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

〔試験計画〕

	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	１４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±１℃ 湿度５０±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±１℃ 湿度５０±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ケ月

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 HOURS 1	2	4	6	DAYS 1	2	3	4	5	6	7	8	9	10	SURVIVAL RATE *
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 11	12	13	14	SURVIVAL RATE *
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					

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	

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 1	2	3	4	5	6	7	8	9	10	11	12	13	14	SURVIVAL RATE *
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

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
MALE	CONTROL	134 ± 4	139 ± 4	143 ± 4	153 ± 5	168 ± 6	183 ± 7	202 ± 8
	278	134 ± 4	138 ± 4	143 ± 5	153 ± 5	169 ± 6	184 ± 7	202 ± 7
	833	134 ± 4	128 ± 4***	128 ± 5***	138 ± 6***	151 ± 6***	163 ± 7***	179 ± 8***
	2500	134 ± 4	124 ± 3***	117 ± 3***	108 ± 5***	98 ± 8***	88 ± 8***	81 ± 10***
	7500	134 ± 4	123 ± 4***	114 ± 4***	101 ± 4***	86 ± 4***	72 ± 4***	
	22500	134 ± 4	122 ± 3***	114 ± 3***	101 ± 3***	85 ± 2***	72 ± 2***	
FEMALE	CONTROL	108 ± 4	112 ± 4	113 ± 4	118 ± 4	126 ± 5	134 ± 5	142 ± 7
	278	108 ± 4	109 ± 3	111 ± 3	116 ± 4	124 ± 4	131 ± 4	139 ± 5
	833	109 ± 4	101 ± 4***	98 ± 4***	99 ± 6***	105 ± 5***	111 ± 6***	119 ± 8***
	2500	109 ± 4	99 ± 3***	93 ± 3***	83 ± 4***	71 ± 6***	63 ± 6***	66 ± 0
	7500	109 ± 4	98 ± 3***	92 ± 3***	81 ± 2***	68 ± 2***	57 ± 1***	
	22500	109 ± 4	99 ± 4***	92 ± 3***	81 ± 3***	67 ± 4***	60 ± 0	

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) 1	2	3	4	5	6	7	8	9	10	11	12	13	SURVIVAL RATE *
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) 1	2	3	4	5	6	7	8	9	10	11	12	13	SURVIVAL RATE *
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) 14	15	16	17	18	19	20	21	22	23	24	25	26	SURVIVAL RATE *
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) 27	28	29	30	31	32	33	34	35	36	37	38	39	SURVIVAL RATE *
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) 40	41	42	43	44	45	46	47	48	49	50	51	52	SURVIVAL RATE *
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) 53	54	55	56	57	58	59	60	61	62	63	64	65	SURVIVAL RATE *
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

TABLE SURVIVAL ANIMAL NUMBERS STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS) 66	67	68	69	70	71	72	73	74	75	76	77	78	SURVIVAL RATE *
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

TABLE SURVIVAL ANIMAL NUMBERS STUDY NO. : 0059

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS) 79	80	81	82	83	84	85	86	87	88	89	90	91	SURVIVAL RATE *
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) 92	93	94	95	96	97	98	99	100	101	102	103	104	SURVIVAL RATE *
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) BAIS

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

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 7	8	9	10	11	12	13
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) BAIS

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***

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

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 28	30	32	34	36	38	40
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***

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

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

(C200) BAIS

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

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 56	58	60	62	64	66	68
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***

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

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 70	72	74	76	78	80	82
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***

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***

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

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 84	86	88	90	92	94	96
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***

表１０　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１０　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１１　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１１　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 50	64 50	160 50	400 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	#MALIGNANT 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

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS) STUDY NO. : 0059

SEX : MALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPM) / NO. OF EXAMINED ANIMALS	0 50	64 50	160 50	400 50
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)
	+FIBROMA		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)
	#MALIGNANT 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)
	#MALIGNANT 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)
	#MALIGNANT 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)
ZYMBAL GLAND						
	+PAPILLOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)

+ : 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 50	64 50	160 50	400 50
LUNG	+ALVEOLAR/BRONCHIOLAR ADENOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
	#ALVEOLAR/BRONCHIOLAR CARCINOMA		0 (0.0)	1 (2.0)	0 (0.0)	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)
	+KERATOACANTHOMA		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 50	64 50	160 50	400 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	#MALIG.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１２　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 HOURS 1	2	4	6	DAYS 1	2	3	4	5	6	7	8	9	10	SURVIVAL RATE *
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 DAYS 11	12	13	14	SURVIVAL RATE *
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 ± 1.4
	68	25.7 ± 0.7
	102	25.4 ± 1.8
	153	24.7 ± 0.7*
	230	
	345	
FEMALE	CONTROL	19.3 ± 1.2
	68	19.2 ± 1.0
	102	19.2 ± 1.1
	153	19.9 ± 0.5
	230	20.3 ± 0.0
	345	

表１４　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 1	2	3	4	5	6	7	8	9	10	11	12	13	14	SURVIVAL RATE *
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１５　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１６　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) 1	2	3	4	5	6	7	8	9	10	11	12	13	SURVIVAL RATE *
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１７　体重値（マウス・１３週間試験）

TABLE 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***

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) 1	2	3	4	5	6	7	8	9	10	11	12	13	SURVIVAL RATE *
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) 14	15	16	17	18	19	20	21	22	23	24	25	26	SURVIVAL RATE *
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) 27	28	29	30	31	32	33	34	35	36	37	38	39	SURVIVAL RATE *
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) 40	41	42	43	44	45	46	47	48	49	50	51	52	SURVIVAL RATE *
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) 53	54	55	56	57	58	59	60	61	62	63	64	65	SURVIVAL RATE *
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) 66	67	68	69	70	71	72	73	74	75	76	77	78	SURVIVAL RATE *
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) 79	80	81	82	83	84	85	86	87	88	89	90	91	SURVIVAL RATE *
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

TABLE SURVIVAL ANIMAL NUMBERS STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ANIMALS INITIALLY IN STUDY	ADMINISTRATION (WEEKS) 92	93	94	95	96	97	98	99	100	101	102	103	104	SURVIVAL RATE *
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

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**

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 ± 3.3	47.0 ± 3.2	47.5 ± 3.2	47.6 ± 3.8	48.7 ± 4.7	48.3 ± 4.3	49.4 ± 3.0
	20	46.0 ± 3.9	45.9 ± 3.9	46.2 ± 4.0	46.6 ± 3.7	48.1 ± 3.9	47.7 ± 3.7	48.2 ± 3.7
	60	45.4 ± 4.4*	45.7 ± 4.3	46.2 ± 4.2	46.8 ± 4.0	47.8 ± 4.1	47.6 ± 3.9	48.1 ± 3.7
	180	45.7 ± 4.4	45.8 ± 4.6	46.1 ± 4.9	46.8 ± 5.1	47.7 ± 5.4	47.6 ± 5.0	48.6 ± 3.6
FEMALE	CONTROL	33.7 ± 3.1	33.6 ± 3.1	33.5 ± 3.2	34.2 ± 3.2	34.4 ± 3.5	34.6 ± 3.5	34.5 ± 3.9
	20	34.5 ± 3.4	33.7 ± 3.6	33.5 ± 3.6	34.4 ± 3.7	34.6 ± 4.1	35.0 ± 3.9	34.9 ± 4.0
	60	33.7 ± 3.2	33.4 ± 3.5	33.6 ± 2.9	34.0 ± 3.0	34.4 ± 3.6	34.6 ± 3.1	34.8 ± 3.1
	180	32.8 ± 3.3	32.7 ± 3.3	33.0 ± 3.1	33.4 ± 3.1	33.9 ± 3.6	33.9 ± 3.5	34.0 ± 3.4

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

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*

TABLE BODY WEIGHT CHANGES (G) STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 70	72	74	76	78	80	82
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

TABLE BODY WEIGHT CHANGES (G) STUDY NO. : 0060

SEX	DOSE LEVEL (PPM)	ADMINISTRATION (WEEKS) 84	86	88	90	92	94	96
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

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２０　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	38	30	43	41
NO. OF TOTAL TUMORS	78	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) STUDY NO. : 0060
AND NO. OF ANIMALS WITH TUMORS (SINGLE/MULTIPLE)

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２１　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２１　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) / NO. OF EXAMINED ANIMALS	0 50	20 50	60 47	180 50
BRAIN	#EPENDYMOMA		1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
LUNG	+ALVEOLAR/BRONCHIOLAR ADENOMA		4 (8.0)	3 (6.0)	1 (2.1)	2 (4.0)
	#ALVEOLAR/BRONCHIOLAR 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)
	#SARCOMA		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)
	#HEMANGIOSARCOMA		0 (0.0)	1 (2.0)	1 (2.1)	0 (0.0)
	#HEPATOBLASTOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
URETER	+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)
	+KERATOACANTHOMA		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						
	+HEMANGIOMA		0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)
	#ANGIOSARCOMA		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)
EPIDIDYMIS	+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)
PROSTATE	+ADENOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
	#RHABDOMYOSARCOMA		0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)
SPLEEN	#MALIGNANT LYMPHOMA		5 (10.0)	2 (4.0)	1 (2.1)	2 (4.0)
	+HEMANGIOMA		5 (10.0)	1 (2.0)	6 (12.8)	3 (6.0)
LYMPH NODES						
	#MALIGNANT LYMPHOMA		3 (6.0)	9 (18.0)	13 (27.7)	9 (18.0)
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

TABLE NEOPLASTIC FINDINGS - INCIDENCE(%) (ALL ANIMALS) STUDY NO. : 0060

SEX : MALE

ORGAN	TYPE OF TUMOR	DOSE LEVEL (PPP) / NO. OF EXAMINED ANIMALS	0 50	20 50	60 47	180 50
SKIN	+EPIDERMAL CYST		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
SUBCUTANEOUS TISSUE						
	+HEMANGIOMA		1 (2.0)	1 (2.0)	0 (0.0)	1 (2.0)
	+HEMANGIOENDOTHELIOMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
	#MALIGNANT FIBROUS HISTIOCYTOMA		1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)
MUSCLE	#HEMANGIOSARCOMA		1 (2.0)	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)
PITUITARY	+ADENOMA		6 (12.0)	1 (2.0)	0 (0.0)	0 (0.0)
ADRENAL	+ADENOMA		4 (8.0)	4 (8.0)	0 (0.0)	2 (4.0)
	+PHEOCHROMOCYTOMA		0 (0.0)	1 (2.0)	0 (0.0)	2 (4.0)
HARDERIAN 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)
	#RHABDOMYOSARCOMA		0 (0.0)	1 (2.0)	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) / NO. OF EXAMINED ANIMALS	0 50	20 50	60 50	180 50
LUNG	+ALVEOLAR/BRONCHIOLAR ADENOMA		2 (4.0)	0 (0.0)	1 (2.0)	1 (2.0)
	#ALVEOLAR/BRONCHIOLAR CARCINOMA		3 (6.0)	2 (4.0)	2 (4.0)	1 (2.0)
THYROID	+C-CELL ADENOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
LIVER	+ADENOMA		5 (10.0)	6 (12.0)	7 (14.0)	8 (16.0)
	#SARCOMA		2 (4.0)	0 (0.0)	4 (8.0)	0 (0.0)
	#HEPATOCELLULAR CARCINOMA		1 (2.0)	1 (2.0)	2 (4.0)	1 (2.0)
	#HEMANGIOSARCOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
URETER	+POLYP		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
URINARY BLADDER						
	+PAPILLOMA		1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)
UTERUS	+POLYP		2 (4.0)	1 (2.0)	2 (4.0)	0 (0.0)
	#SARCOMA		11 (22.0)	7 (14.0)	7 (14.0)	11 (22.0)
	+HEMANGIOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
SPLEEN	#MALIGNANT LYMPHOMA		2 (4.0)	6 (12.0)	3 (6.0)	3 (6.0)
	+HEMANGIOMA		1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)
	#ANGIOSARCOMA		0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)
LYMPH NODES						
	#MALIGNANT LYMPHOMA		20 (40.0)	11 (22.0)	12 (24.0)	19 (38.0)
	#MASTOCYTOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
PANCREATIC ISLET						
	+ADENOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
MAMMARY GLAND						
	#ADENOCARCINOMA		0 (0.0)	1 (2.0)	1 (2.0)	2 (4.0)
SUBCUTANEOUS TISSUE						
	#MASTOCYTOMA		1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE	+HEMANGIOENDOTHELIOMA		1 (2.0)	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)
PITUITARY	+ADENOMA		8 (16.0)	17 (34.0)	15 (30.0)	20 (40.0)
	#ADENOCARCINOMA		0 (0.0)	1 (2.0)	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	50	50	50
ADRENAL	+ADENOMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
OVARY	+CYSTADENOMA		3 (6.0)	2 (4.0)	2 (4.0)	1 (2.0)
HARDERIAN GLAND						
	+ADENOMA		0 (0.0)	0 (0.0)	1 (2.0)	4 (8.0)
	#ADENOCARCINOMA		0 (0.0)	0 (0.0)	1 (2.0)	1 (2.0)
BONE	#OSTEOGENIC SARCOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
PERITONEUM	+HEMANGIOMA		0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)
	#ANGIOSARCOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)
	#MASTOCYTOMA		0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)

