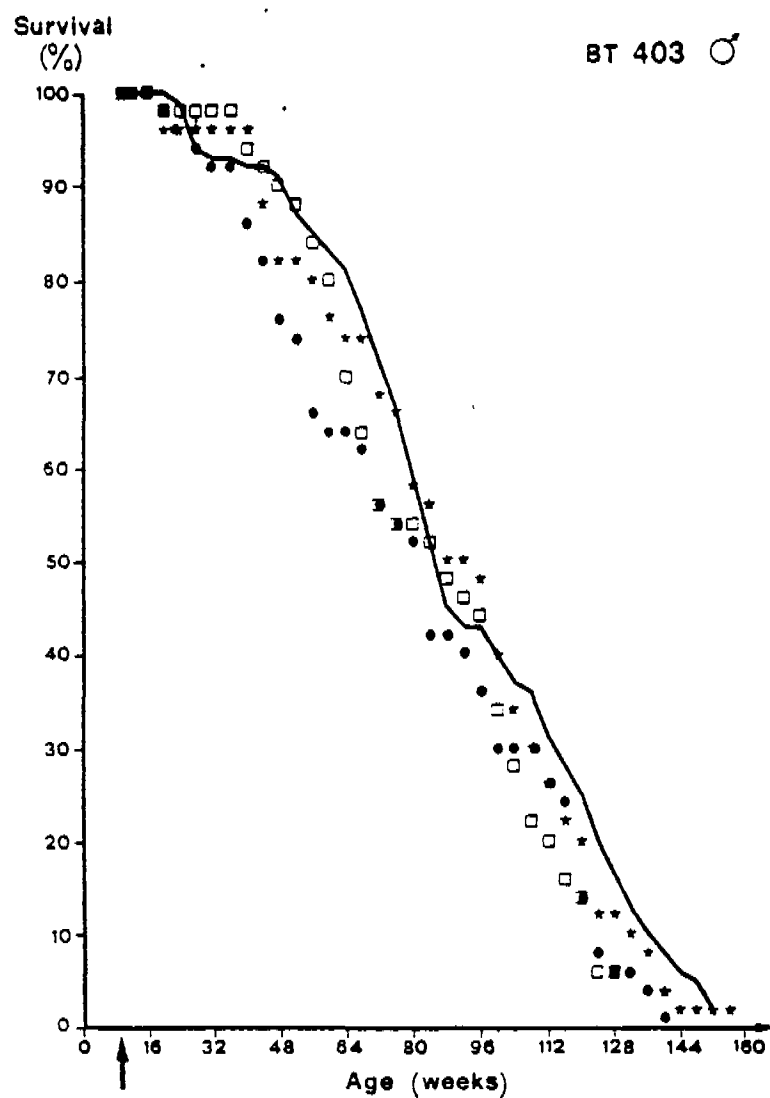
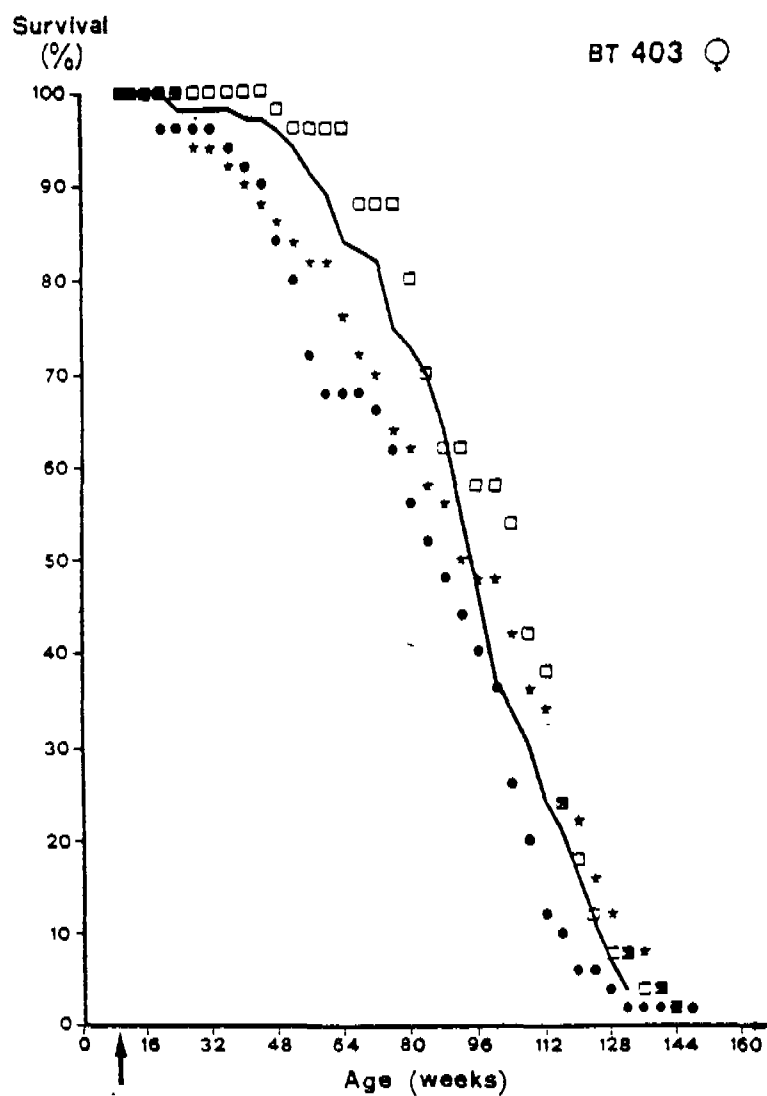




