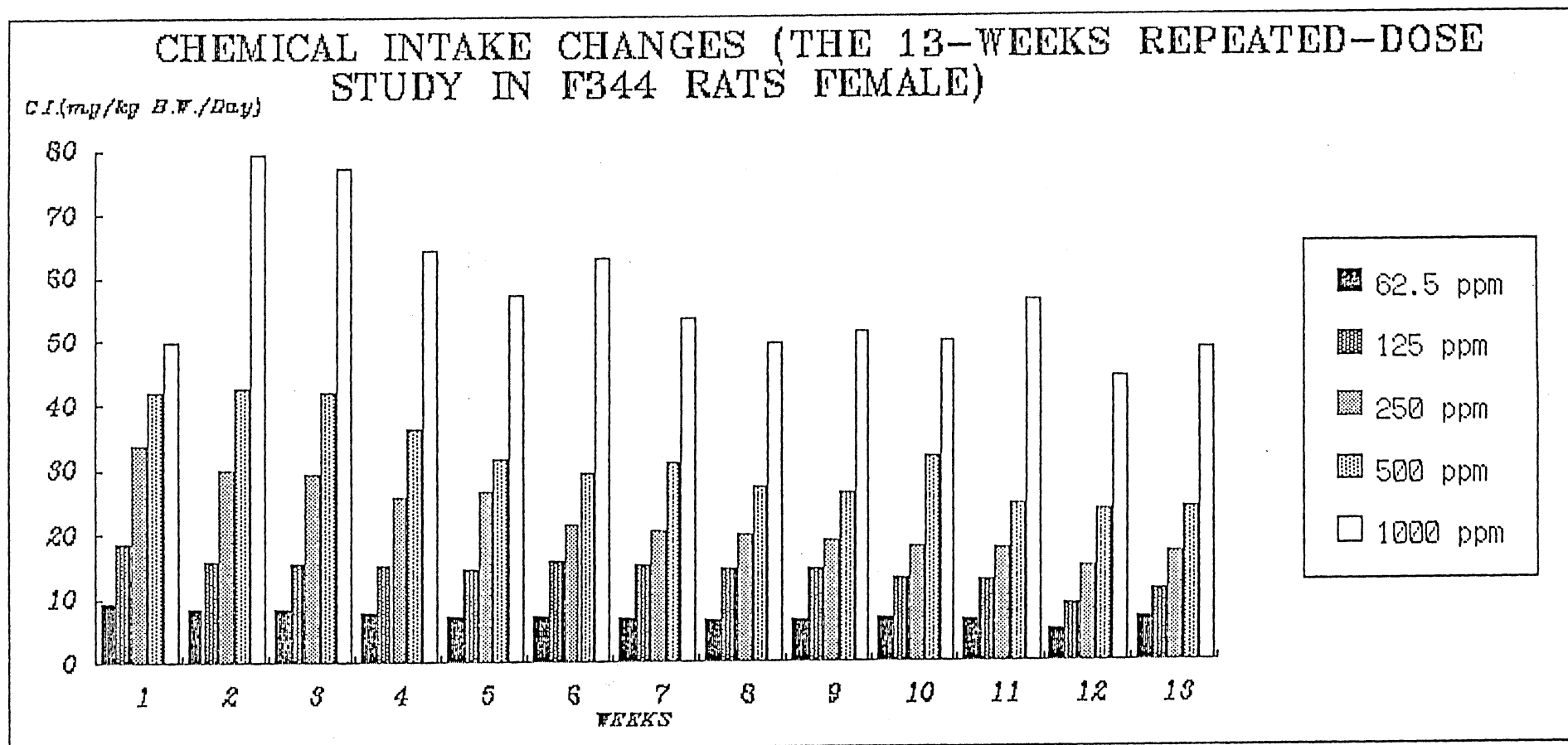
- 0
- 62.5
- △— 125
- ◇— 250
- ×— 500
- 1000

WATER CONSUMPTION



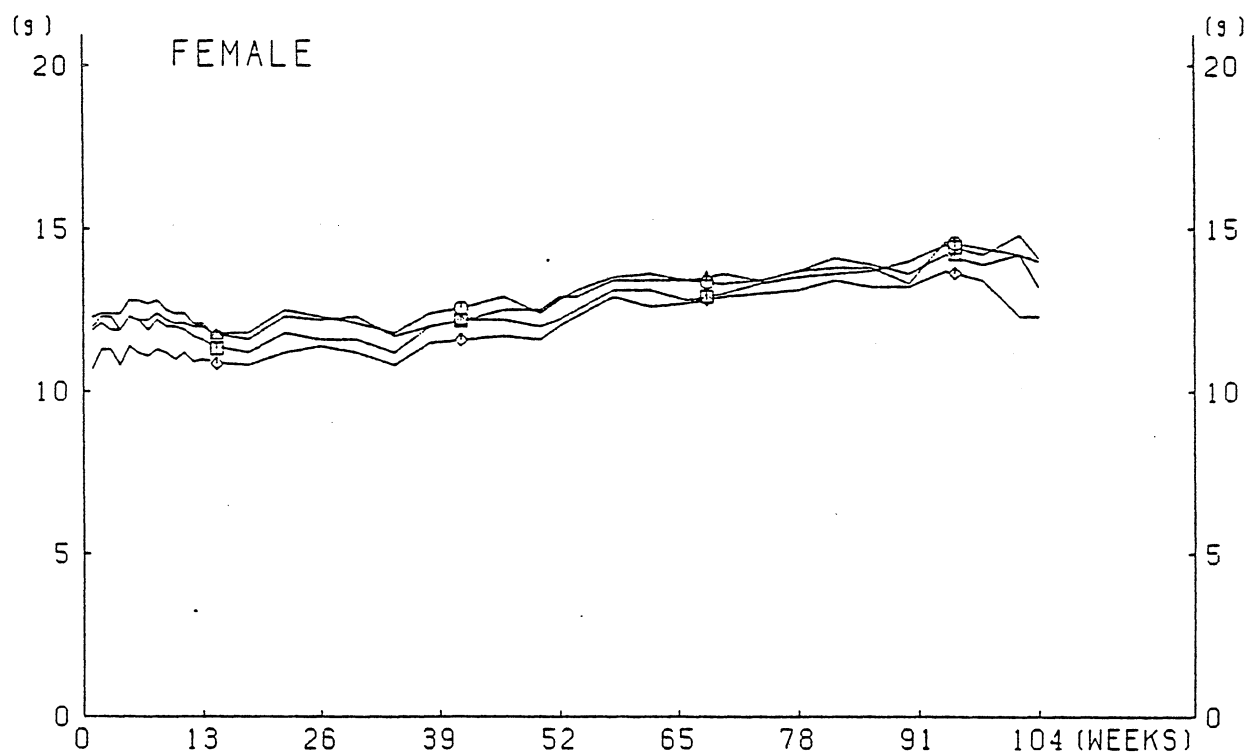
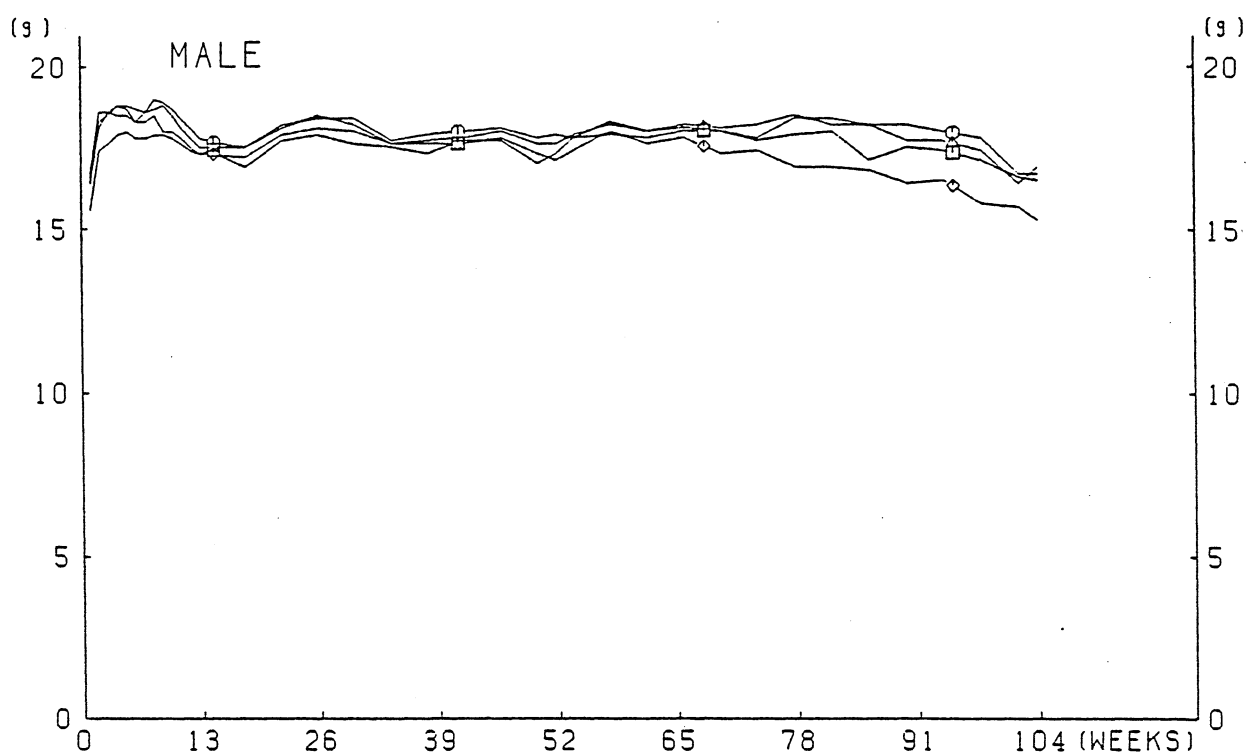
付録図 7