+ : BENIGN # : MALIGNANT

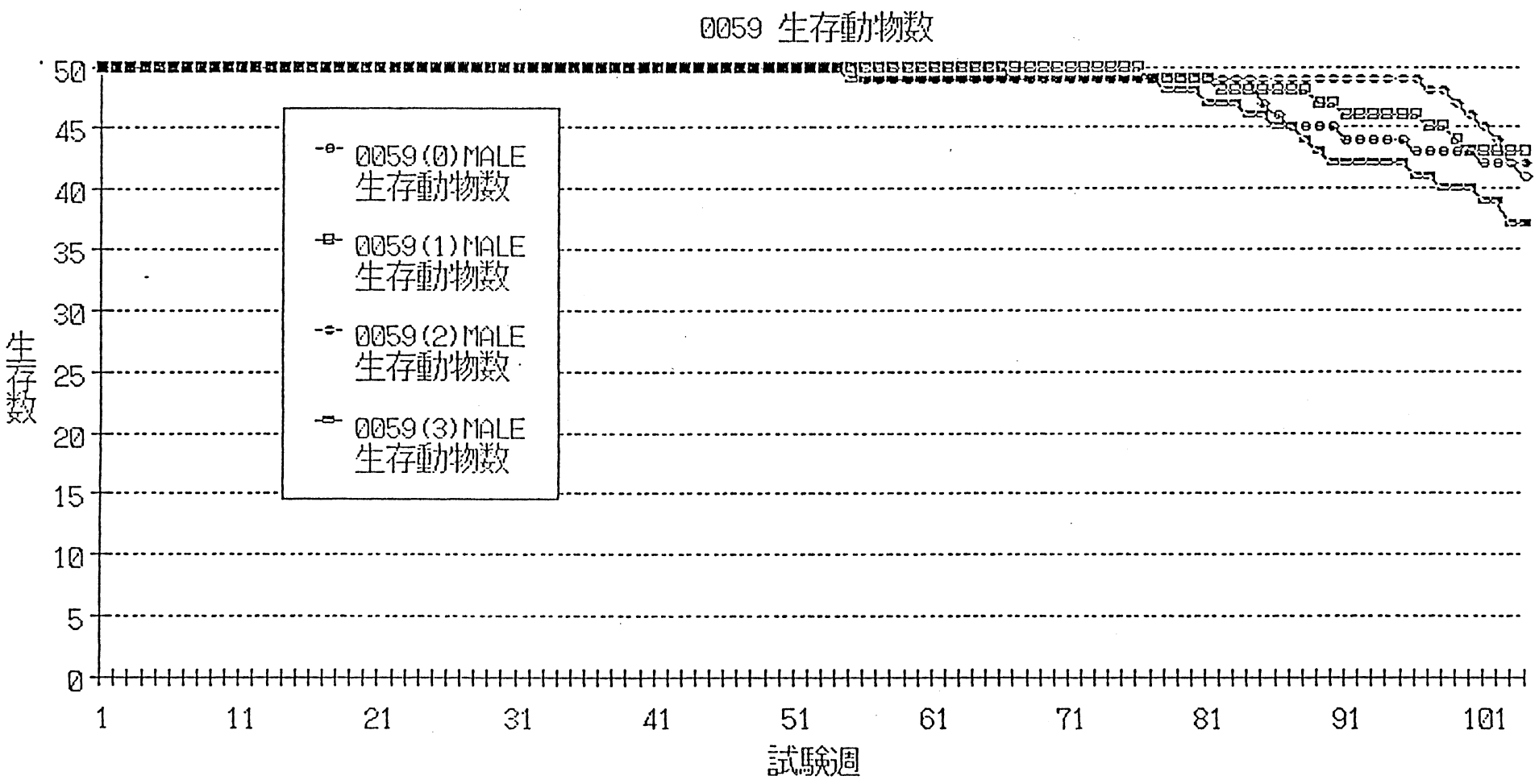


図 1　　生存動物数（ラット・雄・がん原性試験）

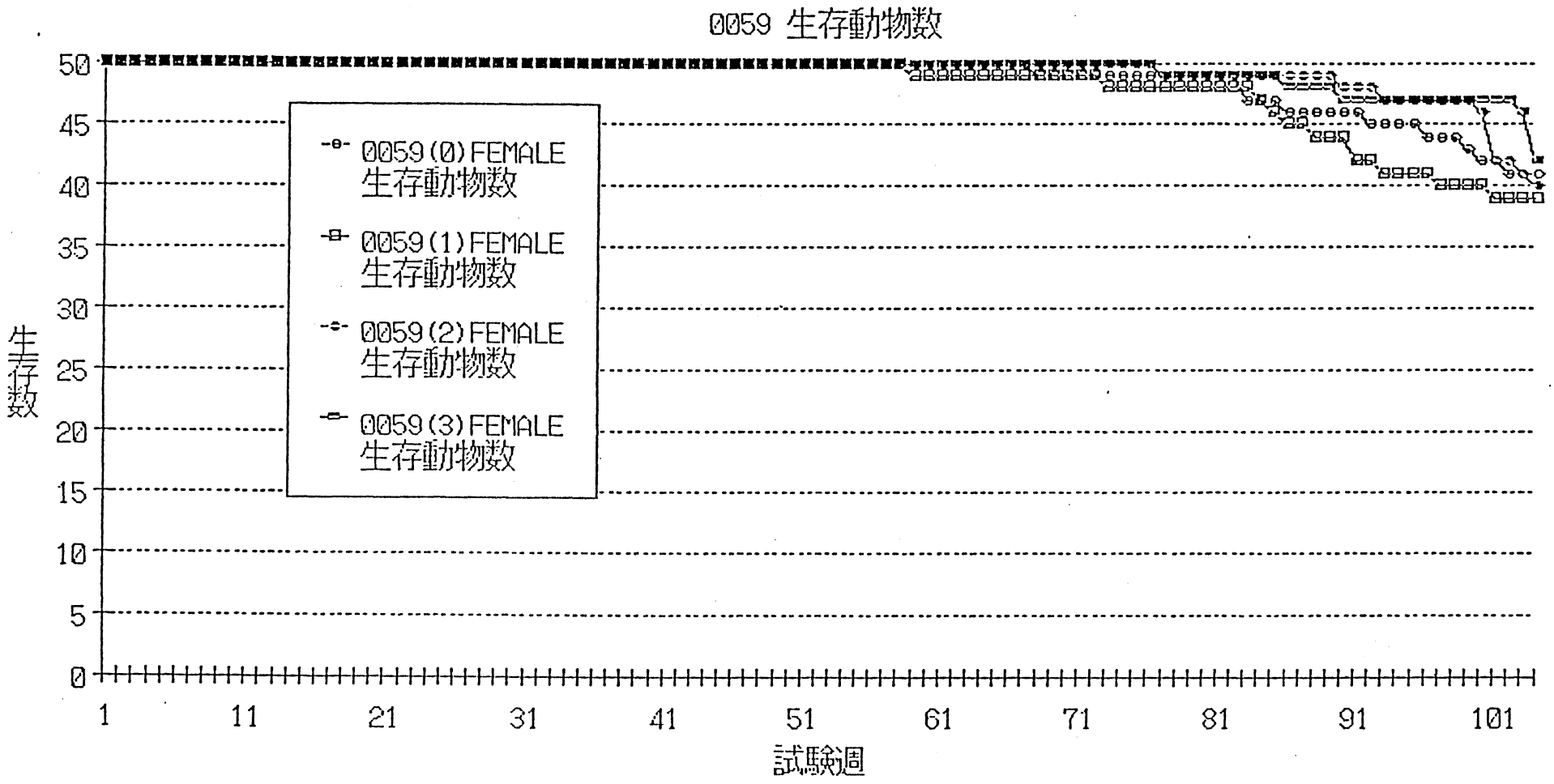
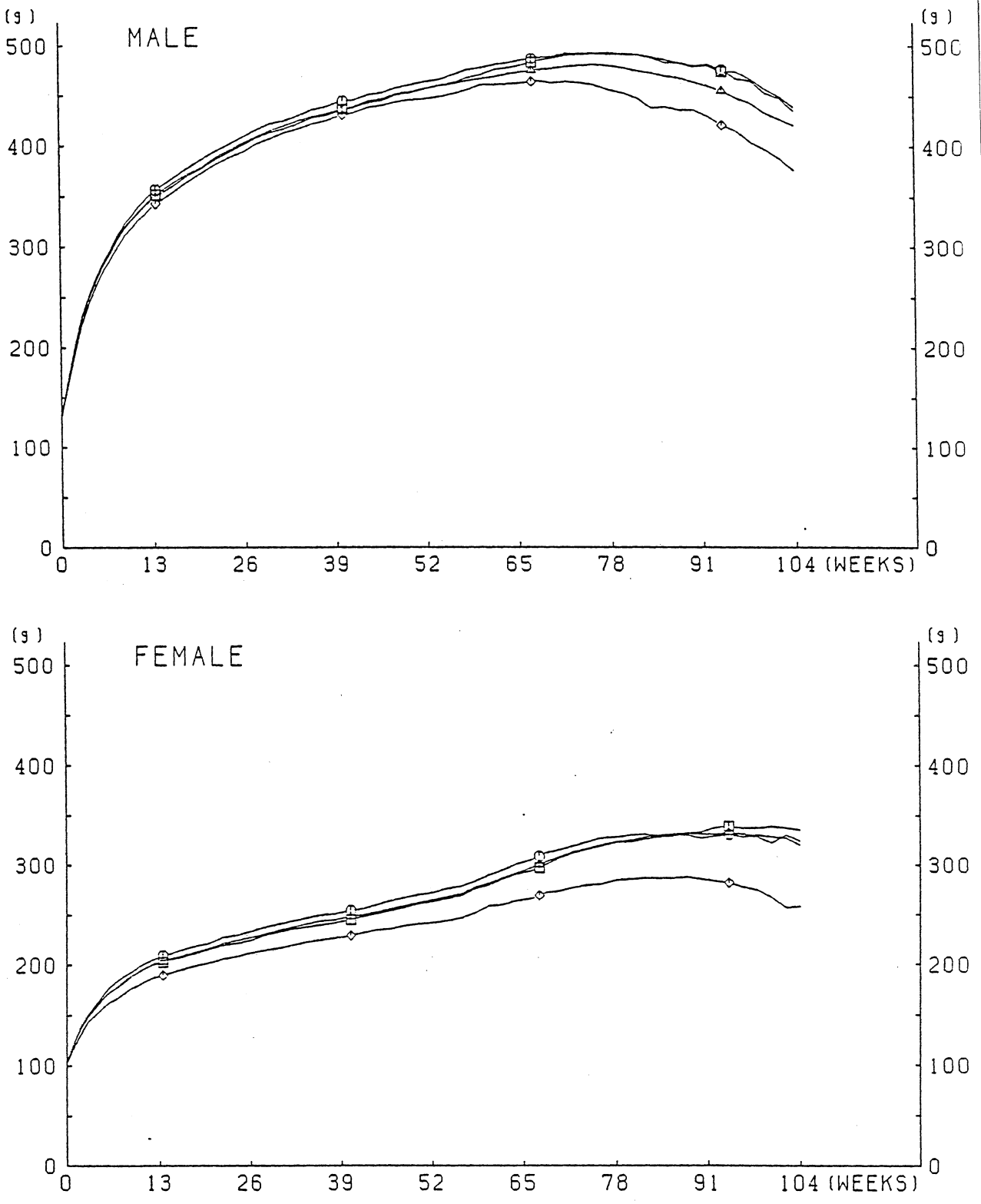