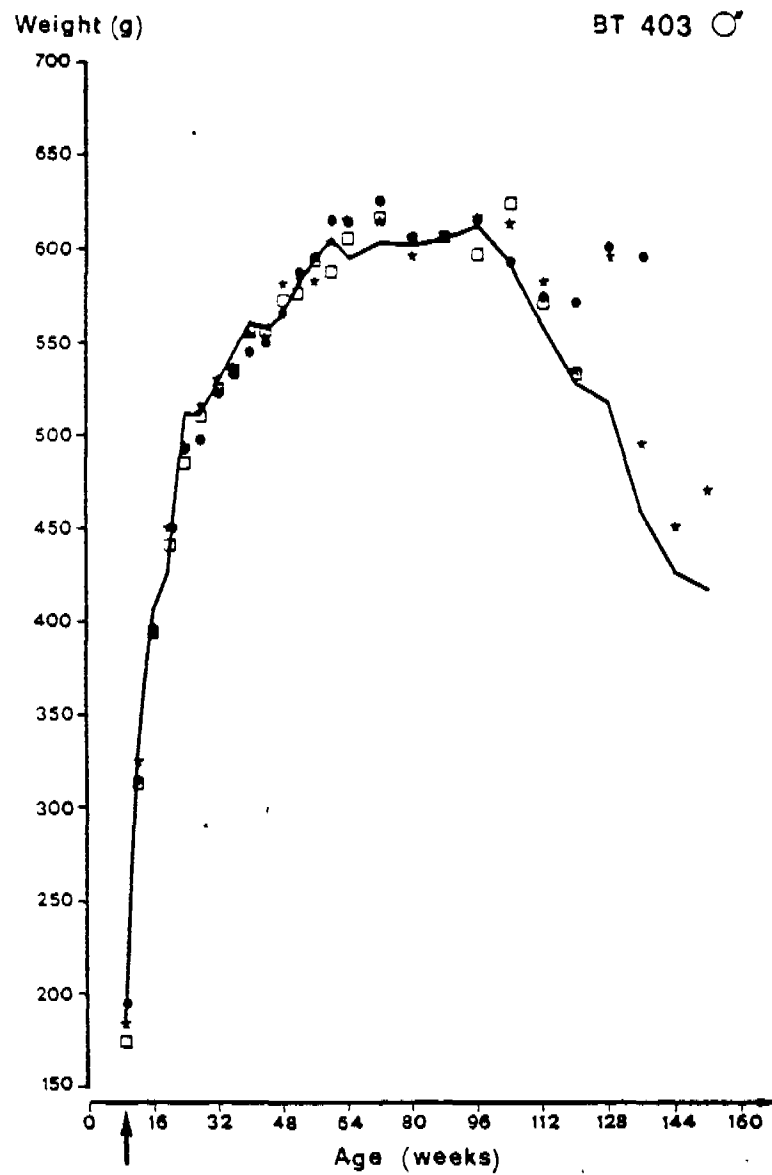
II III GRAPH 1. Survival of male Sprague-Dawley rats of experiment BT403: groups treated with 20 (●), 10 (*) and 5 mg/Kg b.w. (□), and untreated control group (-).
— start of the experiment.