被験物質摂取量（ラット・13週間試験）



付録図 7

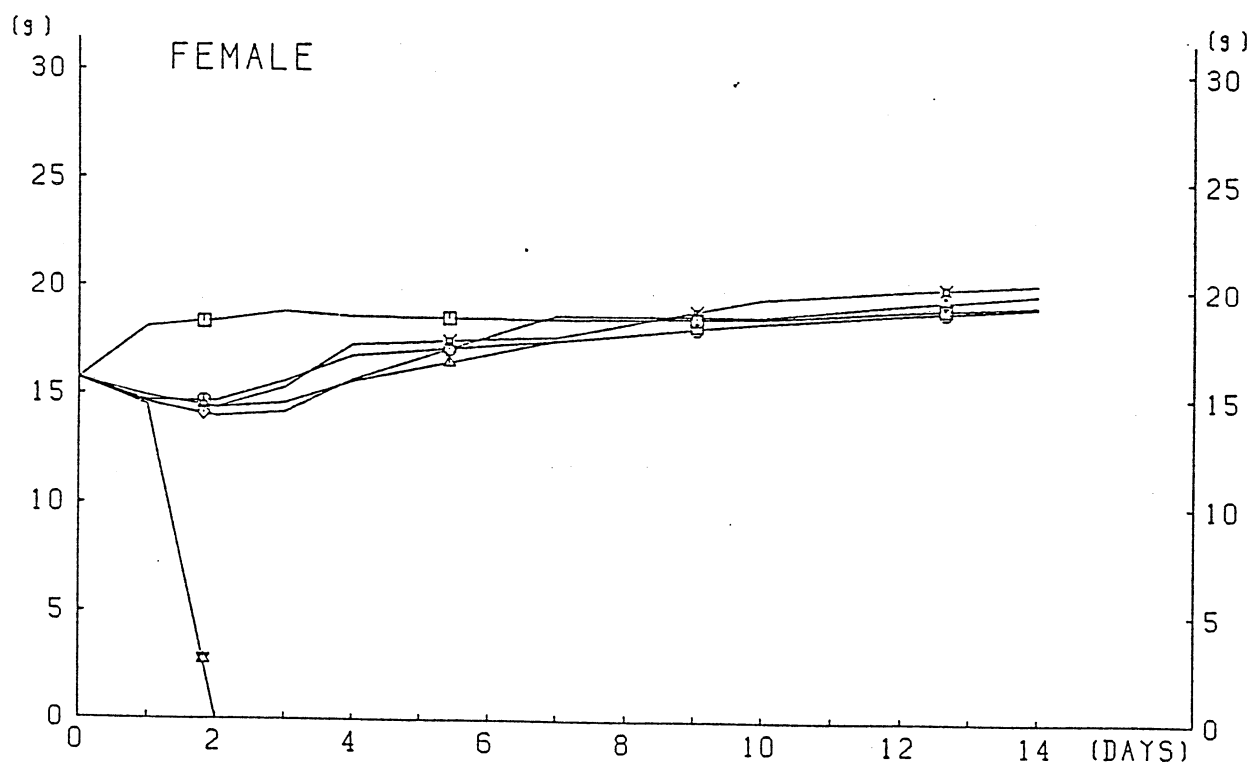
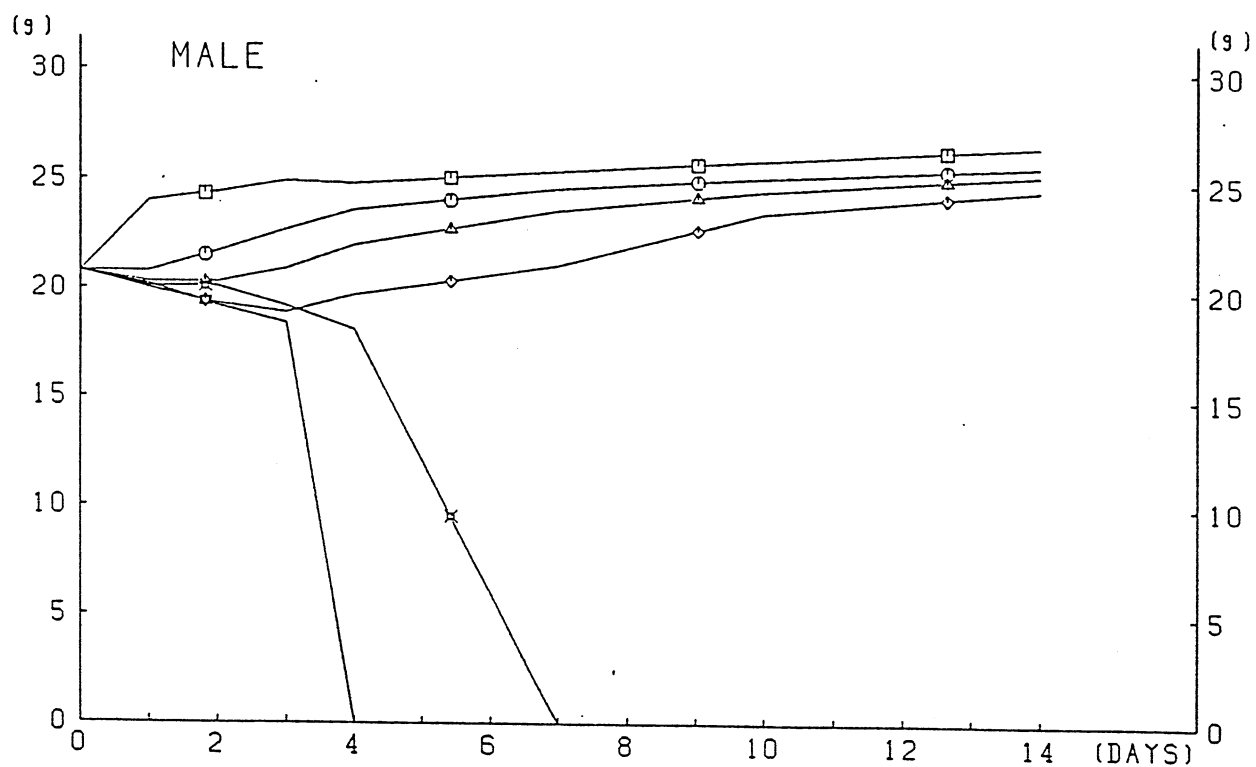
被験物質摂取量（ラット・13週間試験）