図２　　生存動物数（ラット・雌・がん原性試験）



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

DOSE LEVEL (PPM)
CONTROL
64
160
400

BODY WEIGHT

図3 体重値（ラット・がん原性試験）

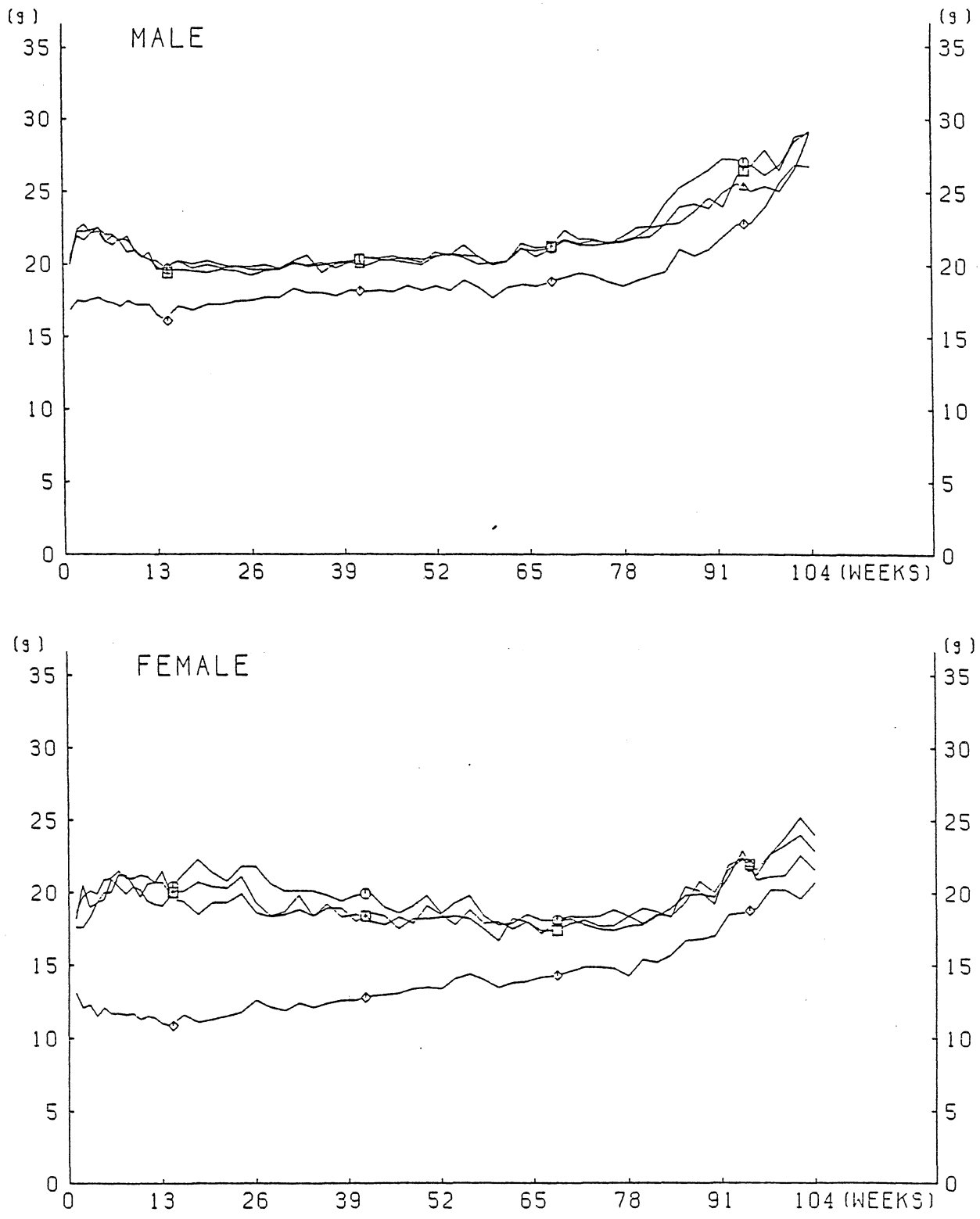


図4　摂水量（ラット・がん原性試験）

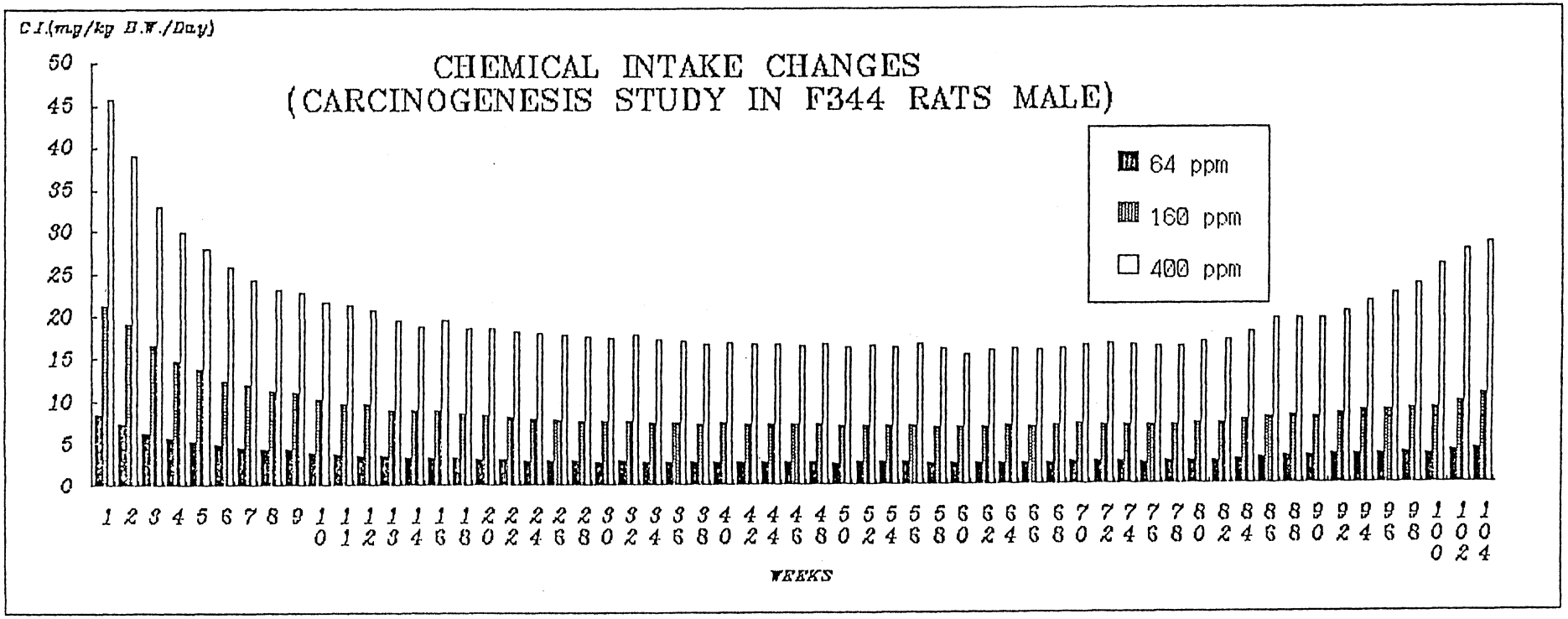


図５　　被験物質摂取量（ラット・雄・がん原性試験）

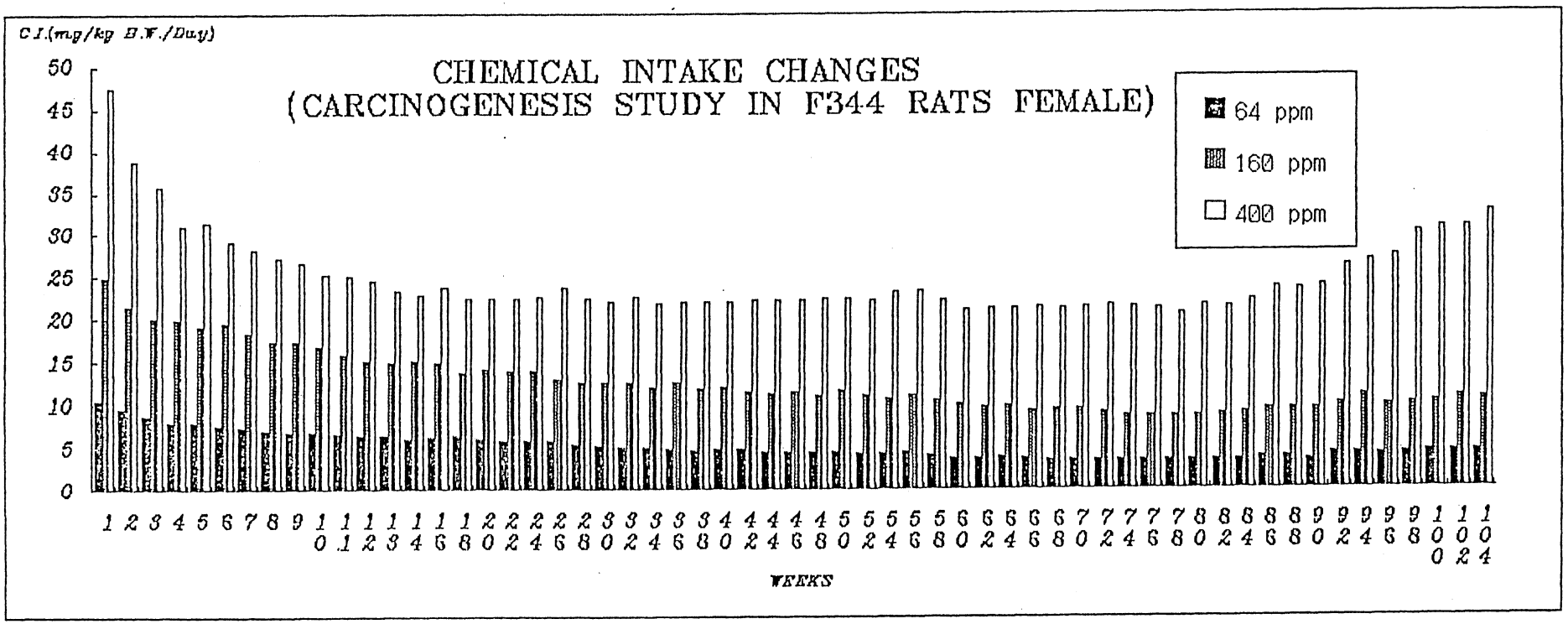


図６　　被験物質摂取量（ラット・雌・がん原性試験）

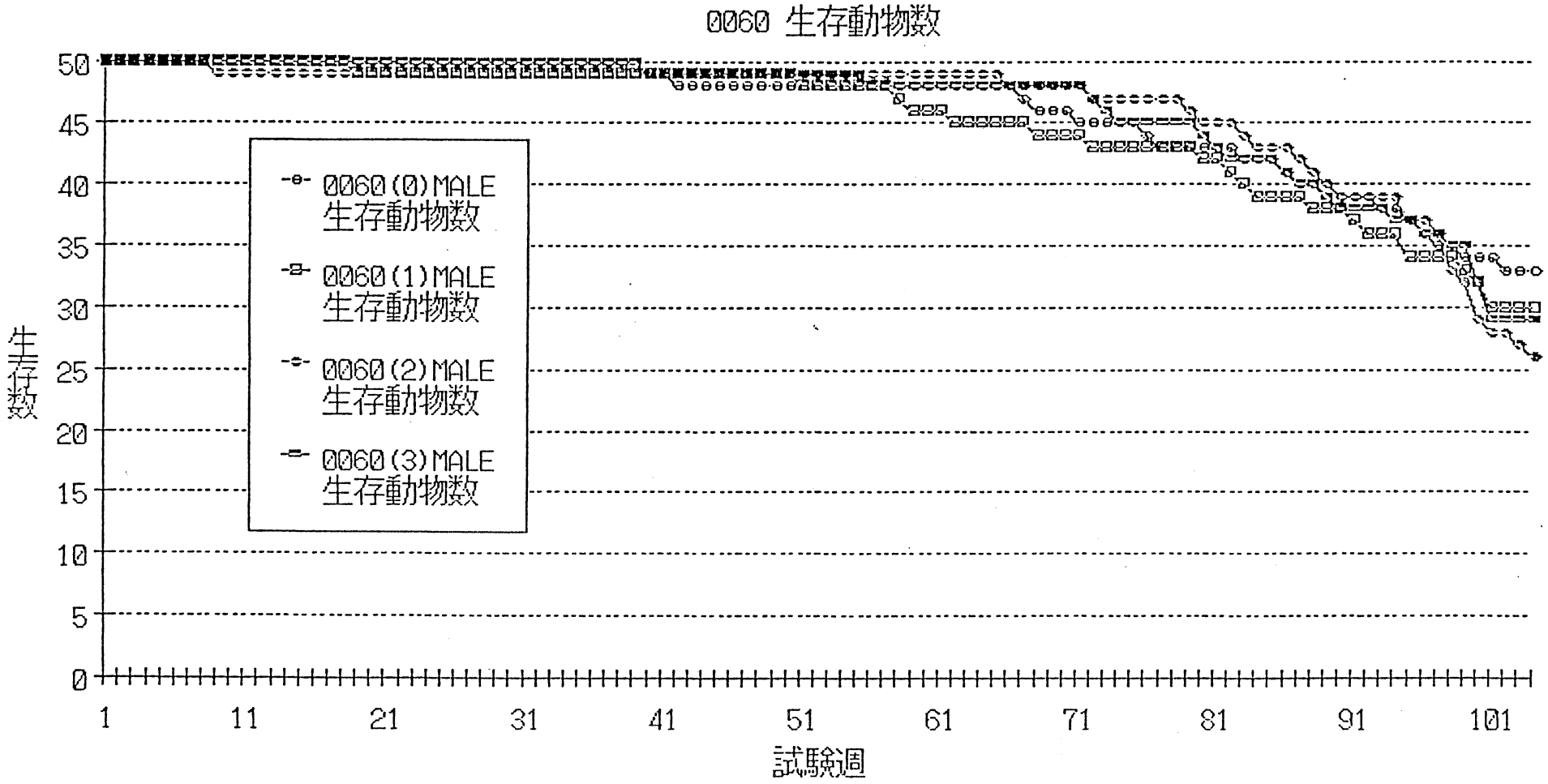


図７　　生存動物数（マウス・雄・がん原性試験）

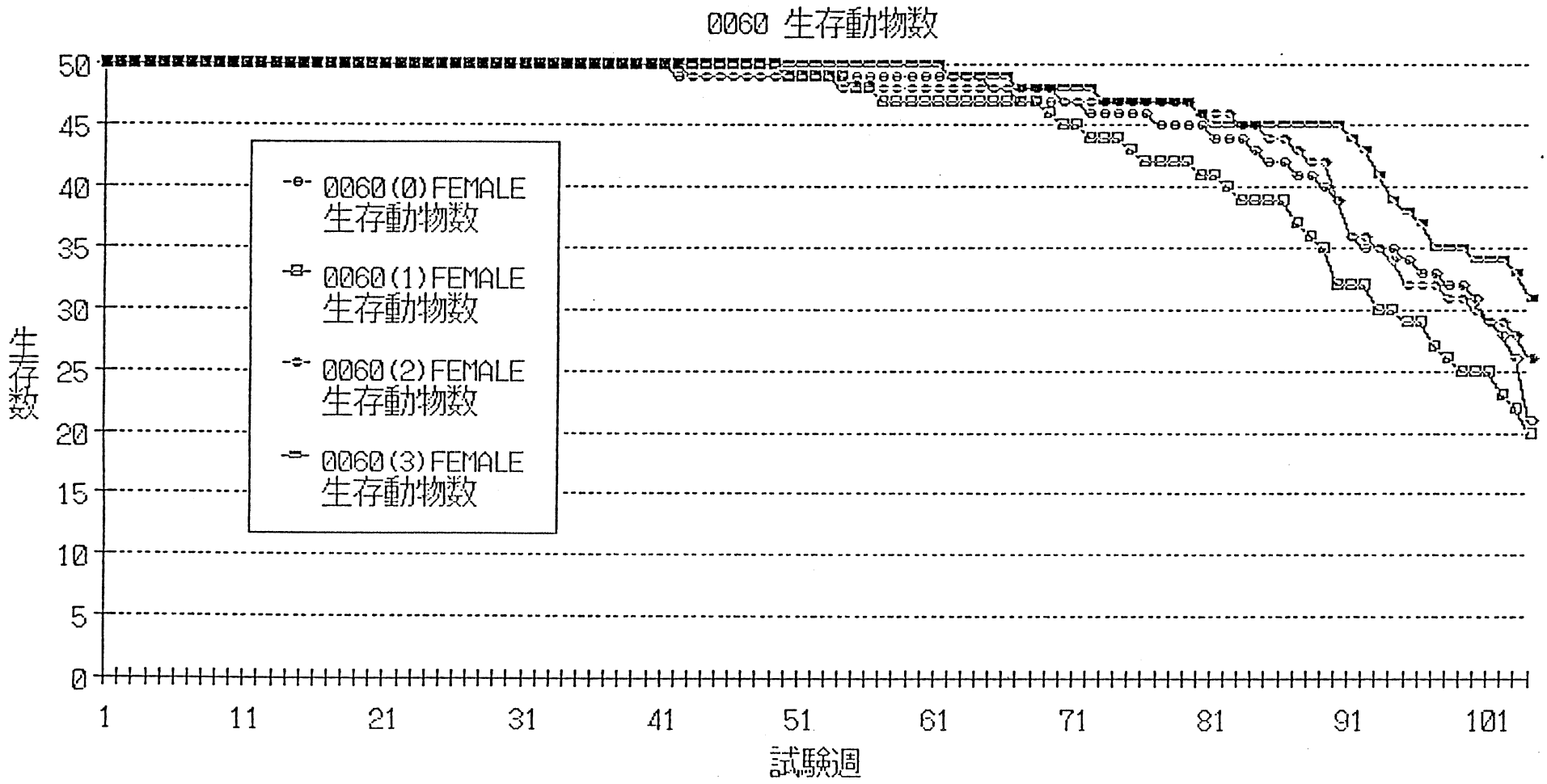
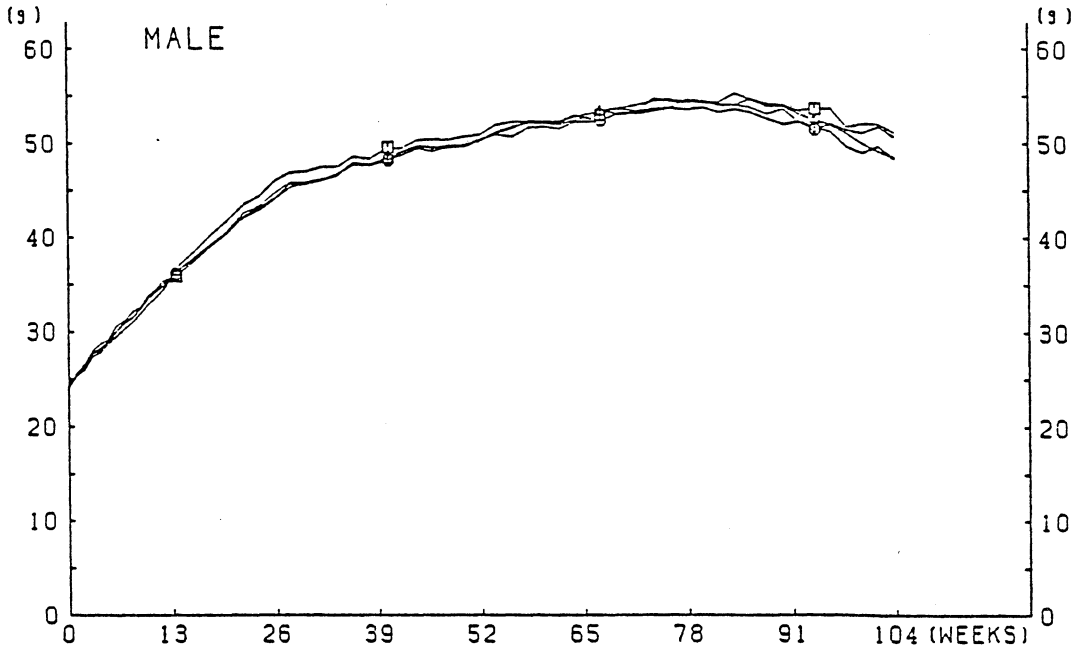
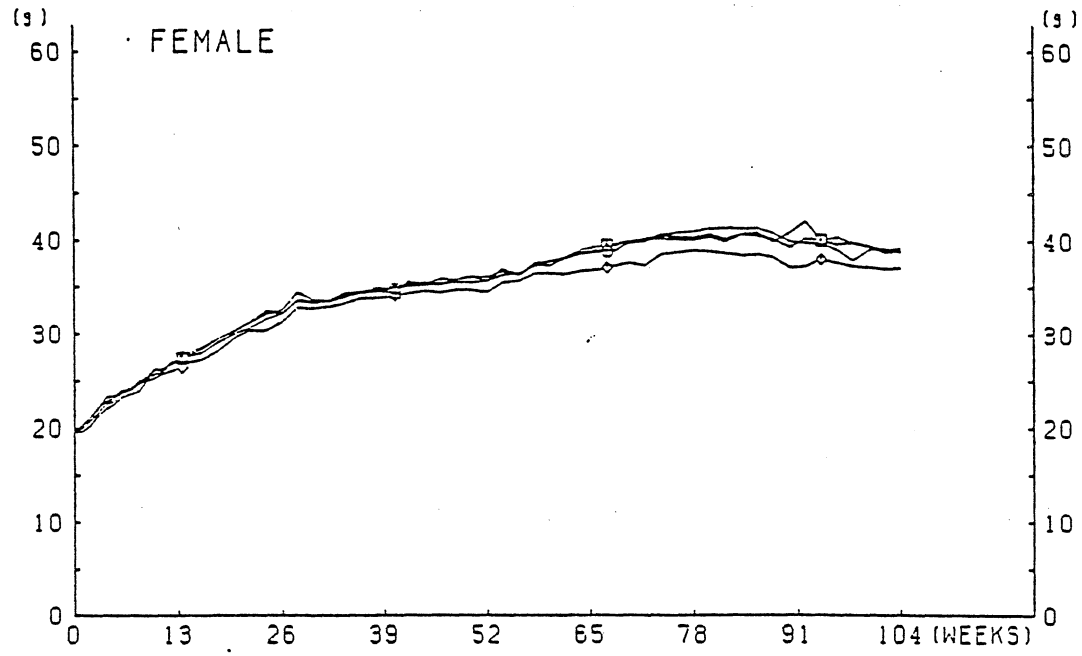