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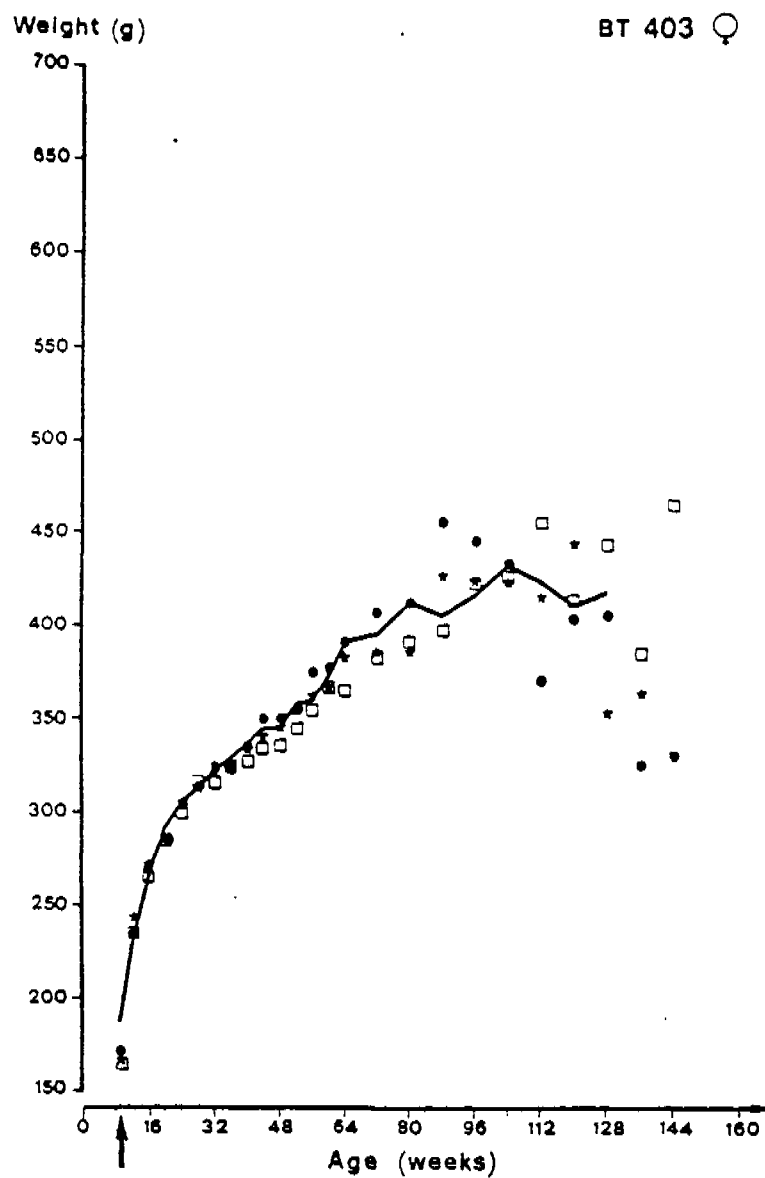


II III GRAPH 2. Survival of female Sprague-Dawley rats of experiment BT 403: groups treated with 20 (●), 10 (*) and 5 mg Kg b.w. (□), and untreated control group (-).
- start of the experiment.

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II III GRAPH 3. Average weight of male Sprague-Dawley rats of experiment BT403: groups treated with 20 (●), 10 (*) and 5 mg/kg b.w. (□), and untreated control group (-).
 — start of the experiment.



II III GRAPH 4. Average weight of female Sprague-Dawley rats of experiment BT403: groups treated with 20 (●), 10 (*) and 5 mg/kg b.w. (□), and untreated control group (-).
 — start of the experiment.