STUDY NO. 0059
 TEST SUB. M-PD.2HCL
 ANIMAL RAT F344

DOSE LEVEL (PPM)
 —□— CONTROL
 —○— 64
 —△— 160
 —◇— 400

FOOD CONSUMPTION

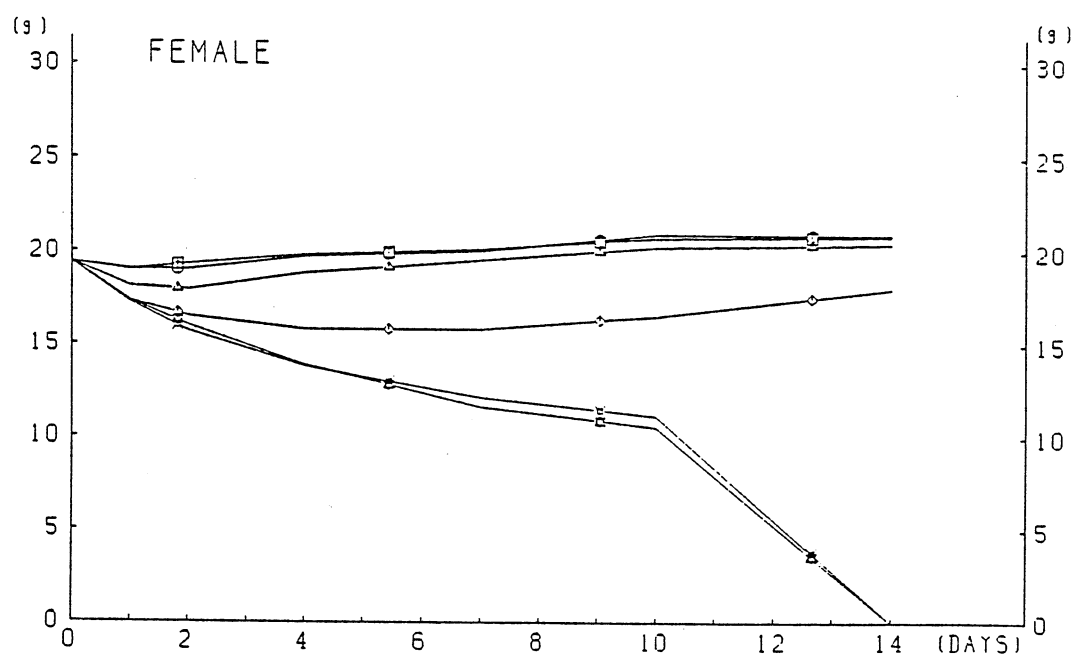
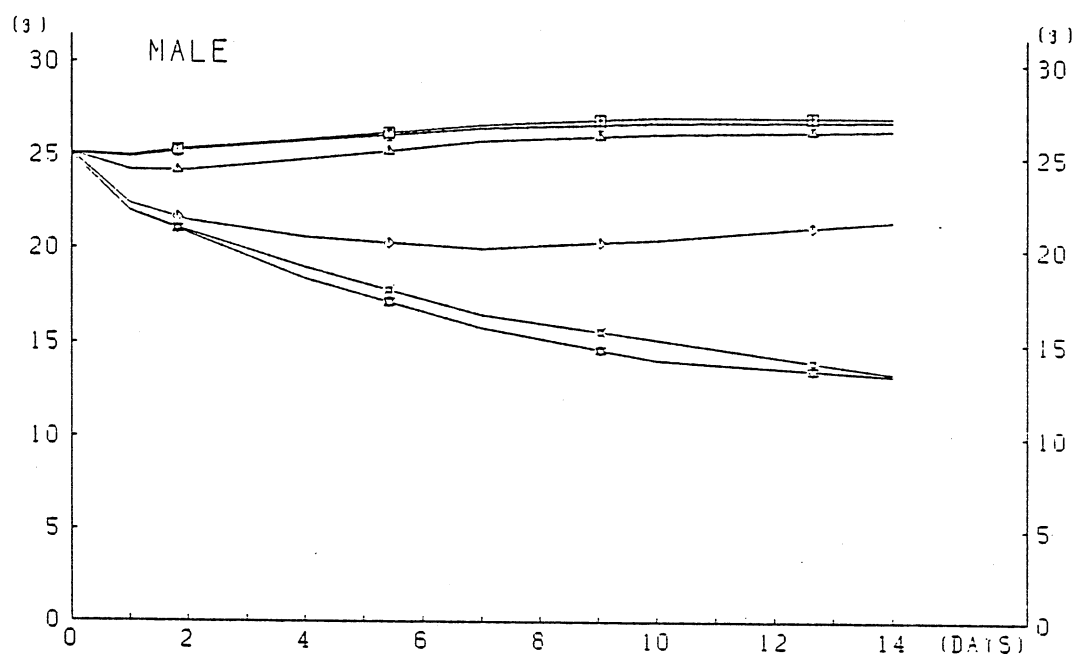