図８　　生存動物数（マウス・雌・がん原性試験）





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）

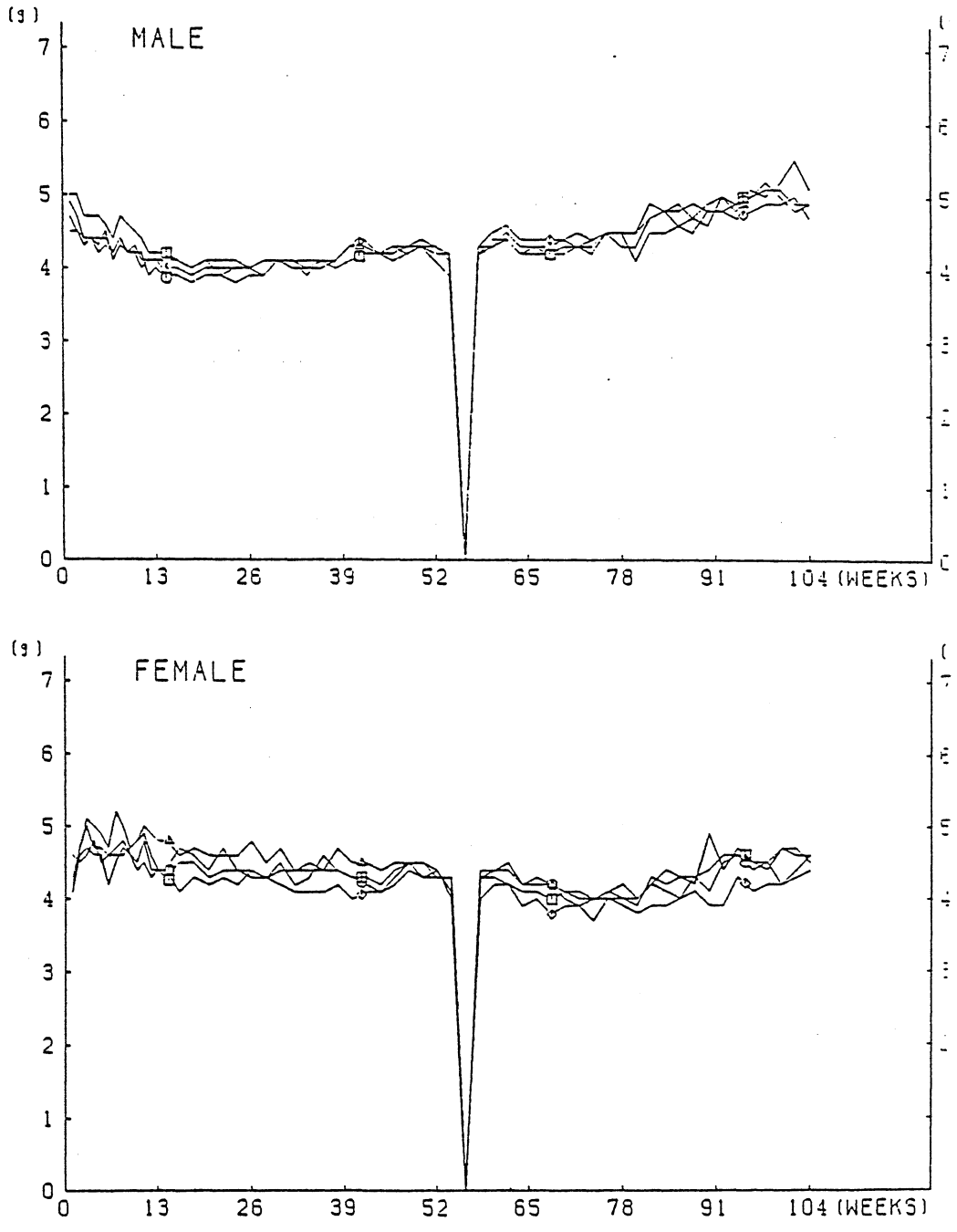


図１０　　摂水量（マウス・がん原性試験）

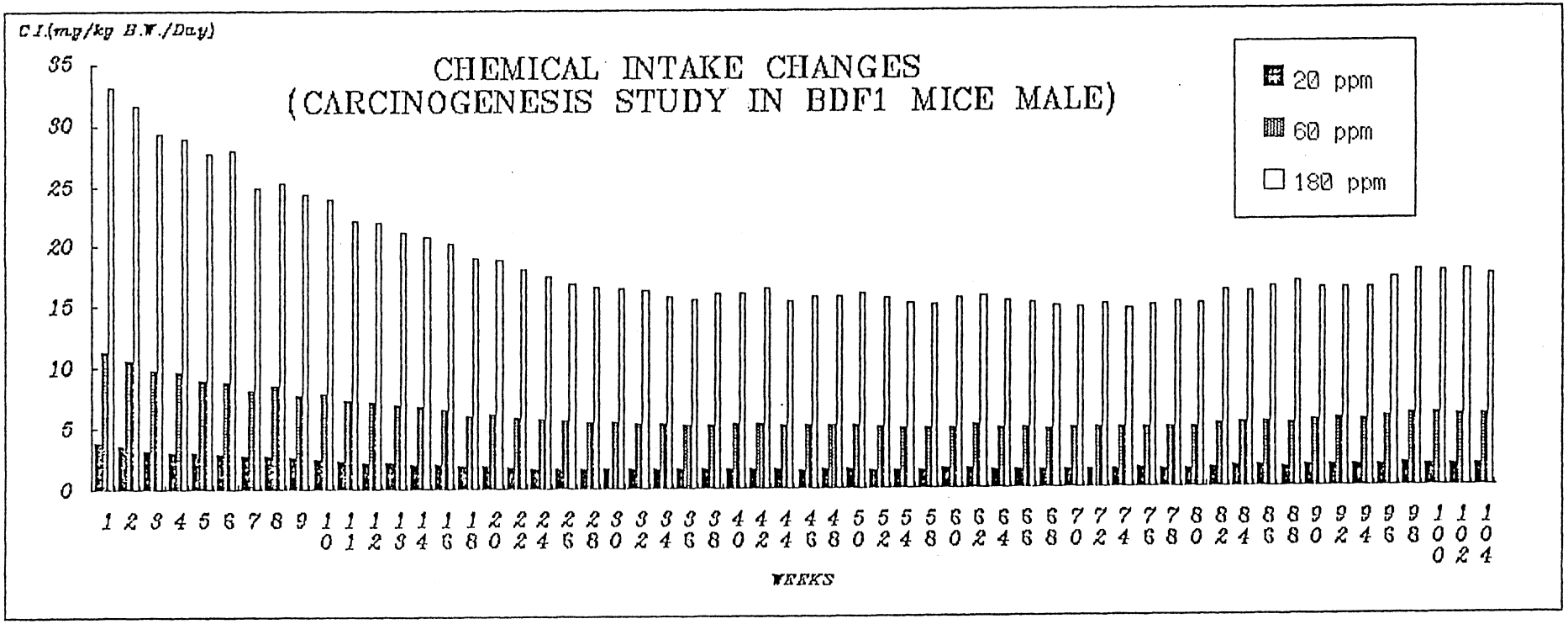


図１１　　被験物質摂取量（マウス・雄・がん原性試験）

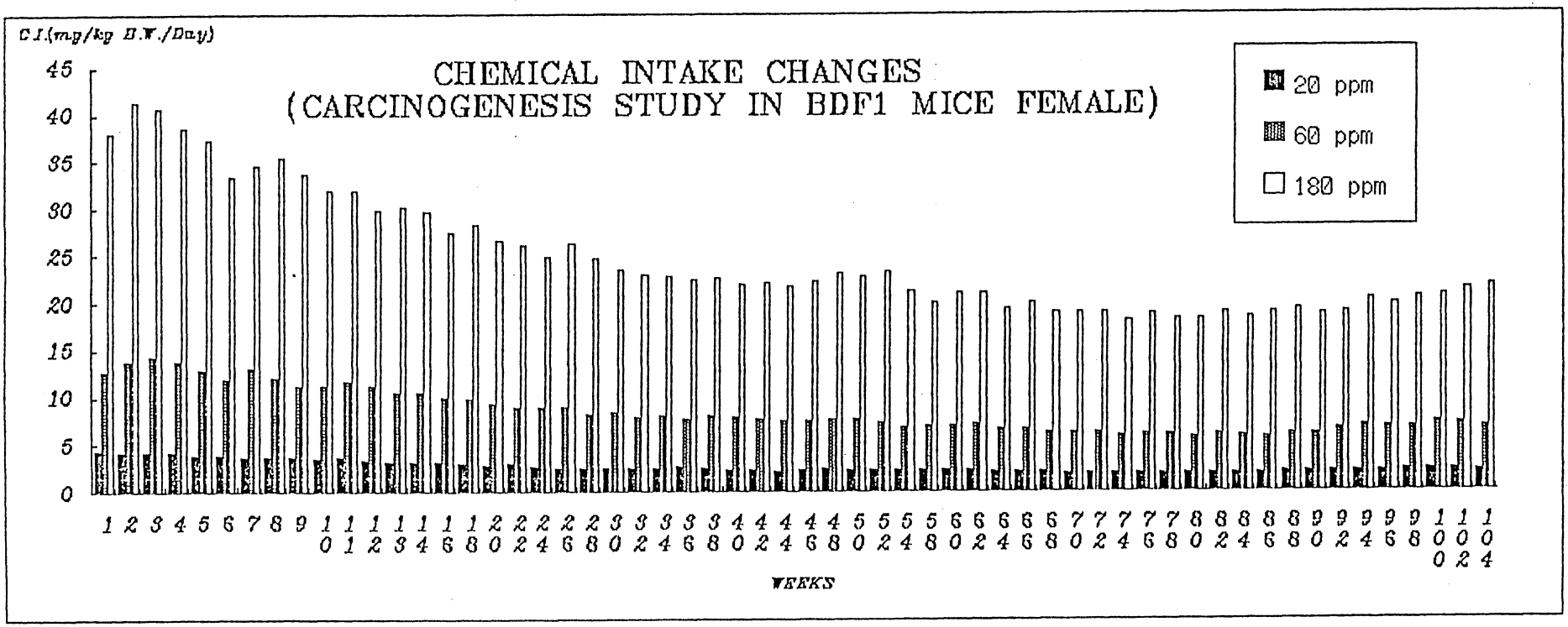
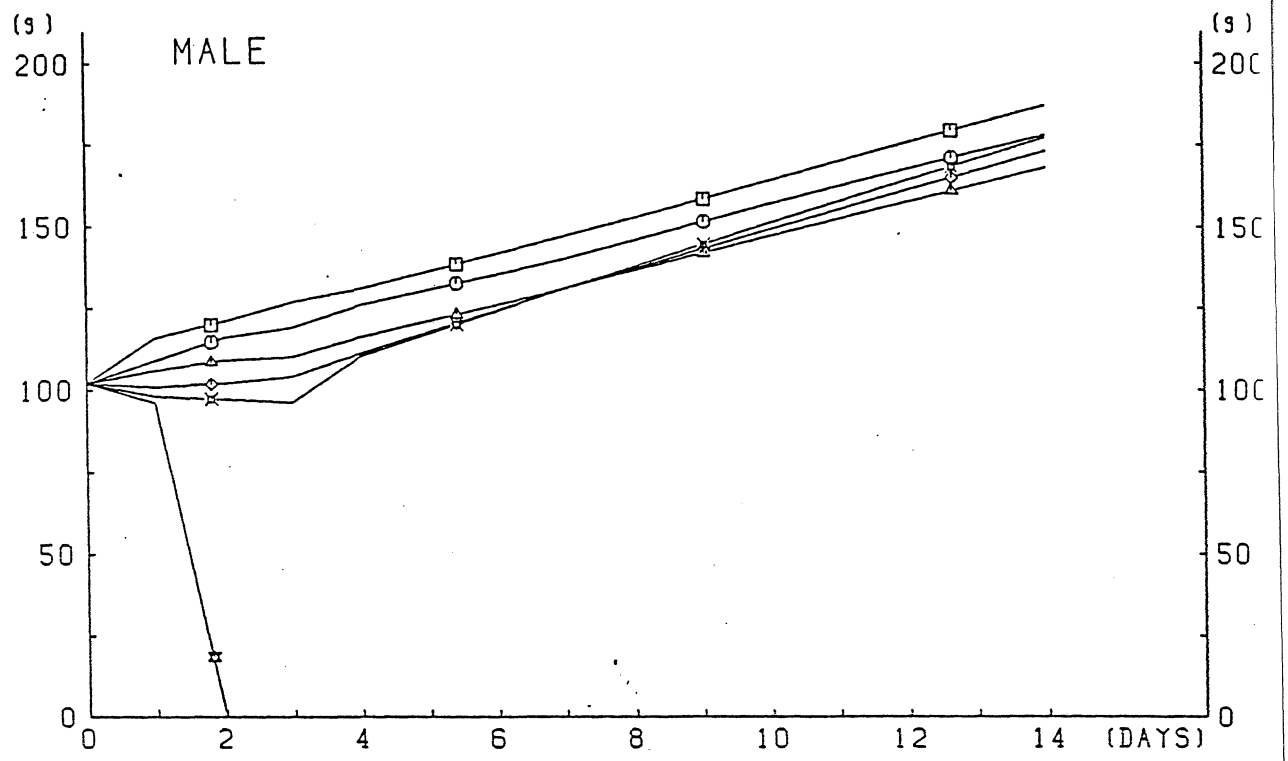
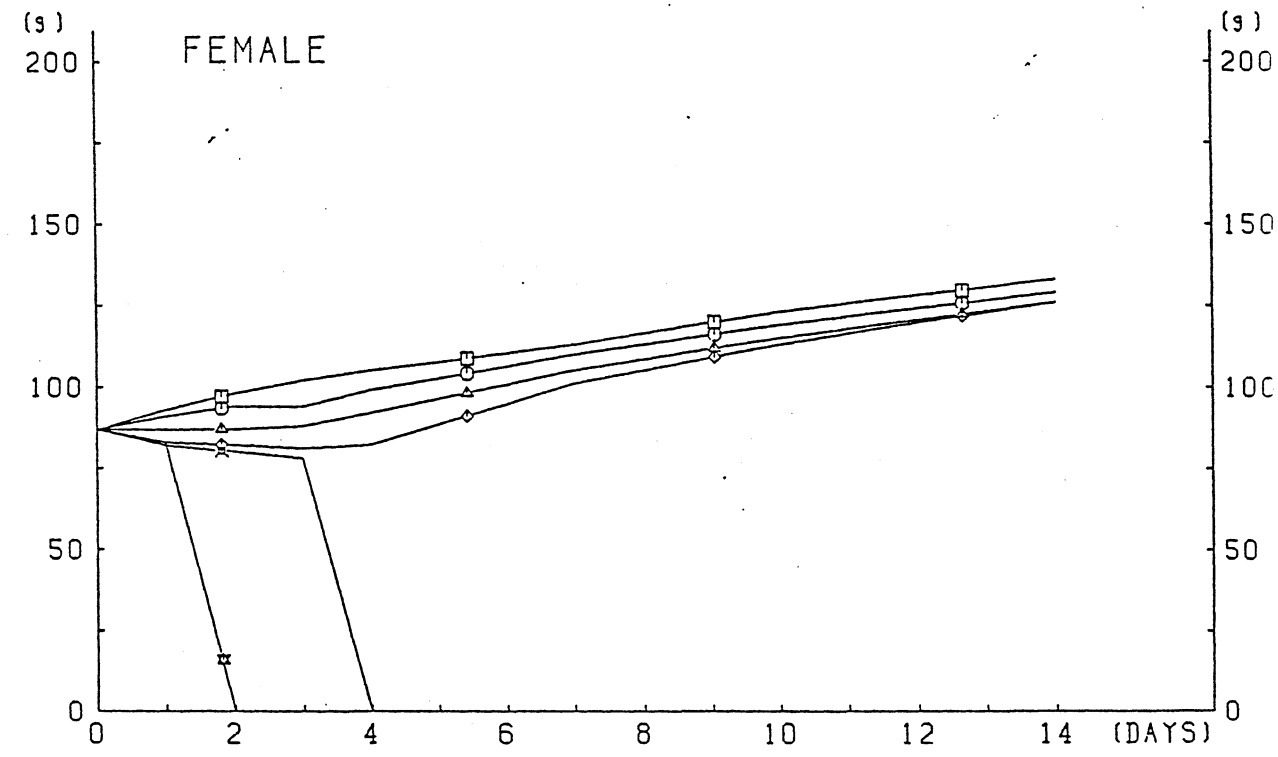