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II III TABLE I

Experiment BT103. Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF REGRESSIVE CHANGES

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		REGRESSIVE CHANGES					
		Sex	No. at start	Liver		Kidneys		Adrenal glands	
				No.	%	No.	%	No.	%
I	20 mg/Kg	♂	50	22	44.0	0	-	0	-
		♀	50	19	38.0	0	-	23	46.0
		♂ and ♀	100	41	41.0	0	-	23	23.0
II	10 mg/Kg	♂	50	26	52.0	0	-	1	2.0
		♀	50	20	40.0	0	-	31	62.0
		♂ and ♀	100	46	46.0	0	-	32	32.0
III	5 mg/Kg	♂	50	19	38.0	0	-	0	-
		♀	50	20	40.0	0	-	28	56.0
		♂ and ♀	100	39	39.0	0	-	28	28.0
IV	Olive oil (Control)	♂	100	28	28.0	0	-	3	3.0
		♀	100	38	38.0	0	-	55	55.0
		♂ and ♀	200	66	33.0	0	-	58	29.0
Total			500						

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II/III TABLE 2

Experiment BF103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF PHLOGISTIC CHANGES

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		PHLOGISTIC CHANGES															
		Sex	No. at start	Encephalic abscesses		Meningitis		Broncho-pneumonia		Pleuritis		Pericarditis		Liver abscesses and hepatitis		Kidney abscesses and nephritis		Peritonitis	
				No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
I	20 mg/kg	♂	50	3	6.0	4	8.0	29	58.0	20	40.0	5	10.0	5	10.0	3	6.0	12	24.0
		♀	50	1	2.0	2	4.0	23	46.0	13	26.0	5	10.0	7	14.0	2	4.0	6	12.0
		♂ and ♀	100	4	4.0	6	6.0	52	52.0	33	33.0	10	10.0	12	12.0	5	5.0	18	18.0
II	10 mg/kg	♂	50	2	4.0	2	4.0	22	44.0	9	18.0	3	6.0	0	-	2	4.0	14	28.0
		♀	50	0	-	0	-	22	44.0	10	20.0	4	8.0	1	2.0	1	2.0	7	14.0
		♂ and ♀	100	2	2.0	2	2.0	44	44.0	19	19.0	7	7.0	1	1.0	3	3.0	21	21.0
III	5 mg/kg	♂	50	1	2.0	4	8.0	31	62.0	12	24.0	8	16.0	1	2.0	2	4.0	14	28.0
		♀	50	2	4.0	3	6.0	17	34.0	6	12.0	2	4.0	3	6.0	2	4.0	5	10.0
		♂ and ♀	100	3	3.0	7	7.0	48	48.0	18	18.0	10	10.0	4	4.0	4	4.0	19	19.0
IV	Olive oil (Control)	♂	100	0	-	3	3.0	41	41.0	18	18.0	6	6.0	1	1.0	12	12.0	12	12.0
		♀	100	2	2.0	2	2.0	26	26.0	11	11.0	9	9.0	0	-	8	8.0	6	6.0
		♂ and ♀	200	2	1.0	5	2.5	67	33.5	29	14.5	15	7.5	1	0.5	20	10.0	18	9.0
Total			500																

II III TABLE 3

Experiment BT403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 117 weeks (end of the experiment).

INCIDENCE OF ADENOMATOUS HYPERPLASIA OF RESPIRATORY EPITHELIA

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		ADENOMATOUS HYPERPLASIA OF RESPIRATORY EPITHELIA	
		Sex	No. at start	No.	%
I	20 mg/Kg	♂	50	12	24.0
		♀	50	7	14.0
		♂ and ♀	100	19	19.0
II	10 mg/Kg	♂	50	11	22.0
		♀	50	5	10.0
		♂ and ♀	100	16	16.0
III	5 mg/Kg	♂	50	8	16.0
		♀	50	2	4.0
		♂ and ♀	100	10	10.0
IV	Olive oil (Control)	♂	100	14	14.0
		♀	100	5	5.0
		♂ and ♀	200	19	9.5
Total			500		

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II III TABLE 4

Experiment BT 103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF PITUITARY ADENOMATOUS GROWTHS