STUDY NO. 0008
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

DOSE LEVEL (MG/KG)

—□—	CONTROL
—○—	68
—△—	102
—◇—	153
—×—	230
—*—	345

BODY WEIGHT



STUDY NO. 0027
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

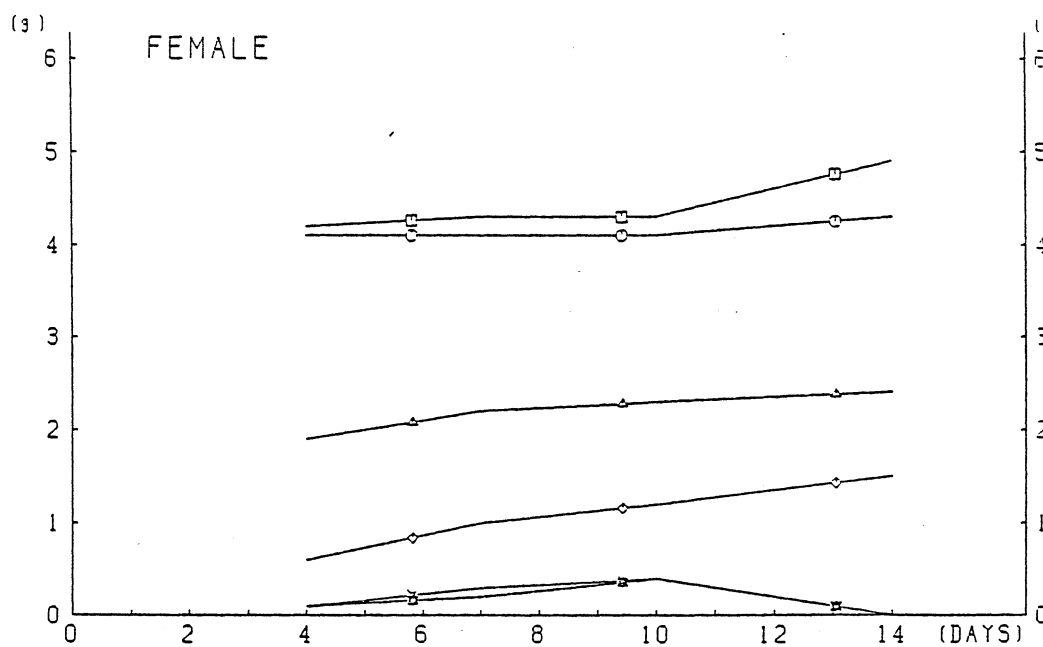
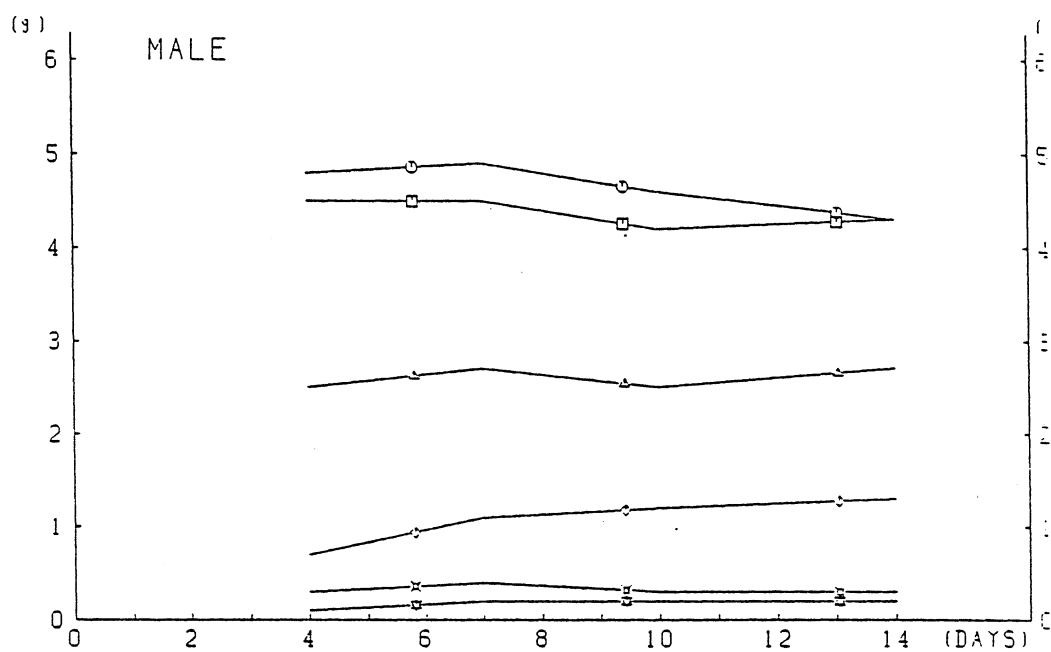
DOSE LEVEL (PPM)

- CONTROL
- 111
- △— 333
- ◇— 1000
- ×— 3000
- *— 9000

BODY WEIGHT

付録図 10

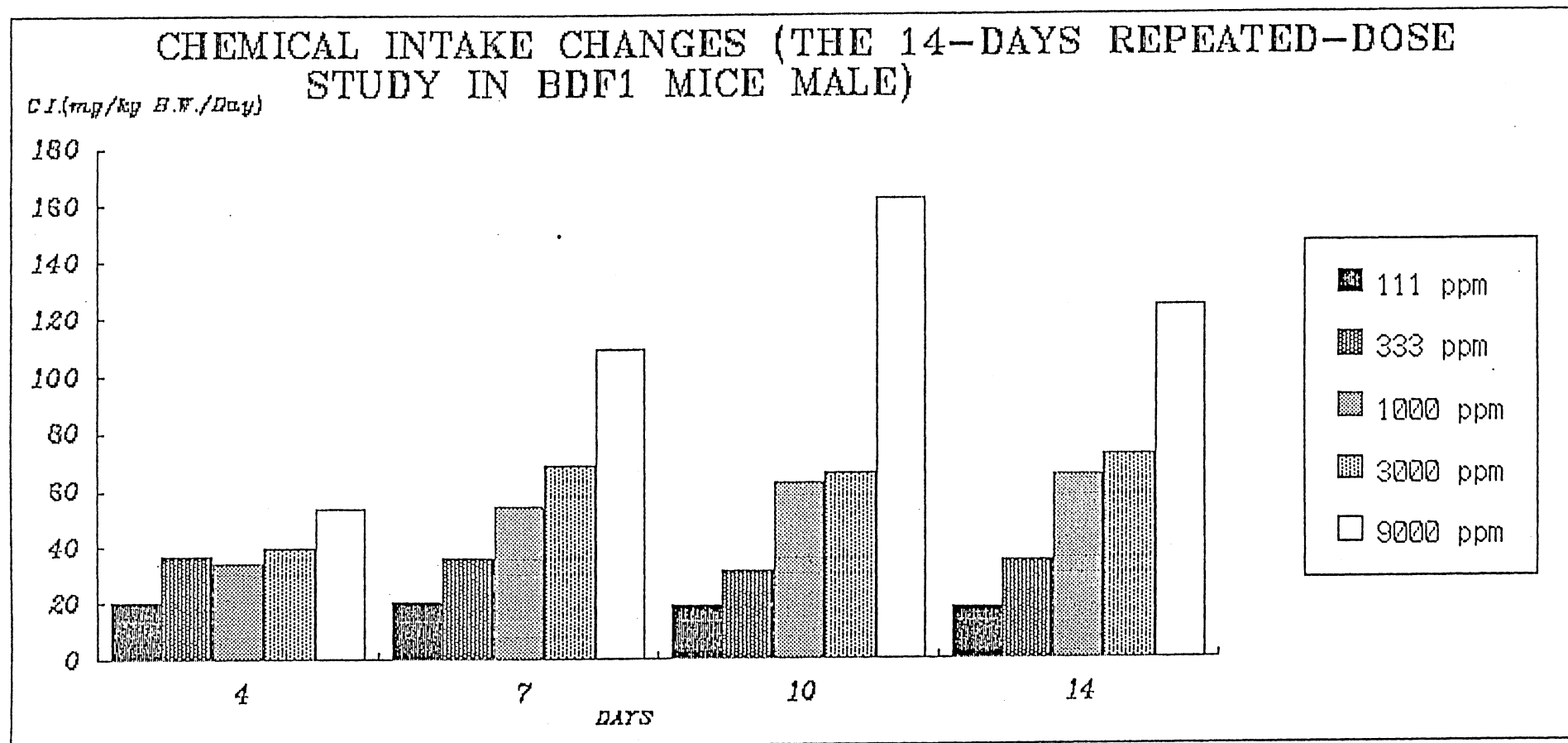
体重値 (マウス・2週間試験)