図１２　　被験物質摂取量（マウス・雌・がん原性試験）



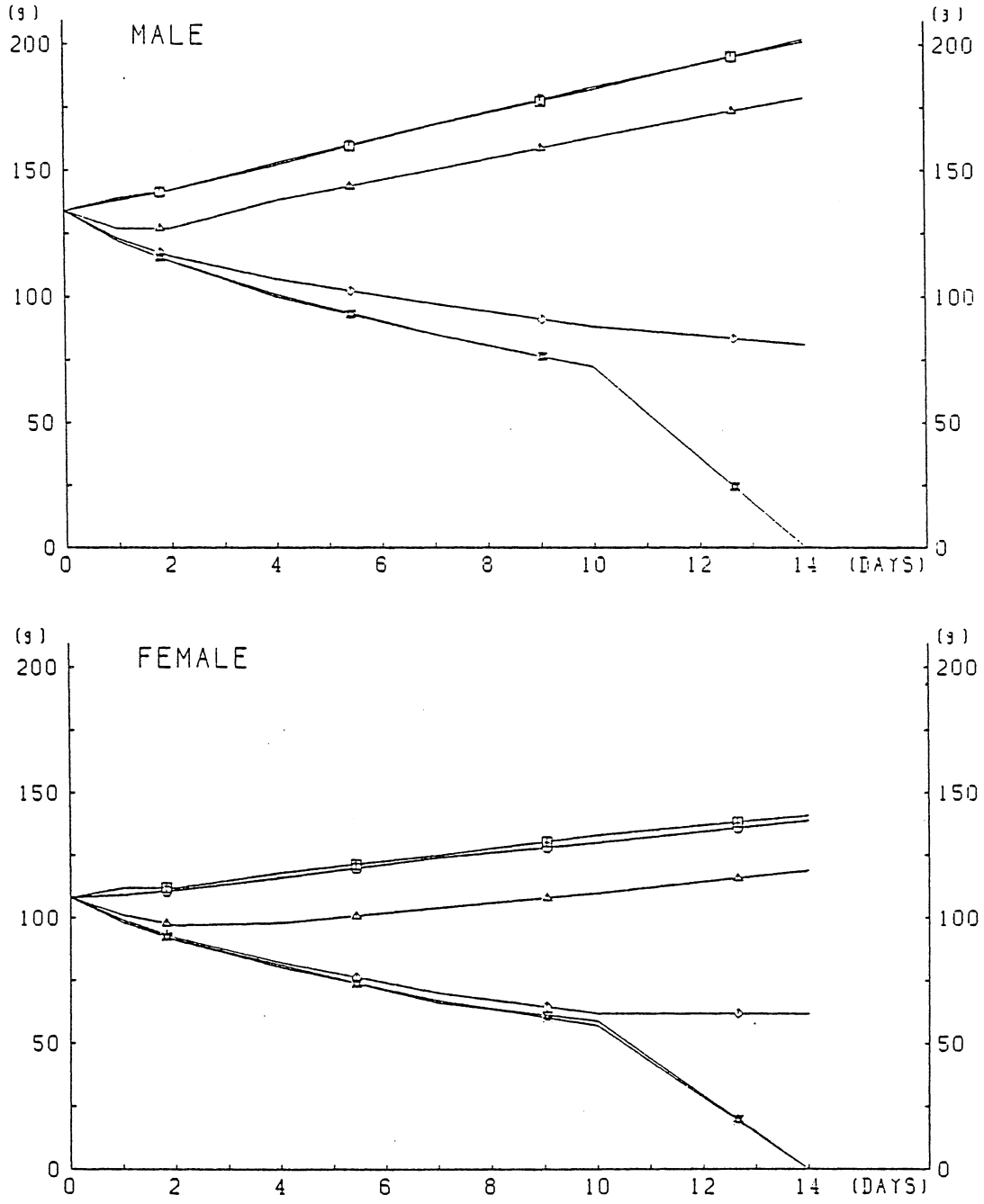


STUDY NO. 0007
TEST SUB. M-PD.2HCL
ANIMAL RAT F344

DOSE LEVEL (MG/KG)
CONTROL
96
163
277
471
800

BODY WEIGHT

付録図1　体重値（ラット・急性試験）

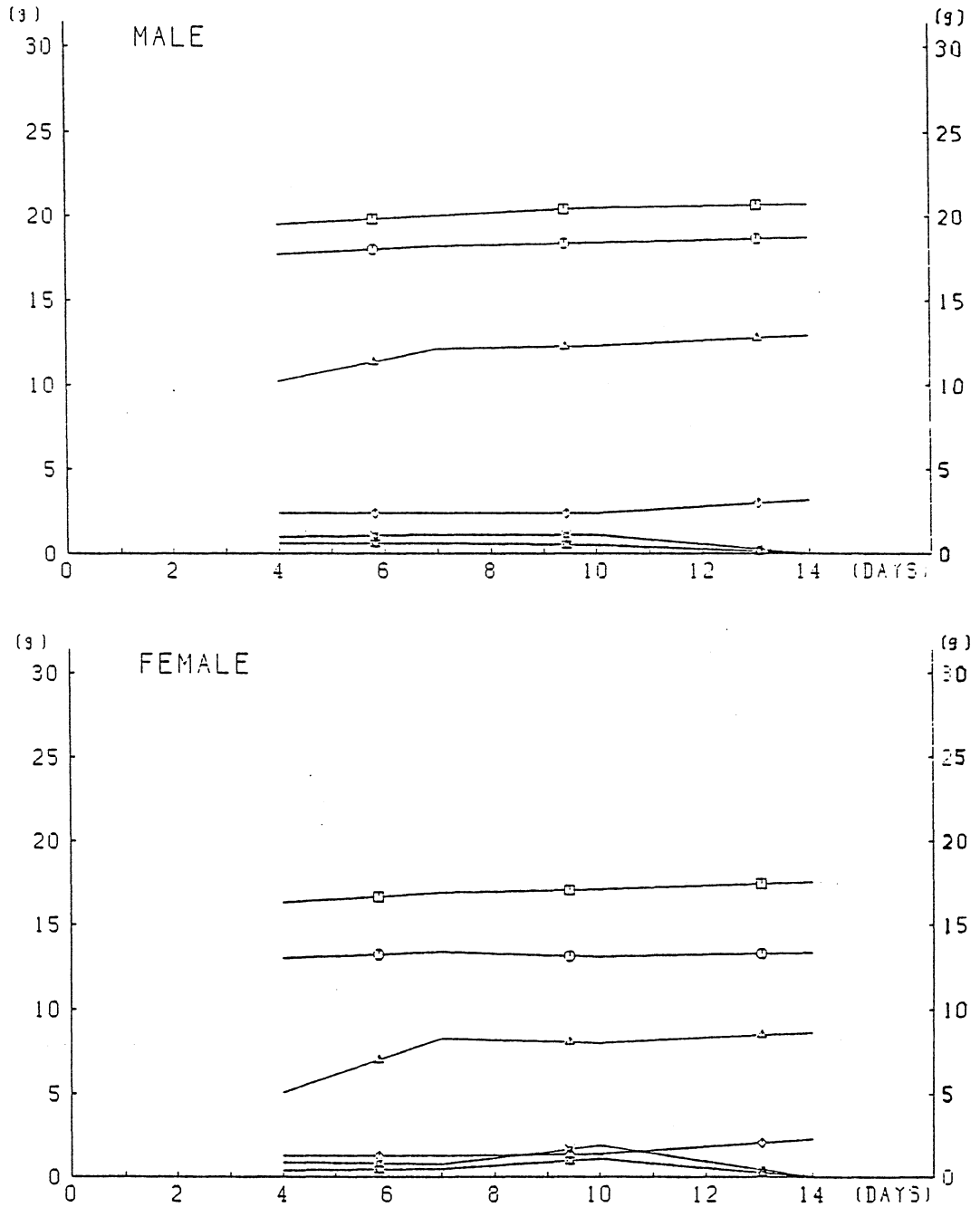


STUDY NO. 0026
TEST SUB. M-PD.2HCL
ANIMAL RAT F344

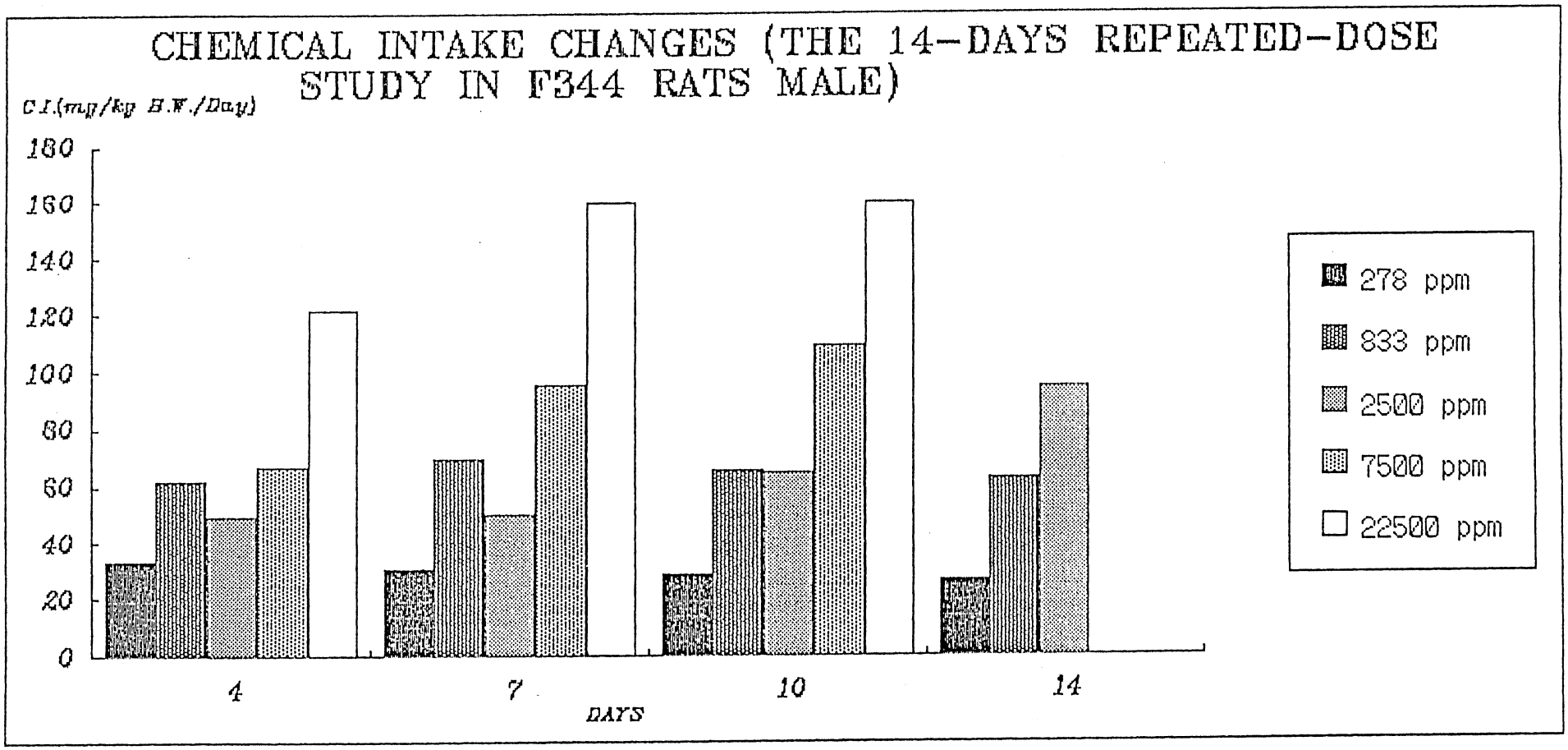
DOSE LEVEL (PPM)
CONTROL
278
833
2500
7500
22500