GROUP NO.	DOSE	ADENOMAS (Sprague-Dawley rats, 9 weeks old at start)		NODULAR ADENOMATOUS HYPERPLASIA		ADENOMAS		TOTAL	
		Sex	No. at start	No.	%	No.	%	No.	%
I	20 mg/Kg	♂	50	0	-	2	4.0	2	4.0
		♀	50	1	2.0	4	8.0	5	10.0
		♂ and ♀	100	1	1.0	6	6.0	7	7.0
II	10 mg/Kg	♂	50	0	-	2	4.0	2	4.0
		♀	50	0	-	1	2.0	1	2.0
		♂ and ♀	100	0	-	3	3.0	3	3.0
III	5 mg/Kg	♂	50	0	-	1	2.0	1	2.0
		♀	50	0	-	7	14.0	7	14.0
		♂ and ♀	100	0	-	8	8.0	8	8.0
IV	Olive oil (Control)	♂	100	3	3.0	1	1.0	4	4.0
		♀	100	5	5.0	3	3.0	8	8.0
		♂ and ♀	200	8	4.0	4	2.0	12	6.0
Total			500						

SL 100361

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II/III TABLE 5

Experiment BF403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.

Results after 147 weeks (end of the experiment).

DISTRIBUTION OF THE DIFFERENT TYPES OF TUMOURS

(first part)

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)			ANIMALS WITH TUMOURS																							
		Sex	No. at start	Corrected number (a)	Mammary tumours (b)			Zymbal gland carcinomas			Leukaemias			Nephroblastomas			Angiosarcomas						Angiomas and fibromyomas					
					Total No.	%	Average latency time (weeks) (d)	Total No.	%	Average latency time (weeks) (e)	Total No.	%	Average latency time (weeks) (e)	Total No.	%	Average latency time (weeks) (e)	Liver			Other sites			Liver			Other sites		
																	Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)	Average latency time (weeks) (e)
I	20 mg/kg	♂	50	49	2	4.1	92.0	0	-	-	2	4.1	99.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
		♀	50	48	23	47.9	71.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
		♂ and ♀	100	97	25	25.8	73.5	0	-	-	2	2.1	99.5	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
II	10 mg/kg	♂	50	48	2	4.2	114.0	2	4.2	77.0	1	2.1	131.0	0	-	-	0	-	-	0	-	-	0	-	-	1	2.1	133.0
		♀	50	50	24	48.0	86.2	0	-	-	1	2.0	105.0	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
		♂ and ♀	100	98	26	26.5	88.3	2	2.0	77.0	2	2.0	118.0	0	-	-	0	-	-	0	-	-	0	-	-	1	1.0	133.0
III	5 mg/kg	♂	50	49	3	6.1	90.0	0	-	-	3	6.1	92.0	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
		♀	50	50	28	56.0	85.5	0	-	-	1	2.0	87.0	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
		♂ and ♀	100	99	31	31.3	85.9	0	-	-	4	4.0	90.7	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-
IV	Olive oil (Control)	♂	100	100	10	10.0	114.6	2	2.0	132.0	9	9.0	78.3	0	-	-	0	-	-	1	1.0	54.0	0	-	-	0	-	-
		♀	100	99	57	57.6	83.8	0	-	-	2	2.0	84.5	0	-	-	1	1.0	119.0	0	-	-	0	-	-	0	-	-
		♂ and ♀	200	199	67	33.7	88.4	2	1.0	132.0	11	5.6	79.4	0	-	-	1	0.5	119.0	1	0.5	54.0	0	-	-	0	-	-
Total			500	493																								

(a) Alive animals at 14 weeks, when the first tumour (a mammary adenocarcinoma) was observed.

(b) Two or more tumours of the same and/or different types (fibroadenomas, carcinomas, sarcomas, carcinosarcomas) may be present in the same animal.

(c) The percentages are referred to the corrected number.

(d) Average age at the onset of the first mammary tumour per animal detected at the periodic examination or at autopsy.

(e) Average time from the start of the experiment to the detection (at the periodic examination or at autopsy).

(f) Several animals with two or more tumours.

II/III TABLE 5

Experiment BT403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.

Results after 147 weeks (end of the experiment).