STUDY NO. 0027
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

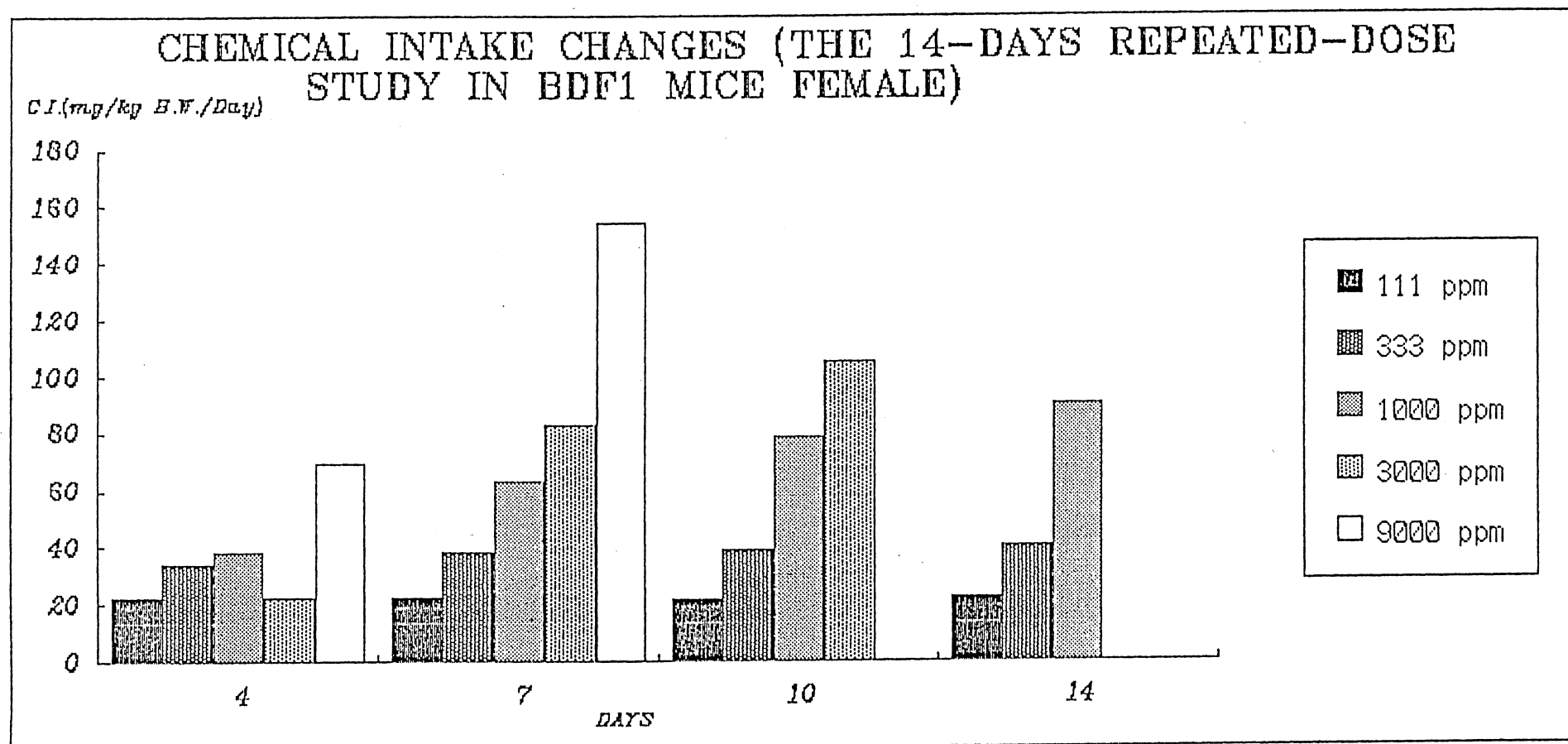
DOSE LEVEL (PPM)
 —□— CONTROL
 —○— 111
 —△— 333
 —◇— 1000
 —×— 3000
 —*— 9000