BODY WEIGHT

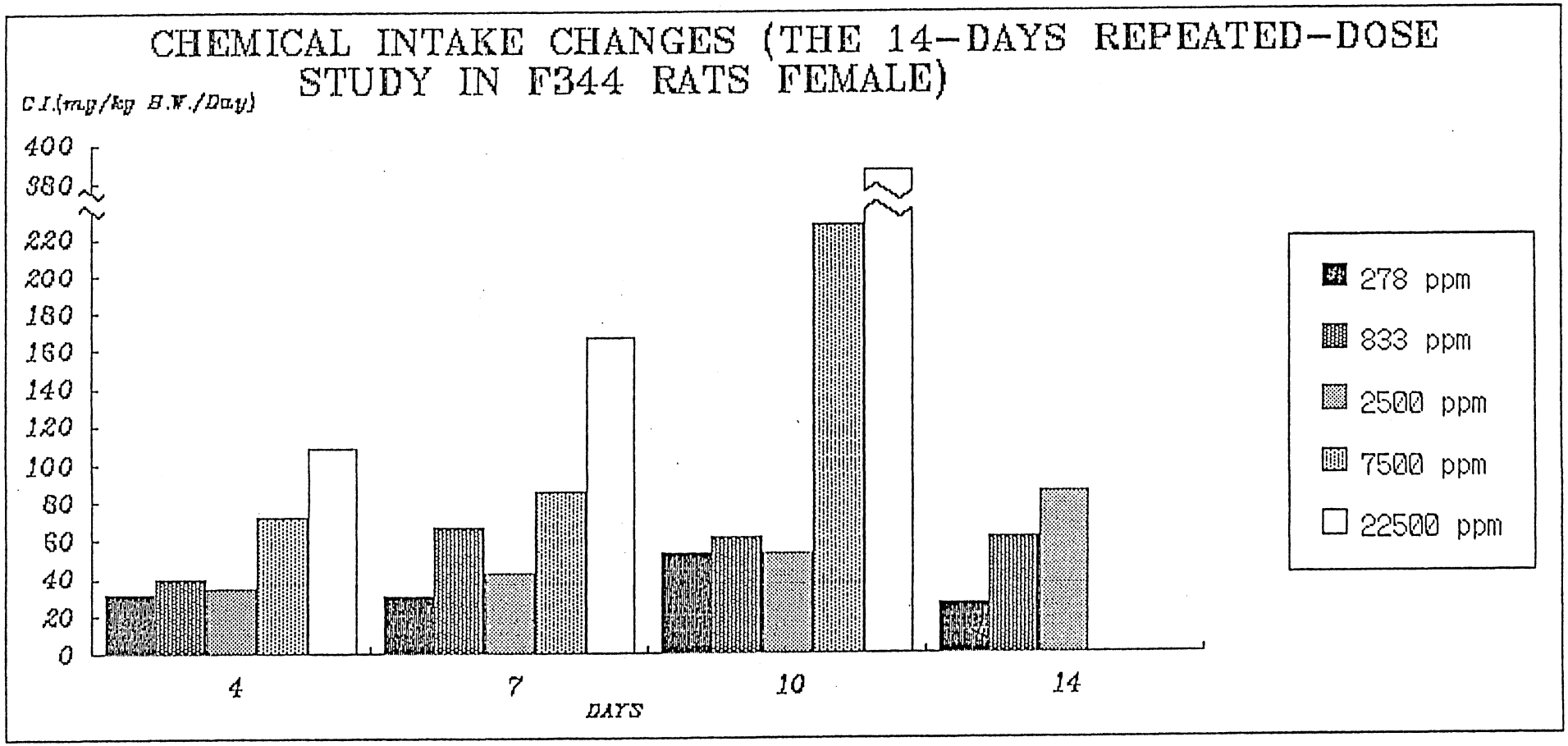
付録図2　体重値（ラット・2週間試験）



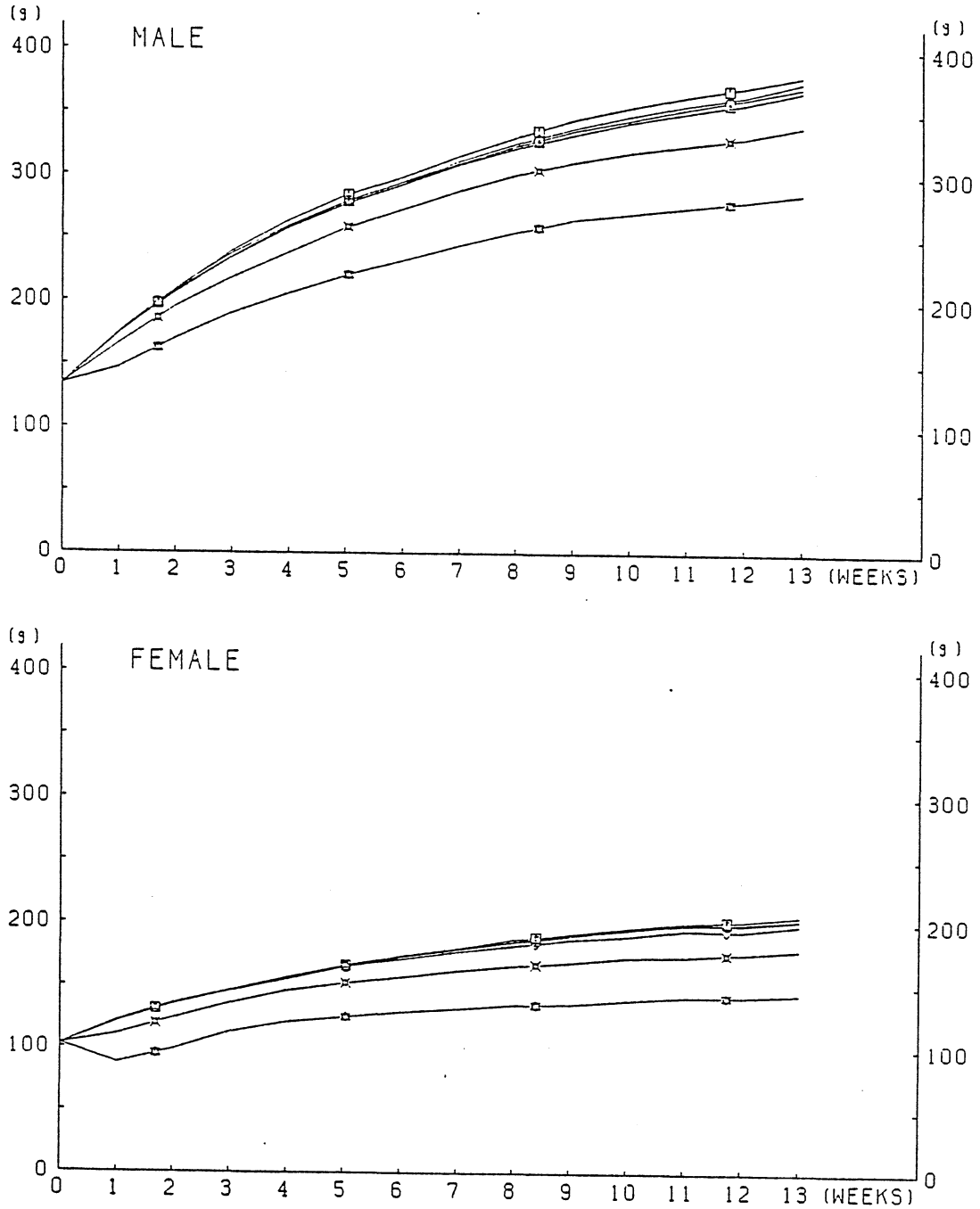
付録図３　　摂水量（ラット・２週間試験）



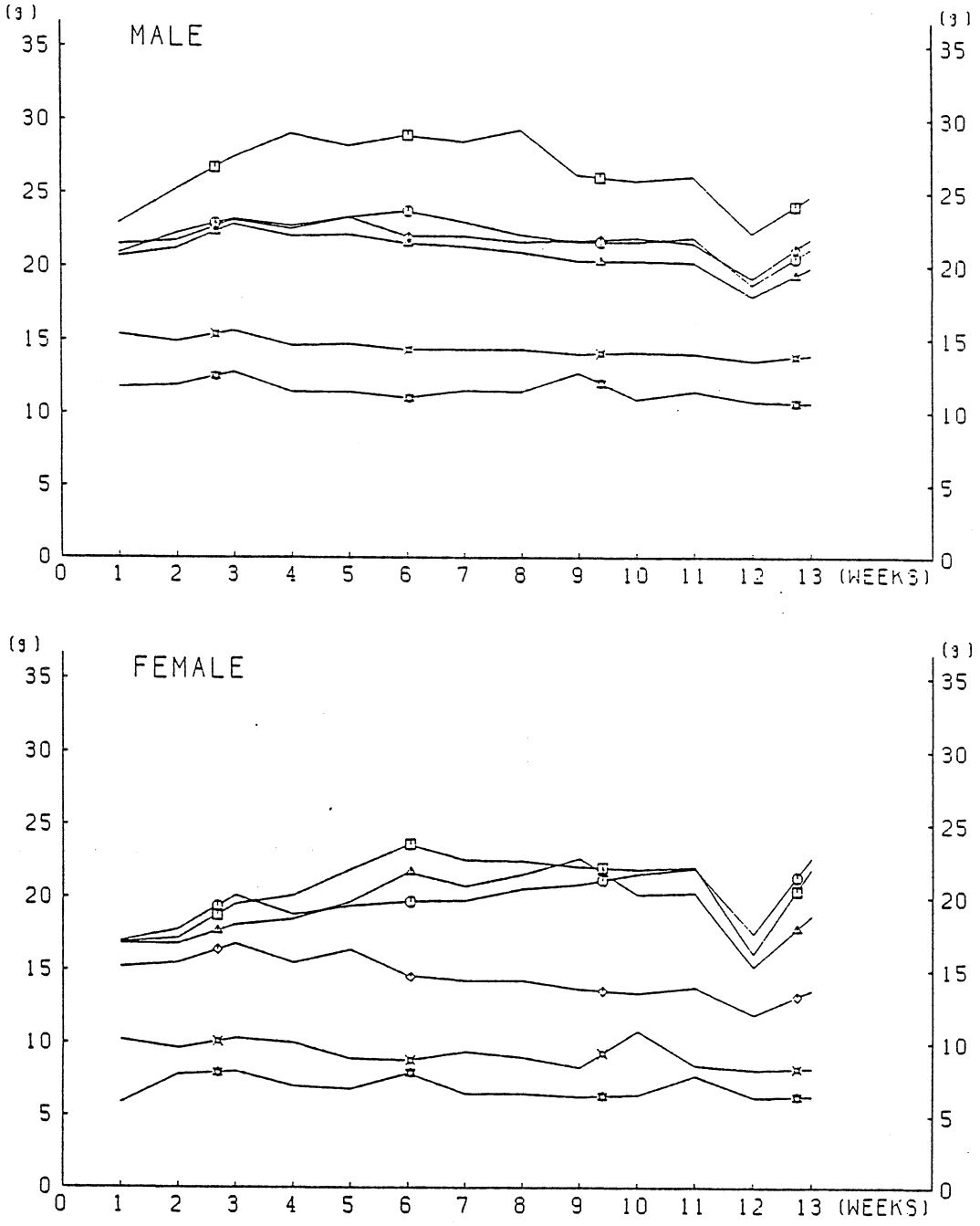
付録図４　　被験物質摂取量（ラット・２週間試験）



付録図４　　被験物質摂取量（ラット・２週間試験）



付録図５　　体重値（ラット・１３週間試験）

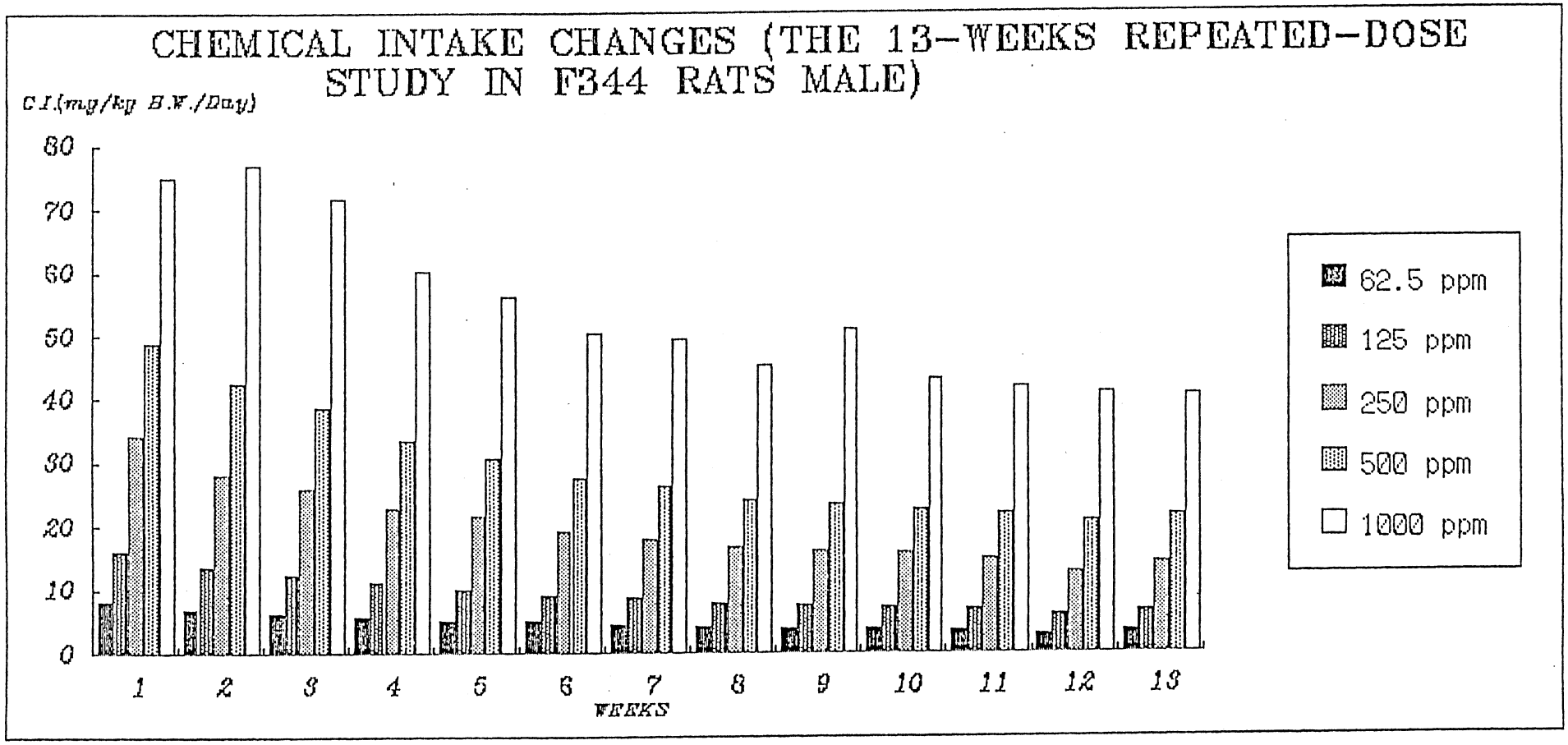


STUDY NO. 0038
TEST SUB. M-PD.2HCL
ANIMAL RAT F344

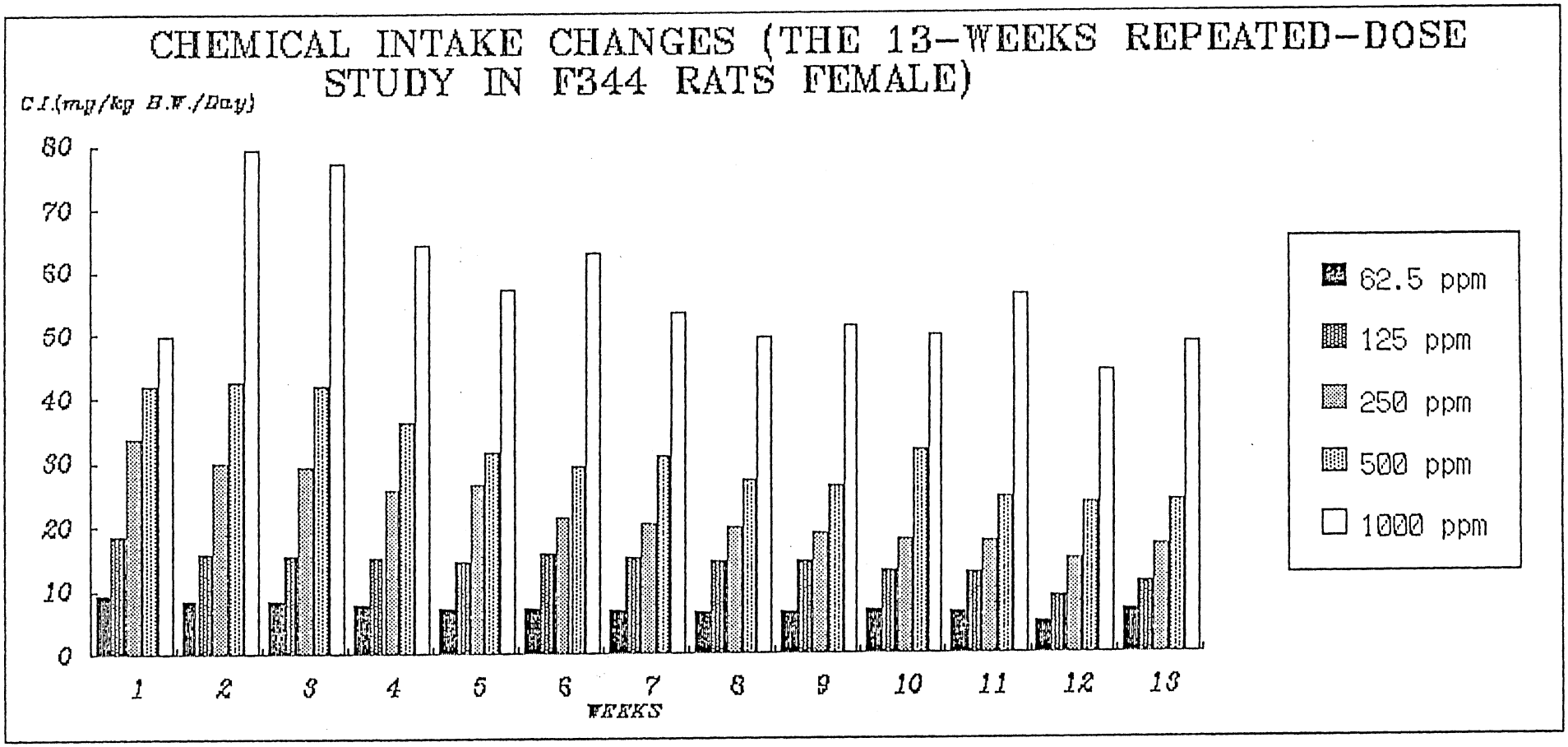
DOSE LEVEL (PPM)
0
62.5
125
250
500
1000

WATER CONSUMPTION

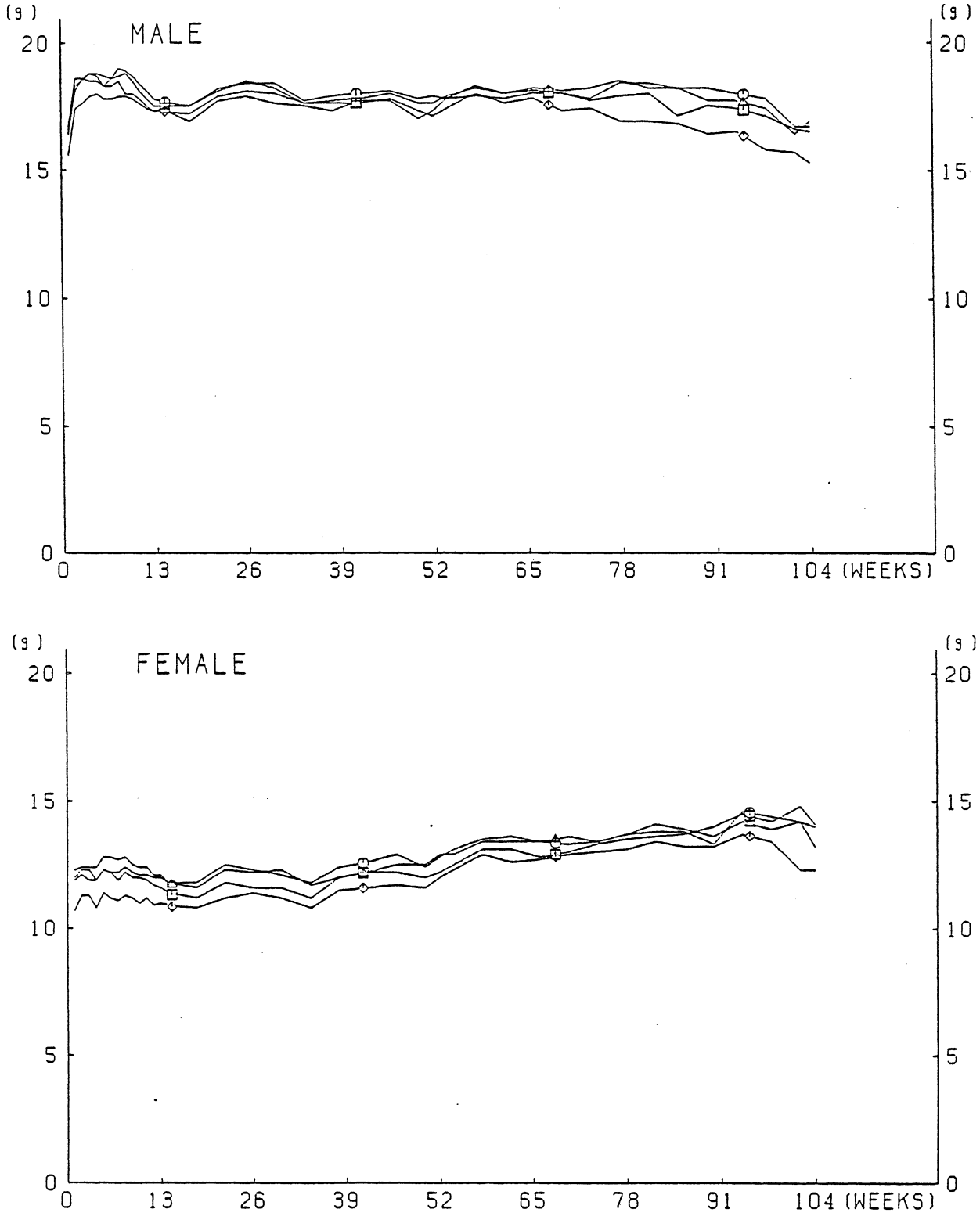
付録図6　　摂水量（ラット・１３週間試験）



付録図７　　被験物質摂取量（ラット・１３週間試験）



付録図７　　被験物質摂取量（ラット・１３週間試験）

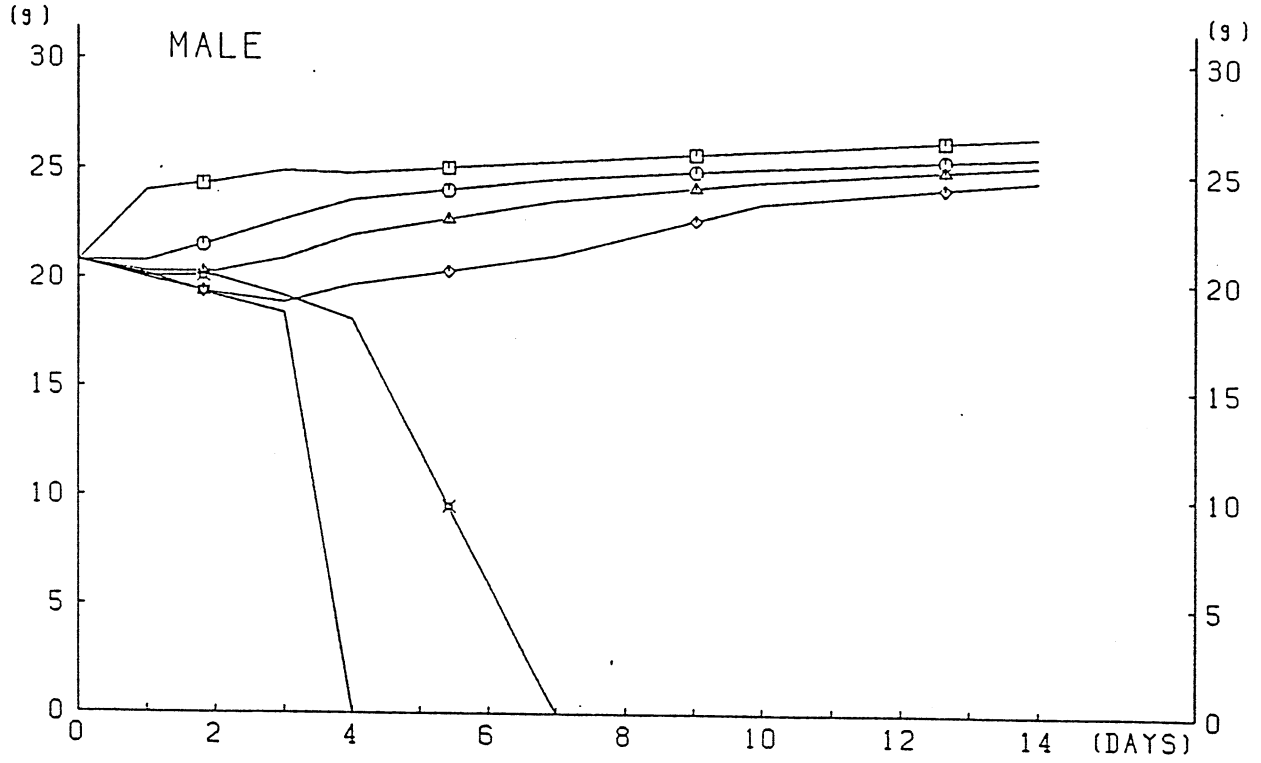


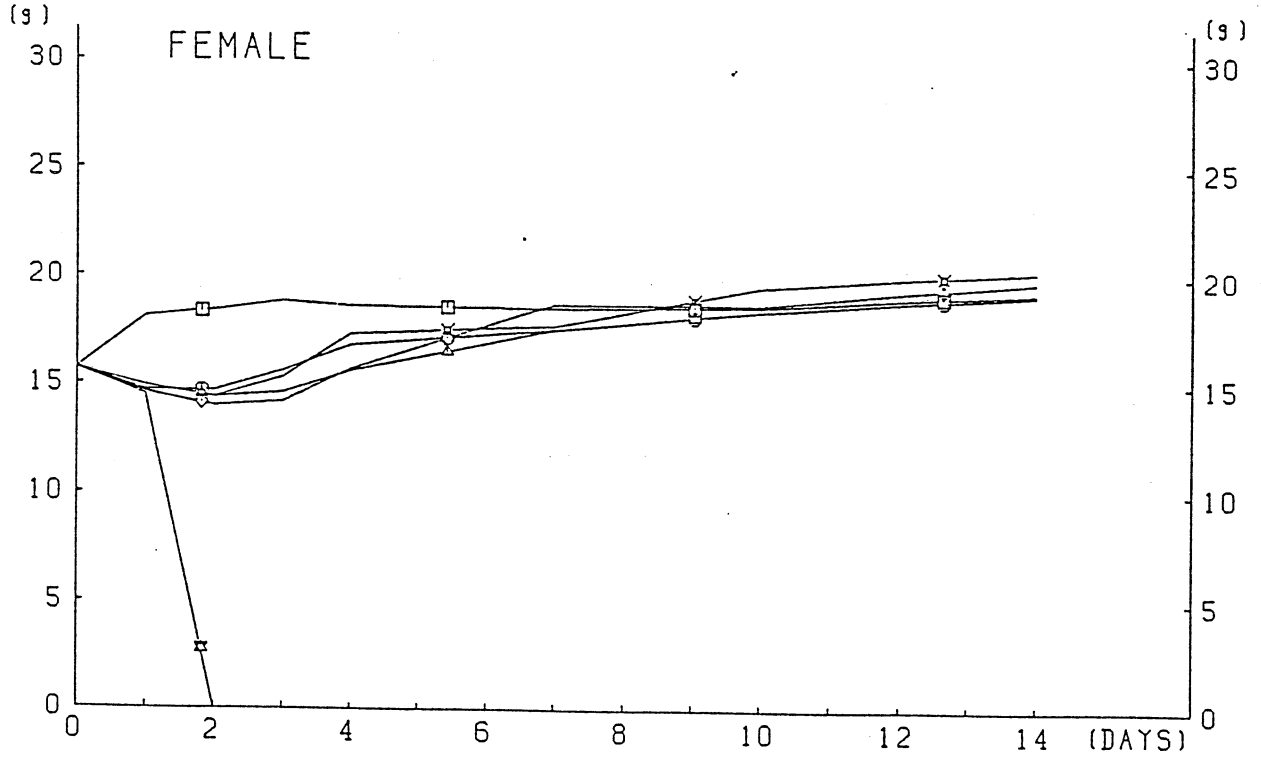
STUDY NO. 0059
TEST SUB. M-PD.2HCL
ANIMAL RAT F344