DISTRIBUTION OF THE DIFFERENT TYPES OF TUMOURS

(second part)

GROUP NO.	DOSE	ANIMALS WITH TUMOURS																						
		Hepatomas			Forestomach epithelial tumours			Skin carcinomas			Subcutaneous sarcomas			Encephalic tumours			Others			Total (f)				
		Total No.	%	Average latency time (weeks) (e)	Total No.	%	Average latency time (weeks) (e)	Total No.	%	Average latency time (weeks) (e)	Total No.	%	Average latency time (weeks) (e)	Neuroblastomas		Other types								
														Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)	Average latency time (weeks) (e)	Total No.	%(c)
I	20 mg/Kg	0	-	-	0	-	-	0	-	-	1	2.0	102.0	0	-	-	0	-	7	6	1	9	18.4	1.1
		0	-	-	2	4.2	95.5	0	-	-	0	-	-	0	-	-	0	-	3	1	2	25	52.1	1.1
		0	-	-	2	2.1	95.5	0	-	-	1	1.0	102.0	0	-	-	0	-	10	7	3	34	35.0	1.2
II	10 mg/Kg	0	-	-	0	-	-	0	-	-	2	4.2	111.5	0	-	-	1	2.1	8	5	3	9	10.7	1.5
		1	2.0	120.0	1	2.0	67.0	0	-	-	0	-	-	0	-	-	0	-	6	3	3	28	56.0	1.2
		1	1.0	120.0	1	1.0	67.0	0	-	-	2	2.0	111.5	0	-	-	1	1.0	14	6	6	37	37.7	1.4
III	5 mg/Kg	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	2	4.1	4	2	2	11	22.4	1.1
		0	-	-	0	-	-	0	-	-	2	4.0	75.0	0	-	-	1	2.0	4	2	2	32	64.0	1.2
		0	-	-	0	-	-	0	-	-	2	2.0	75.0	0	-	-	3	3.0	4	4	4	43	43.4	1.2
IV	Olive oil (Control)	0	-	-	1	1.0	100.0	0	-	-	2	2.0	100.0	0	-	-	2	2.0	11	10	1	29	29.0	1.3
		1	1.0	124.0	4	4.0	105.0	0	-	-	0	-	-	0	-	-	3	3.0	13	6	5	63	63.6	1.3
		1	0.5	124.0	5	2.5	104.0	0	-	-	2	1.0	100.0	0	-	-	5	2.5	24	18	6	92	46.2	1.1
Total																								

(a) Alive animals at 11 weeks, when the first tumour (a mammary adenocarcinoma) was observed.

(b) Two or more tumours of the same and/or different types (fibroadenomas, carcinomas, sarcomas, carcinosarcomas) may be present in the same animal.

(c) The percentages are referred to the corrected number.

(d) Average age at the onset of the first mammary tumour per animal detected at the periodic examination or at autopsy.

(e) Average time from the start of the experiment to the detection (at the periodic examination or at autopsy).

(f) Several animals with two or more tumours.

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II/III TABLE 6

Experiment BF403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF THE DIFFERENT TYPES OF TUMOURS REFERRED TO SPECIFIC CORRECTED NUMBERS

(first part)

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats 9 weeks old at start)			ANIMALS WITH TUMOURS																						
		Sex	No. at start	Mammary tumours			Zymbal gland carcinomas			Leukaemias			Nephroblastomas			Angiosarcomas						Angiomas and fibroangiomas					
				Corrected number (a)	No.	%	Corrected number (b)	No.	%	Corrected number (c)	No.	%	Corrected number	No.	%	Corrected number (d)	No.	%	Corrected number (e)	No.	%	Corrected number	No.	%	Corrected number (f)	No.	%
I	20 mg/Kg	♂	50	49	2	4.1	30	0	-	48	2	4.2	-	0	-	3	0	-	32	0	-	-	0	-	3	0	-
		♀	50	48	23	47.9	34	0	-	48	0	-	-	0	-	2	0	-	34	0	-	-	0	-	2	0	-
		♂ and ♀	100	97	25	25.8	64	0	-	96	2	2.1	-	0	-	5	0	-	66	0	-	-	0	-	5	0	-
II	10 mg/Kg	♂	50	48	2	4.2	34	2	5.9	48	1	2.1	-	0	-	6	0	-	37	0	-	-	0	-	6	1	16.7
		♀	50	24	48.0	35	0	-	50	1	2.0	-	0	-	7	0	-	36	0	-	-	0	-	7	0	-	
		♂ and ♀	100	98	26	26.5	69	2	2.9	98	2	2.0	-	0	-	13	0	-	73	0	-	-	0	-	13	1	7.7
III	5 mg/Kg	♂	50	49	3	6.1	30	0	-	49	3	6.1	-	0	-	2	0	-	38	0	-	-	0	-	2	0	-
		♀	50	50	28	56.0	44	0	-	50	1	2.0	-	0	-	4	0	-	48	0	-	-	0	-	4	0	-
		♂ and ♀	100	99	31	31.1	74	0	-	99	4	4.0	-	0	-	6	0	-	86	0	-	-	0	-	6	0	-
IV	Olive oil (Control)	♂	100	100	10	10.0	74	2	2.7	99	9	9.0	-	0	-	17	0	-	83	1	1.2	-	0	-	17	0	-
		♀	100	99	57	57.6	82	0	-	98	2	2.0	-	0	-	7	1	14.3	88	0	-	-	0	-	7	0	-
		♂ and ♀	200	199	67	33.7	156	2	1.3	197	11	5.6	-	0	-	24	1	4.2	171	1	0.6	-	0	-	24	0	-
Total			500	493			363			490			-	0	-	48			398			-			48		