WATER CONSUMPTION



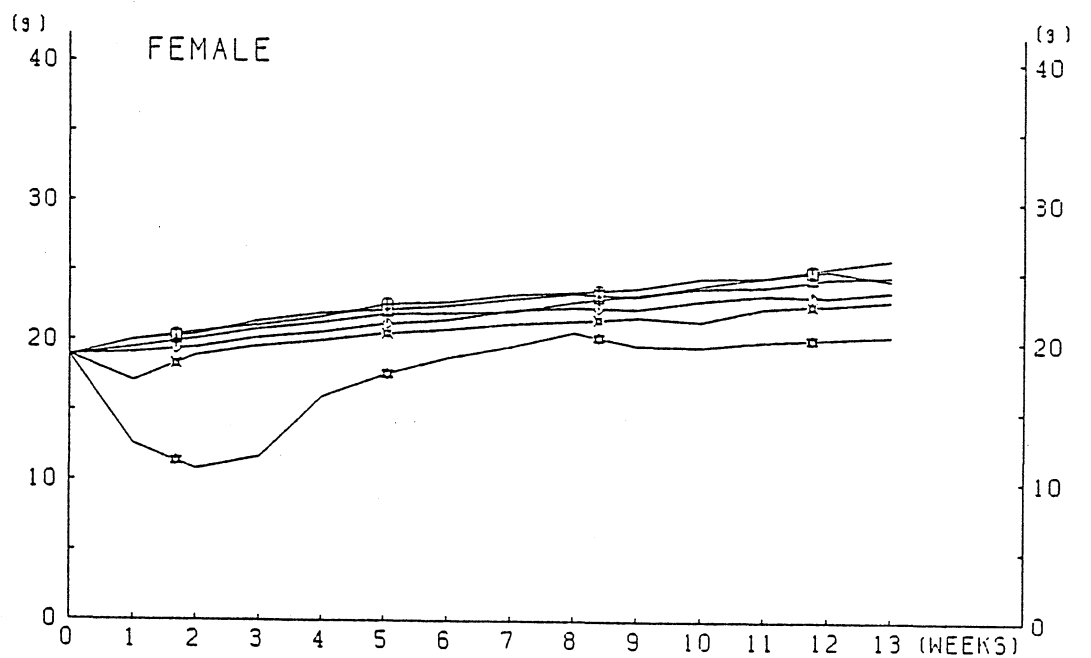
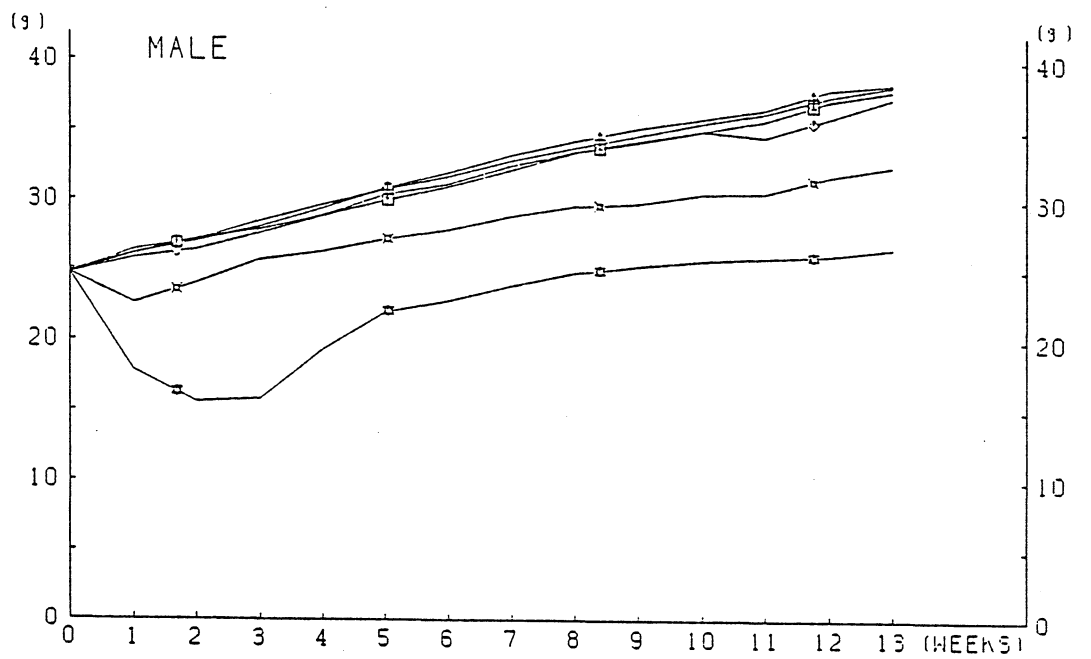
付録図 1 2

被験物質摂取量 (マウス・2週間試験)



付録図 1 2

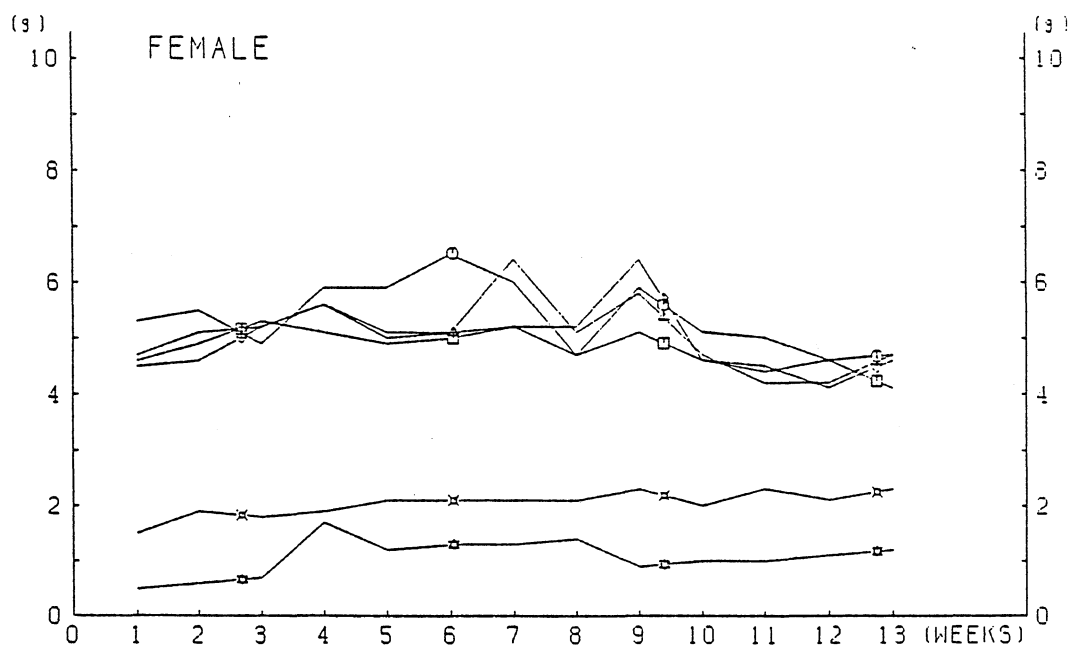
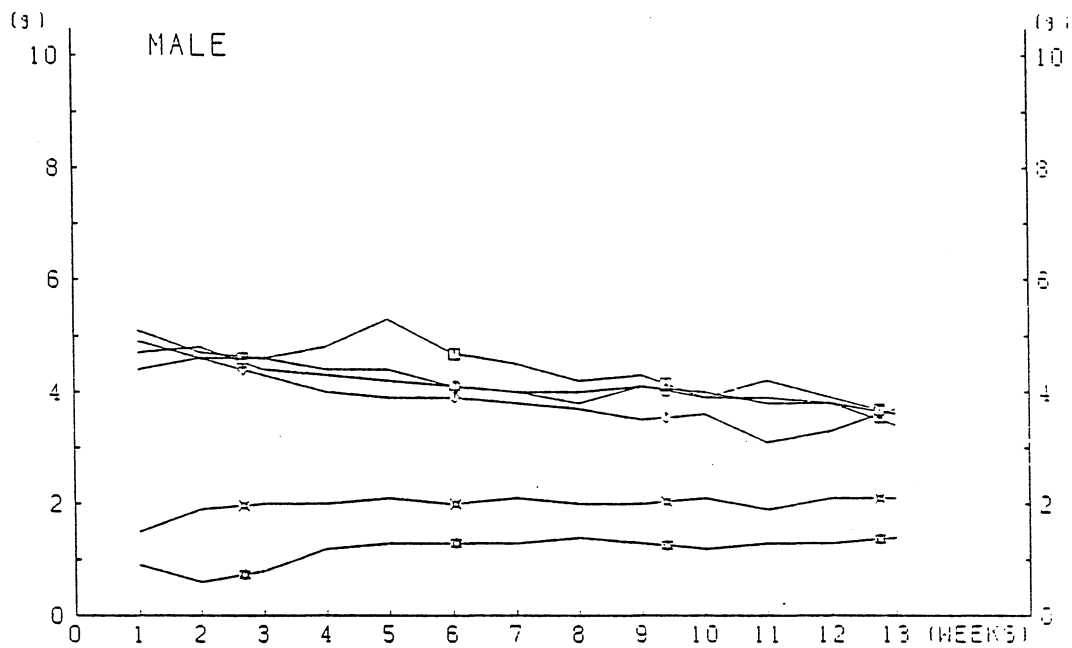
被験物質摂取量 (マウス・2週間試験)