DOSE LEVEL (PPM)
CONTROL
64
160
400

FOOD CONSUMPTION

付録図8　　摂餌量（ラット・がん原性試験）



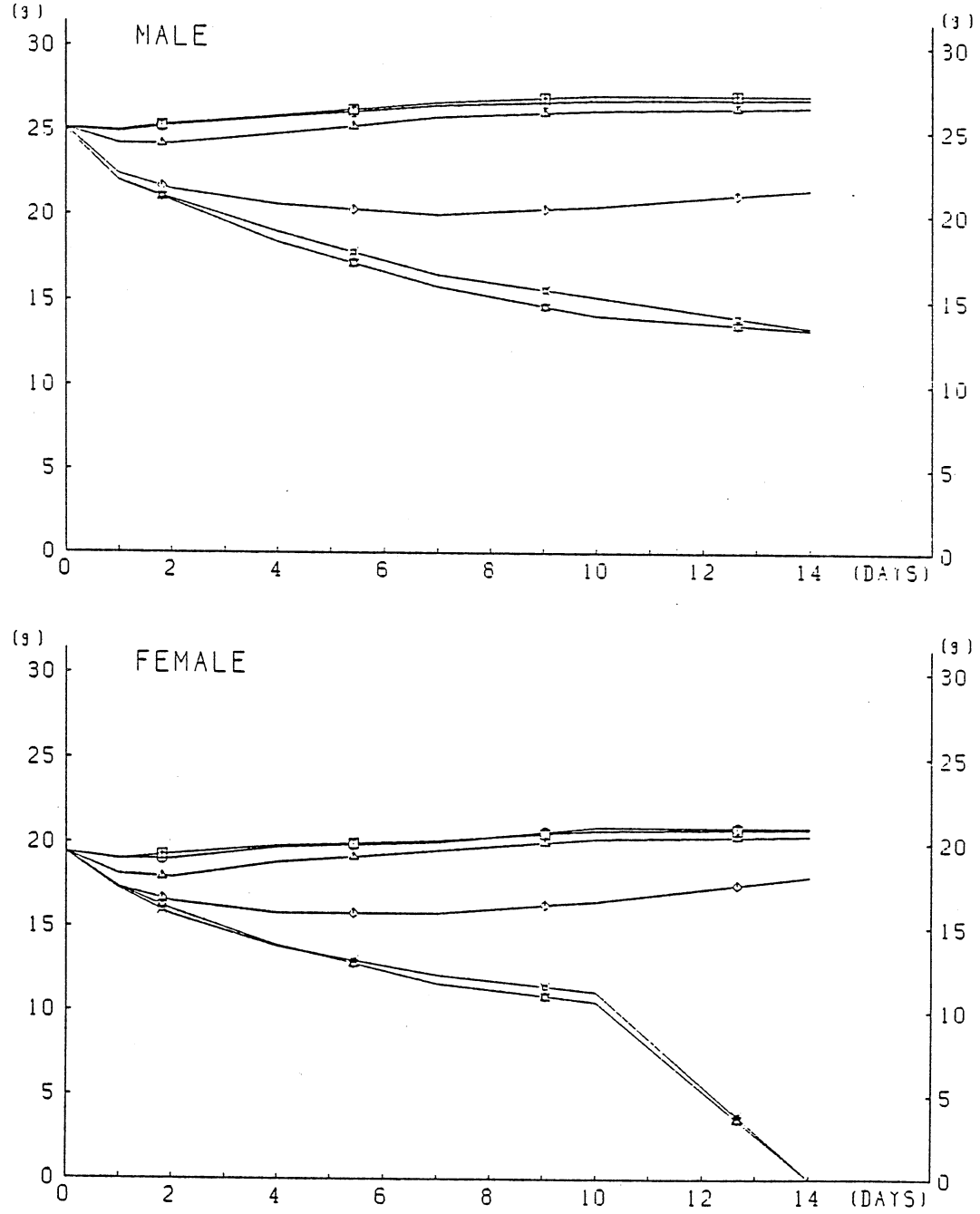


STUDY NO. 0008
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

DOSE LEVEL (MG/KG)
CONTROL
68
102
153
230
345

BODY WEIGHT

付録図9　体重値（マウス・急性試験）

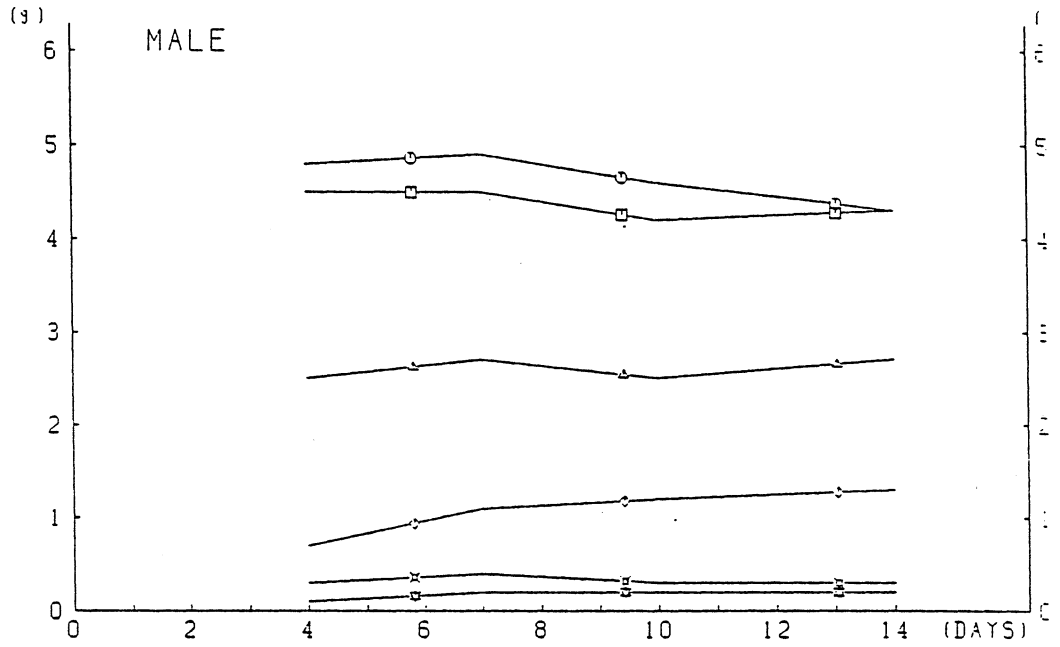


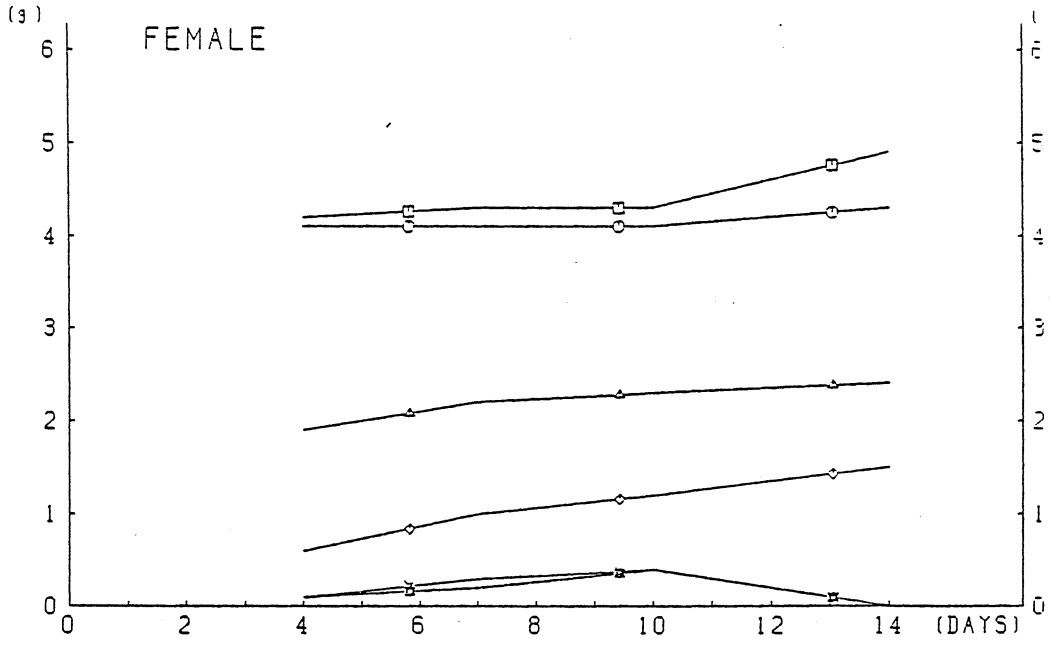
STUDY NO. 0027
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

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）



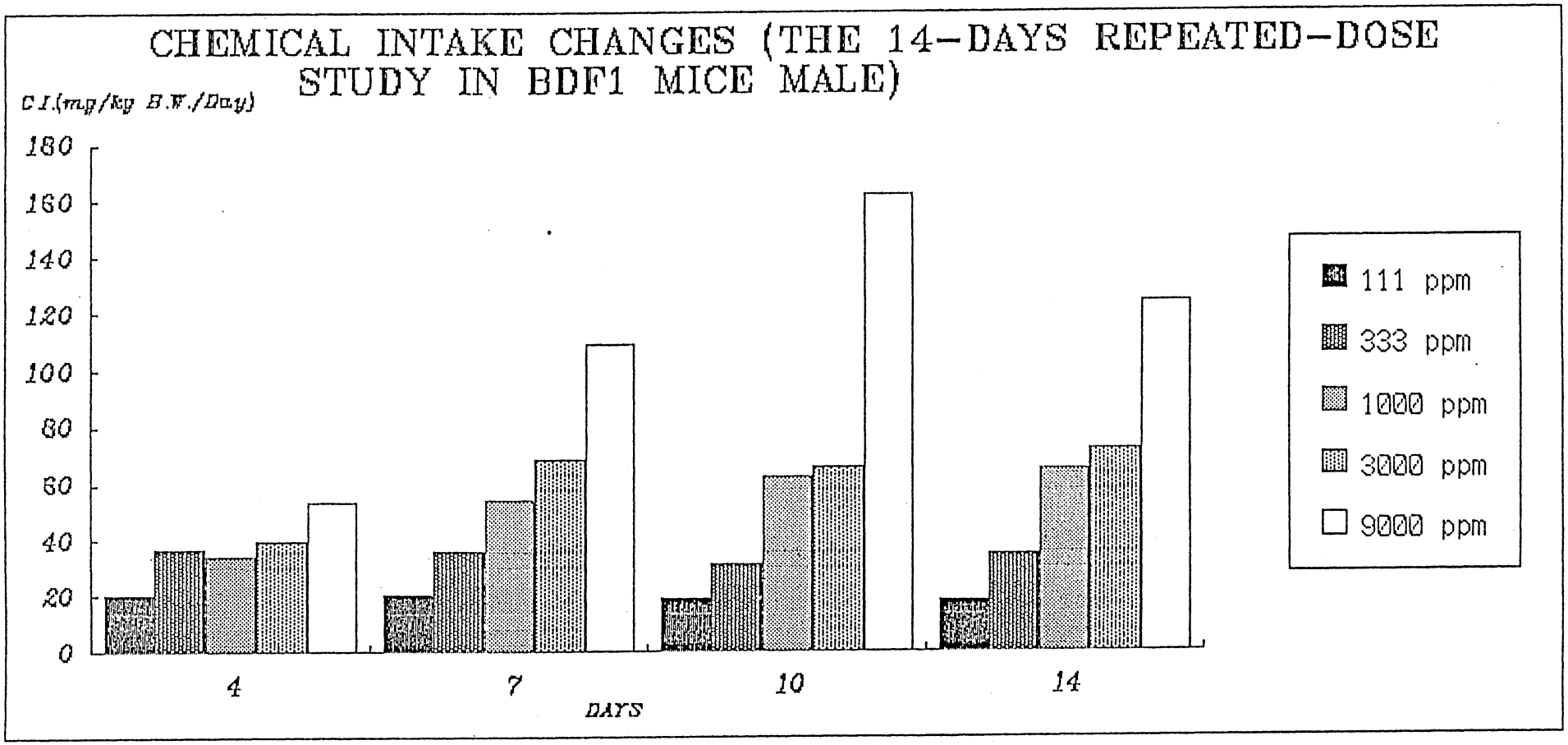


STUDY NO. 0027
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

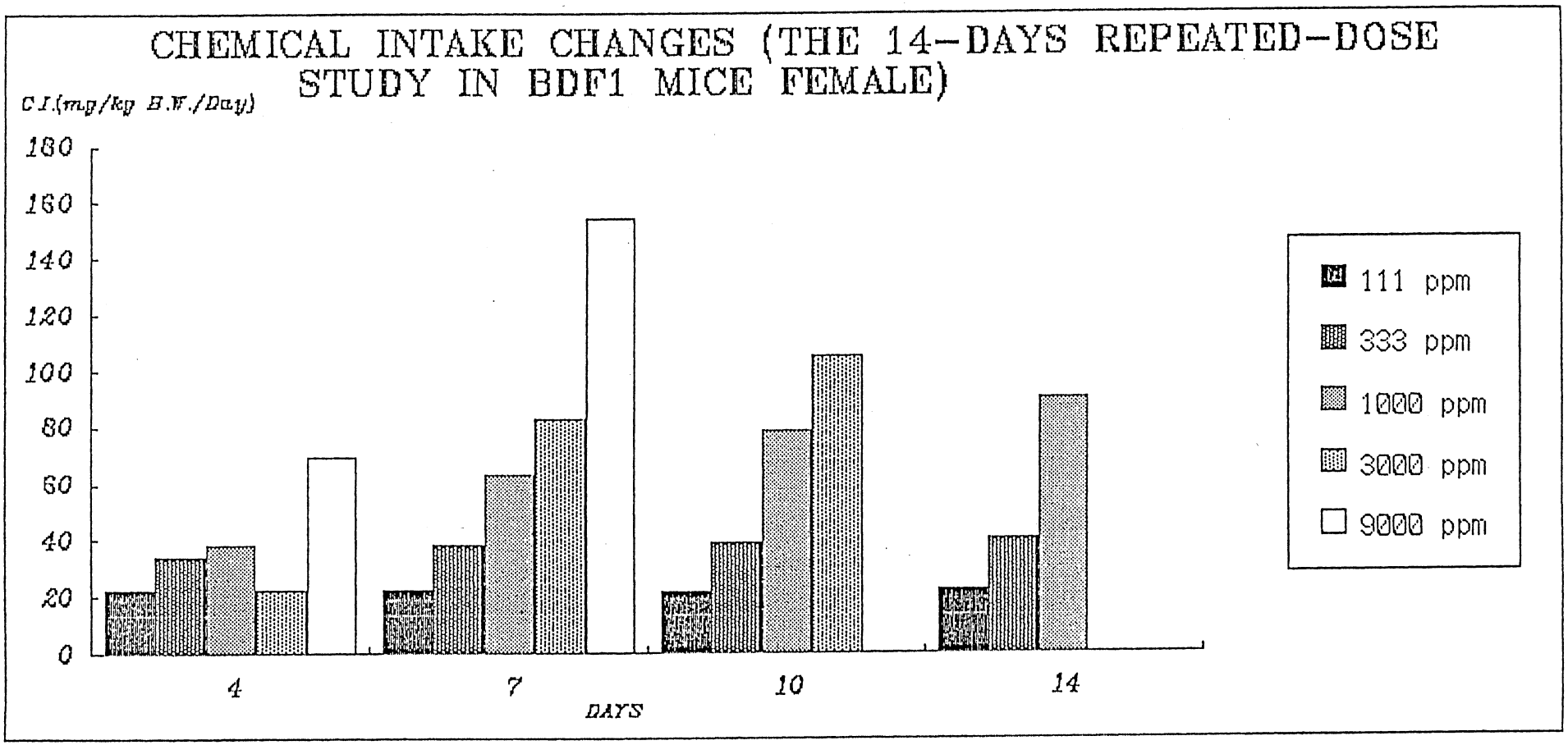
DOSE LEVEL (PPM)
CONTROL
111
333
1000
3000
9000