- (a) Alive animals at 11 weeks, when the first mammary tumour was observed.
(b) Alive animals at 62 weeks, when the first Zymbal gland carcinoma was observed.
(c) Alive animals at 16 weeks, when the first leukaemia was observed.
(d) Alive animals at 119 weeks, when the liver angiosarcoma was observed.
(e) Alive animals at 51 weeks, when the extrahepatic angiosarcoma was observed.
(f) Alive animals at 119 weeks, when the extrahepatic angioma was observed.

SI 100364

SL 100365

II/III TABLE 6

Experiment BT403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF THE DIFFERENT TYPES OF TUMOURS REFERRED TO SPECIFIC CORRECTED NUMBERS

(second part)

GROUP NO.	DOSE	ANIMALS WITH TUMOURS														
		Hepatoma			Forestomach epithelial tumours			Skin carcinomas			Subcutaneous sarcomas			Neuroblastomas		
		Corrected number (g)	No.	%	Corrected number (h)	No.	%	Corrected number	No.	%	Corrected number (i)	No.	%	Corrected number	No.	%
I	20 mg/Kg	3	0	-	27	0	-	-	0	-	32	1	3.1	-	0	-
		2	0	-	31	2	6.4	-	0	-	34	0	-	-	0	-
		5	0	-	58	2	3.4	-	0	-	66	1	1.5	-	0	-
II	10 mg/Kg	6	0	-	33	0	-	-	0	-	38	2	5.3	-	0	-
		6	1	16.7	33	1	3.0	-	0	-	41	0	-	-	0	-
		12	1	8.3	66	1	1.5	-	0	-	79	2	2.5	-	0	-
III	5 mg/Kg	2	0	-	27	0	-	-	0	-	40	0	-	-	0	-
		4	0	-	44	0	-	-	0	-	46	2	4.2	-	0	-
		6	0	-	71	0	-	-	0	-	88	2	2.3	-	0	-
IV	Olive oil (Control)	17	0	-	67	1	1.5	-	0	-	83	2	2.4	-	0	-
		7	1	14.3	77	4	5.2	-	0	-	89	0	-	-	0	-
		24	1	4.2	144	5	3.5	-	0	-	172	2	1.2	-	0	-
Total		47			339			-			405			-		

(g) Alive animals at 120 weeks, when the first hepatoma was observed.

(h) Alive animals at 67 weeks, when the first forestomach epithelial tumour was observed.

(i) Alive animals at 52 weeks, when the first subcutaneous sarcoma was observed.

II/III TABLE 7

Experiment BT403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/ Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF THE DIFFERENT TYPES OF MISCELLANEOUS ("OTHERS")
TUMOURS