STUDY NO. 0039
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

DOSE LEVEL (PPM)
 —□— 0
 —○— 24.7
 —△— 74.1
 —◇— 222
 —×— 667
 —■— 2000

BODY WEIGHT



STUDY NO. 0039
 TEST SUB. M-PD.2HCL
 ANIMAL MOUSE BDF1

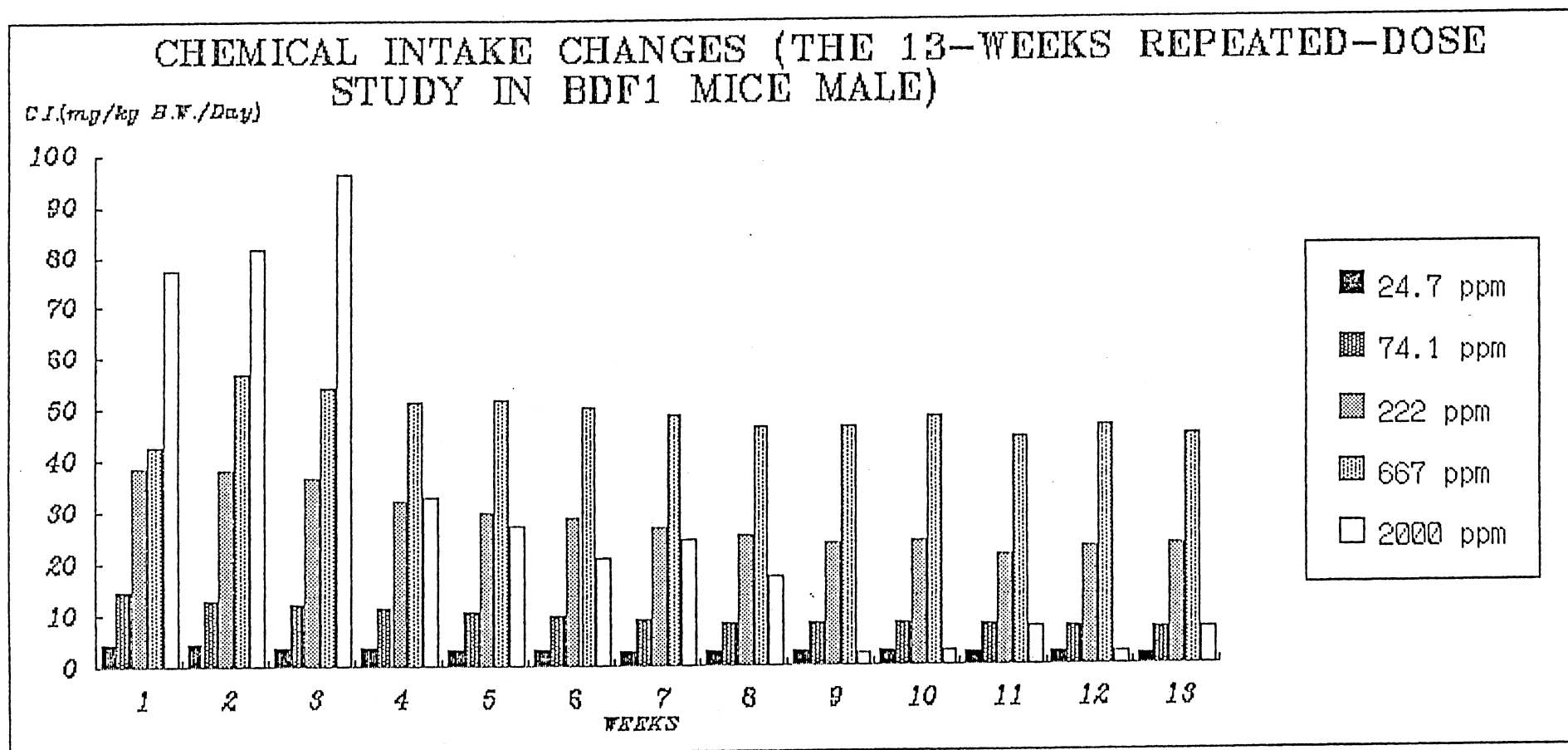
DOSE LEVEL (PPM)