WATER CONSUMPTION

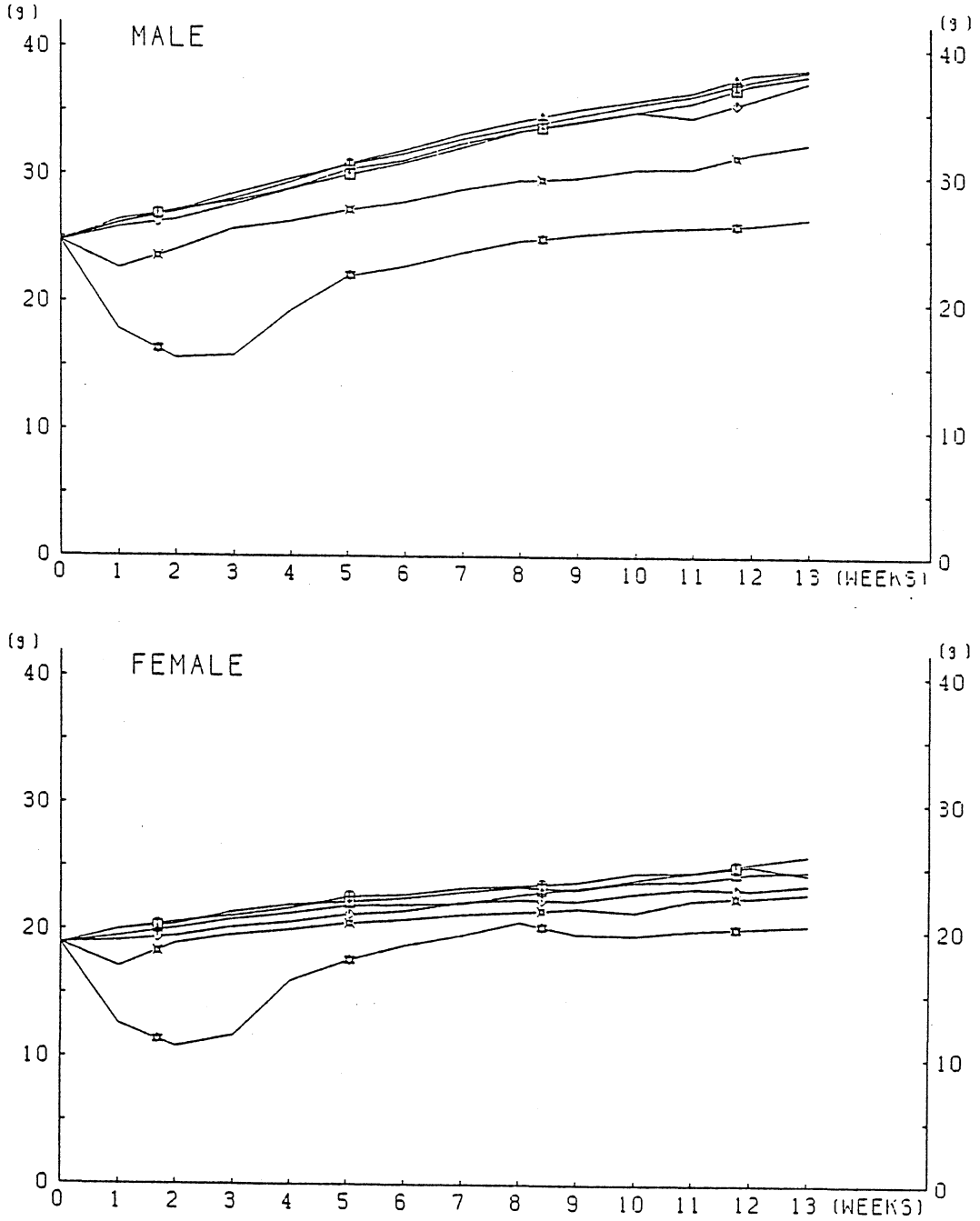
付録図１１　　摂水量（マウス・２週間試験）



付録図１２　　被験物質摂取量（マウス・２週間試験）



付録図１２　　被験物質摂取量（マウス・２週間試験）

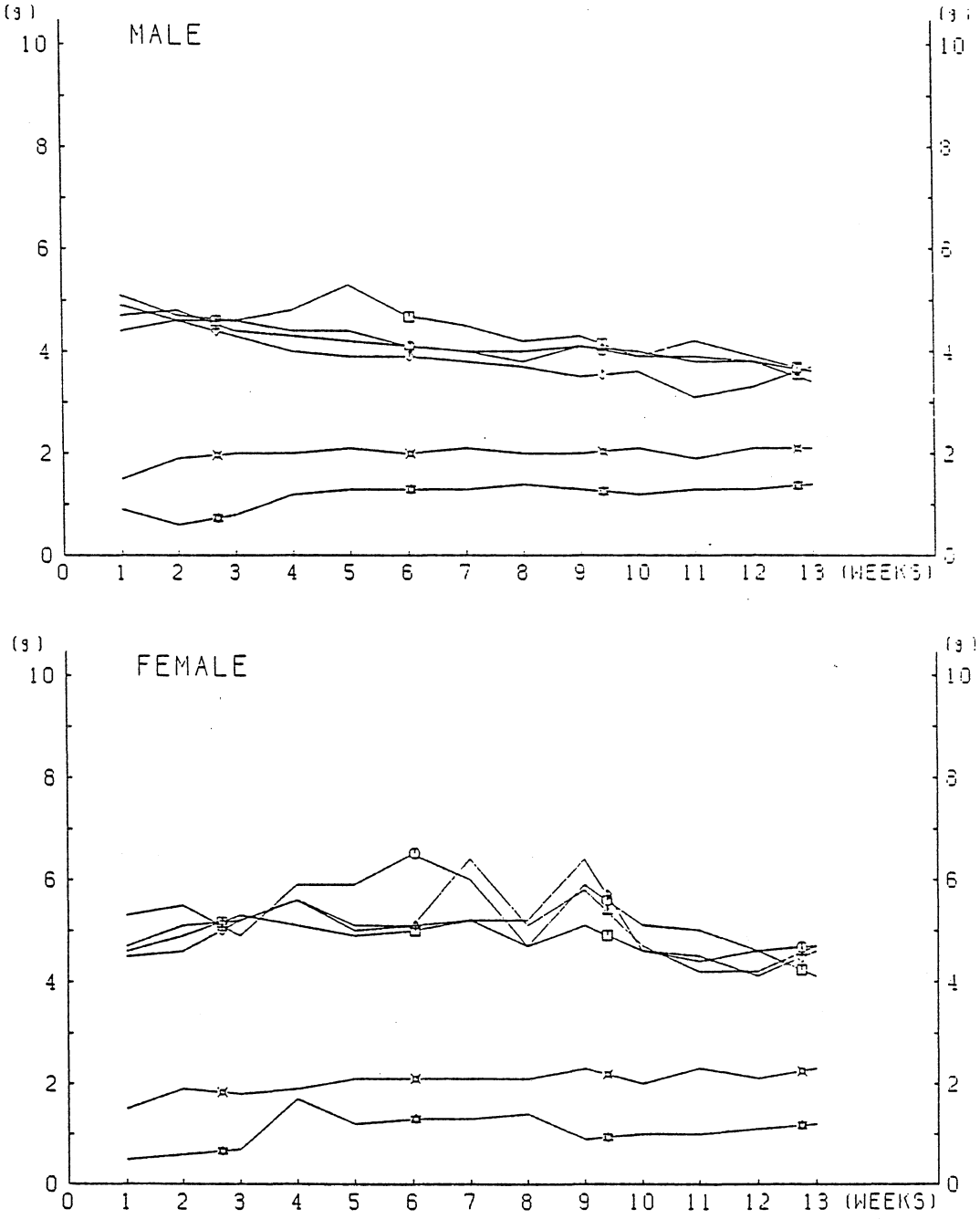


STUDY NO. 0039
TEST SUB. M-PD.2HCL
ANIMAL MOUSE BDF1

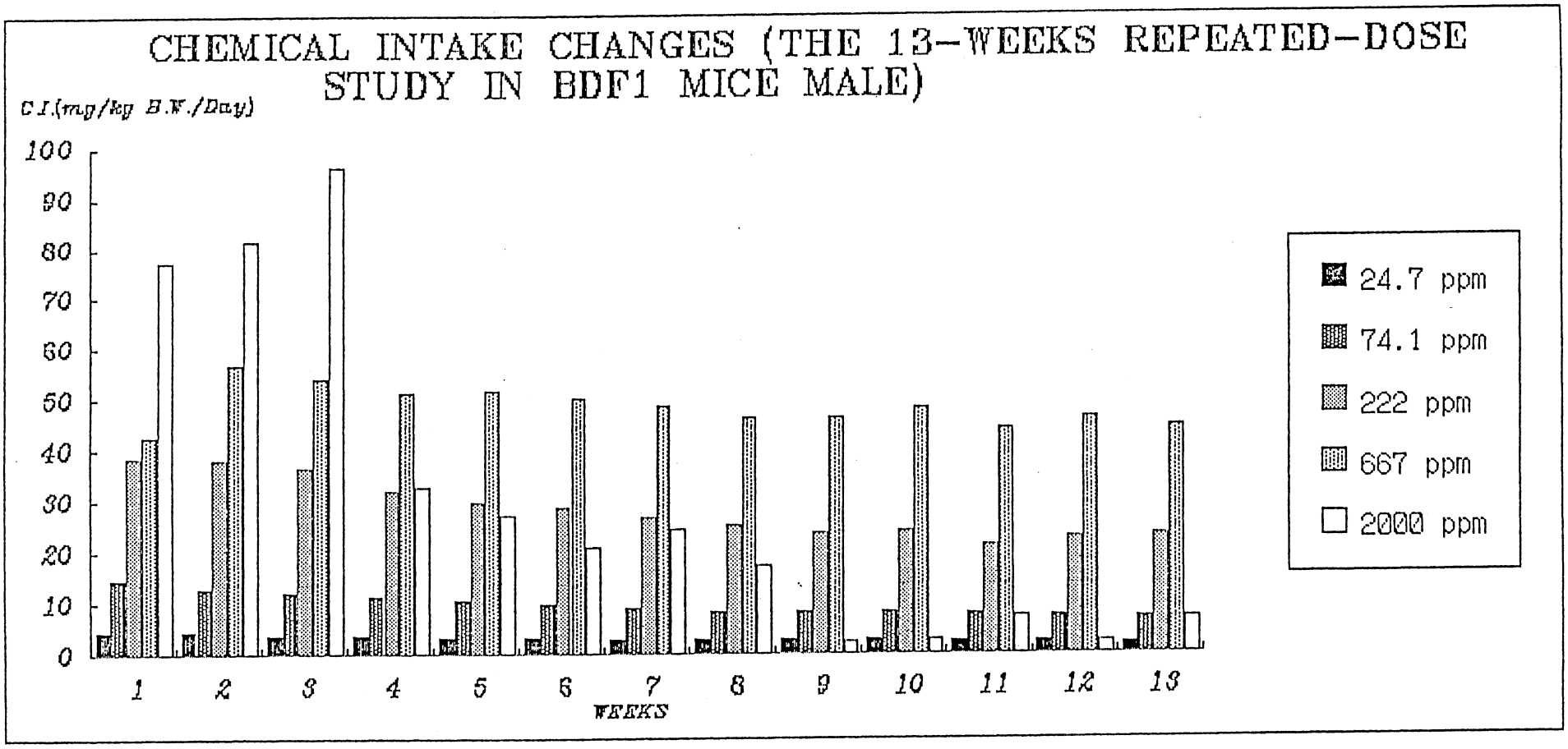
DOSE LEVEL (PPM)
0
24.7
74.1
222
667
2000

BODY WEIGHT

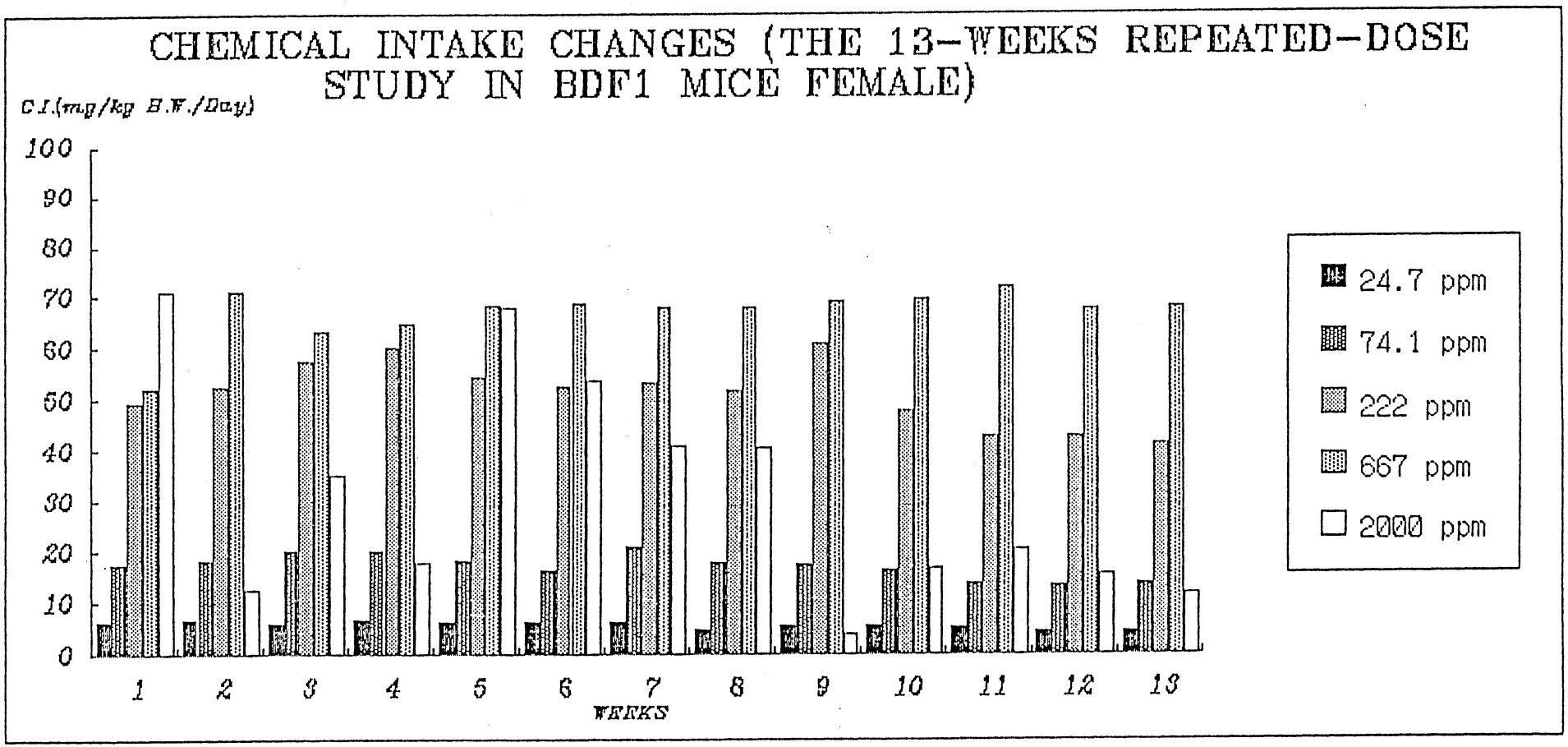
付録図１３　　体重値（マウス・１３週間試験）



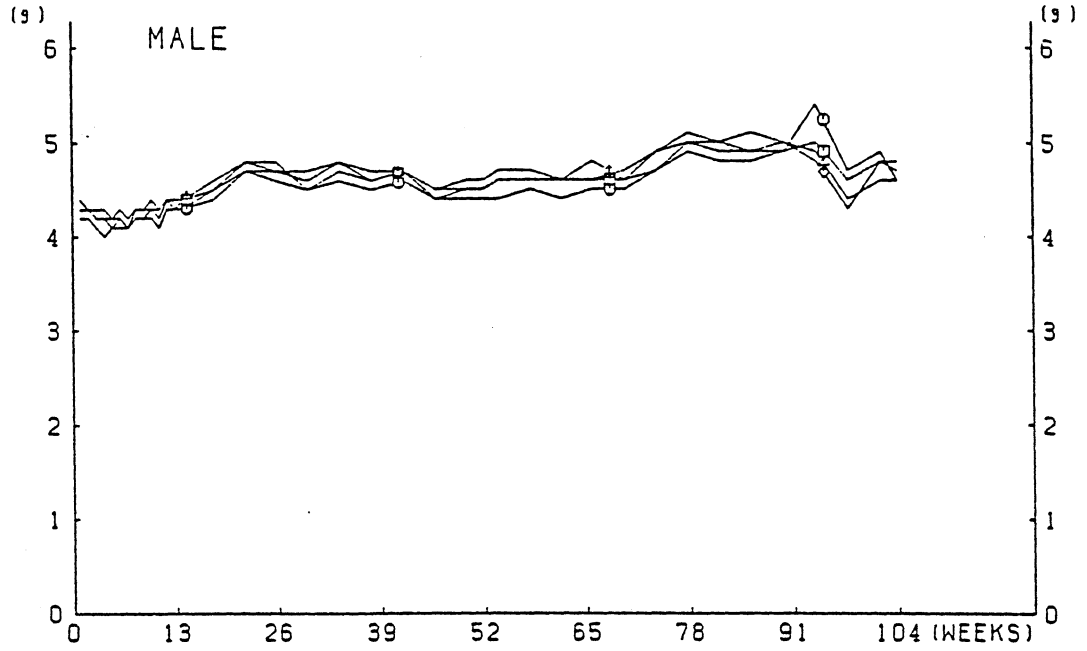
付録図１４　　摂水量（マウス・１３週間試験）

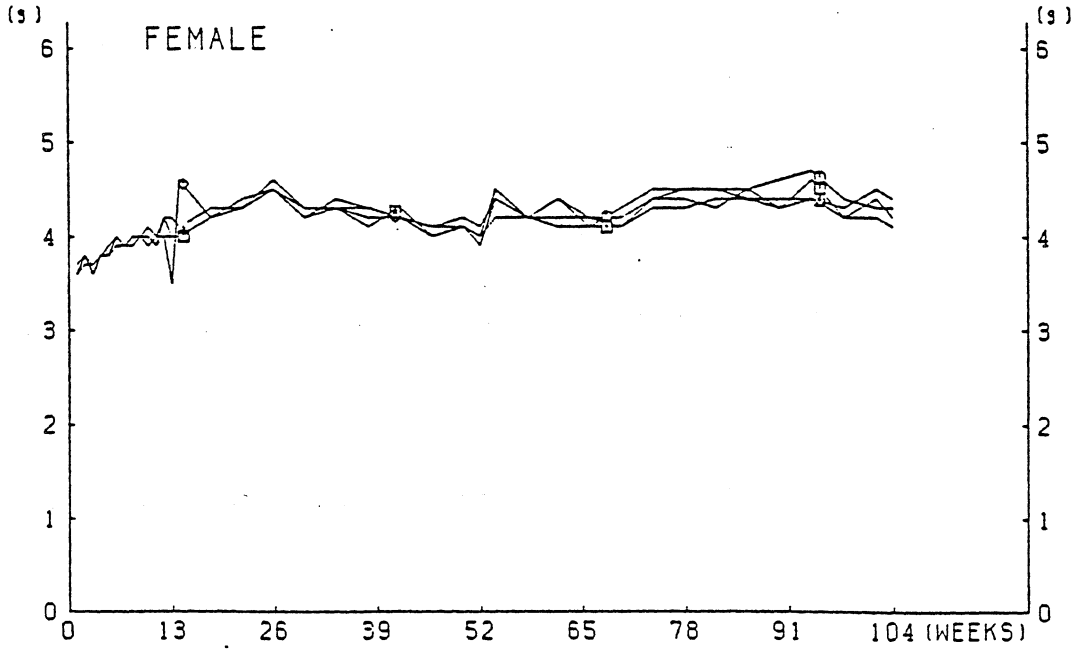


付録図１５　　被験物質摂取量（マウス・１３週間試験）



付録図１５　　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

付録図１６　　摂餌量（マウス・がん原性試験）