- 0
- 24.7
- △— 74.1
- ◇— 222
- ×— 667
- *— 2000

WATER CONSUMPTION

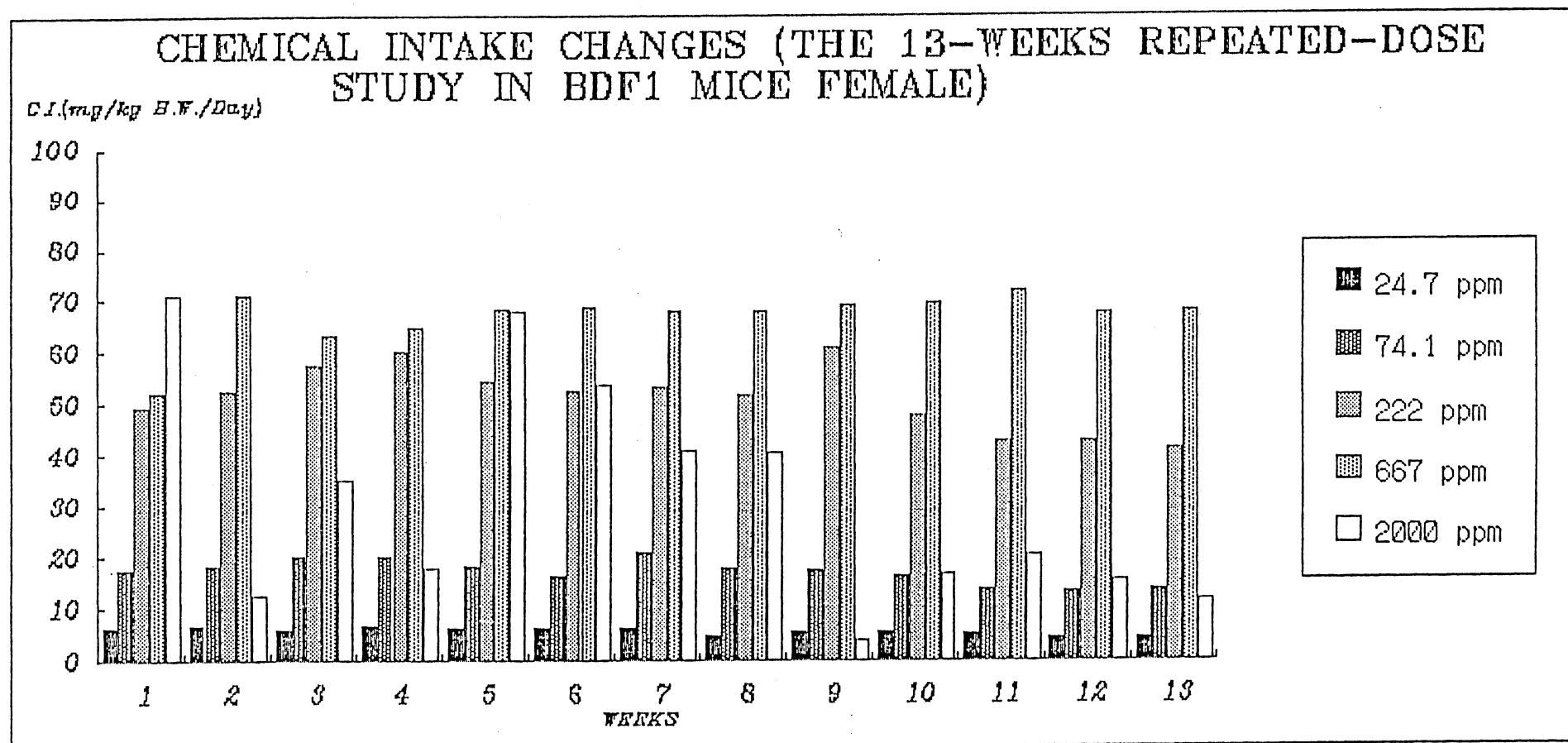
付録図 1 4

摂水量 (マウス・13週間試験)



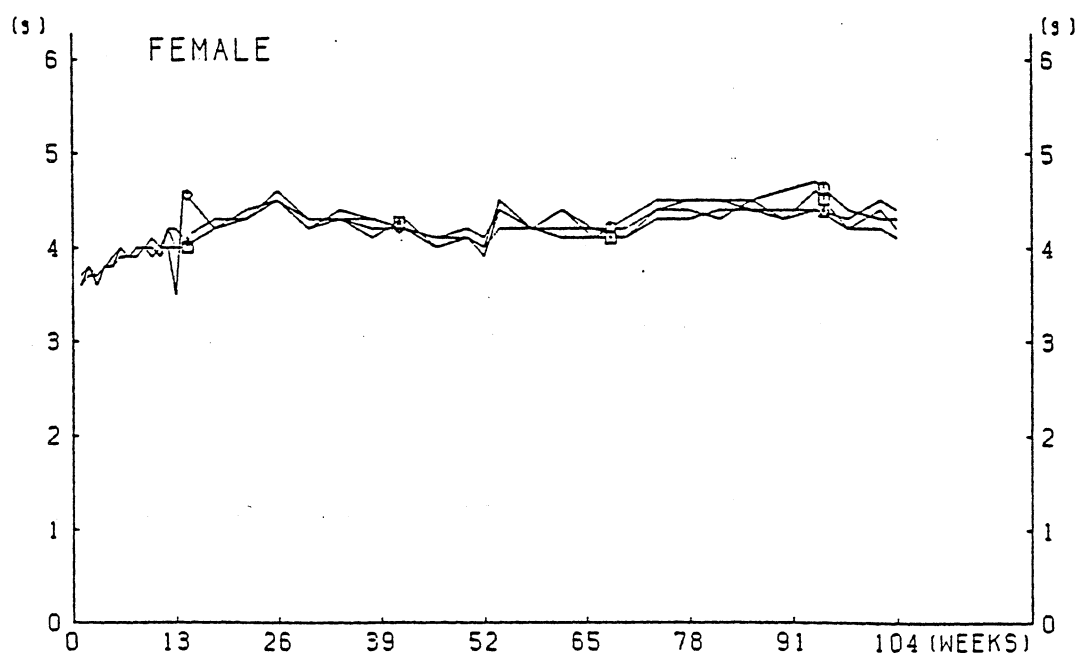
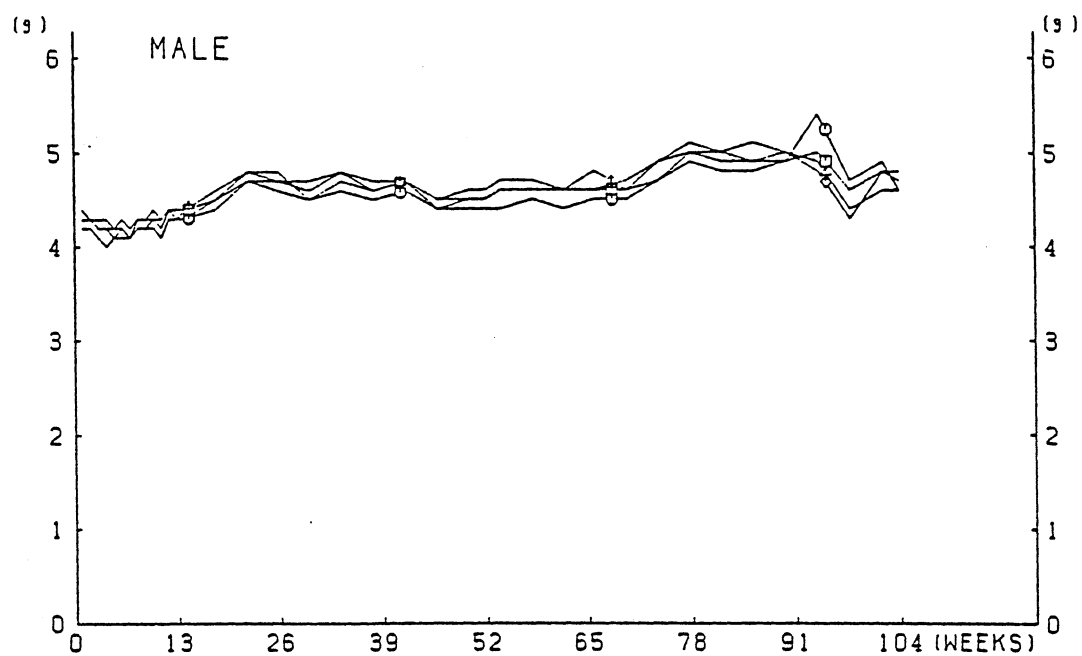
付録図 1 5

被験物質摂取量 (マウス・13週間試験)



付録図 1 5

被験物質摂取量（マウス・13週間試験）



STUDY NO. 0060
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

DOSE LEVEL (PPM)
—□— CONTROL
—○— 20
—△— 60
—◇— 180

FOOD CONSUMPTION