GROUP NO.	SEX	ANIMALS BEARING OTHER TUMOURS				Total
		Benign		Malignant		
		No.	Distribution of histotypes	No.	Distribution of histotypes	
I	♂	6	1 skin acanthoma 1 dermatofibroma 1 islet cell adenoma 1 adrenal gland cortical adenoma 2 pheochromocytomas	1	1 intestinal adenocarcinoma	7
	♀	1	1 pheochromocytoma	2	1 malignant granulosa cell tumour 1 adenocarcinoma of the uterus	3
II	♂	3	3 dermatofibromas 1 subcutaneous fibroma 1 pheochromocytoma	3	1 dermal fibrosarcoma 1 lung pericytoma 1 pleural mesothelioma	6
	♀	3	3 adrenal gland cortical adenomas	3	1 adenocarcinoma of the uterus 1 fibrosarcoma of the uterus 1 pericytoma	6
III	♂	2	2 dermatofibromas	2	1 pericytoma of the thymus 1 peritoneal mesothelioma	4
	♀	2	1 cholangioma 1 adrenal gland cortical adenoma	2	1 adrenal gland cortical adenocarcinoma 1 adenocarcinoma of the uterus	4
IV	♂	10	1 skin sebaceous adenoma 2 dermatofibromas 1 subcutaneous lipoma 1 mammary lipoma 1 islet cell adenoma 3 pheochromocytomas 1 Leydig cell tumour	1	1 carcinoma in thymus	11
	♀	8	1 subcutaneous lipoma 1 Zymbal gland acanthoma 1 pulmonary adenoma 2 adrenal gland cortical adenomas 2 pheochromocytomas 1 leiomyoma of the uterus	5	1 adrenal gland cortical adenocarcinoma 1 sympathetic pheochromoblastoma 1 malignant granulosa cell tumour 2 adenocarcinomas of the uterus	13

SL 100366

II/III TABLE 8

Experiment BT 103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF THE DIFFERENT TYPES OF MAMMARY TUMOURS

GROUP NO.	DOSE	ANIMALS "prague-Dawley rats, 9 weeks old at start")			MAMMARY TUMOURS (b)																	
					Histologically examined																	
		Sex	No. at start	Corrected number (a)	Total No.	%	(c)	Average latency time (weeks) (d)	No. of tumours/ tumour bearing animals	Total No.	%	(c)	Histotype									
													Fibromas and fibroadenomas			Carcinomas			Sarcomas			Carcinosarcomas
No.	% (f)	Average latency time (weeks) (d)	No.	% (f)	Average latency time (weeks) (d)	No.	% (f)	Average latency time (weeks) (d)	No.	% (f)	Average latency time (weeks) (d)	No.	% (f)	Average latency time (weeks) (d)								
I	20 mg/Kg	♂	50	49	2	4.1	92.0	1.0	2	100.0	2	100.0	92.0	0	-	-	0	-	-	0	-	-
		♀	50	48	23	47.9	71.9	1.3	22	55.6	17	77.3	75.6	7	31.8	72.4	0	-	-	0	-	-
		♂ and ♀	100	97	25	25.8	73.5	1.3	24	96.0	19	79.2	77.3	7	29.2	72.4	0	-	-	0	-	-
II	10 mg/Kg	♂	50	46	2	4.2	114.0	1.0	2	100.0	2	100.0	114.0	0	-	-	0	-	-	0	-	-
		♀	50	50	24	48.0	86.2	1.4	24	100.0	20	83.3	93.1	7	29.2	73.3	0	-	-	0	-	-
		♂ and ♀	100	96	26	26.5	88.3	1.3	26	100.0	22	84.6	95.0	7	26.9	73.3	0	-	-	0	-	-
III	5 mg/Kg	♂	50	49	3	6.1	90.0	1.0	3	100.0	2	66.7	103.0	1	33.3	64.0	0	-	-	0	-	-
		♀	50	50	28	56.0	89.9	1.5	28	100.0	26	92.8	88.9	3	10.7	107.0	1	3.6	137.0	0	-	-
		♂ and ♀	100	99	31	31.3	89.9	1.5	31	100.0	28	90.3	89.9	4	12.9	96.2	1	3.2	137.0	0	-	-
IV	Olive oil (Control)	♂	100	100	10	10.0	114.6	1.1	10	100.0	10	100.0	115.6	1	10.0	131.0	0	-	-	0	-	-
		♀	100	99	57	57.6	83.8	1.3	57	100.0	42	73.7	55.7	16	28.1	83.8	1	1.7	103.0	1	1.7	99.0
		♂ and ♀	200	199	67	33.7	88.4	1.3	67	100.0	52	77.6	81.4	17	25.4	86.6	1	1.5	103.0	1	1.5	99.0
Total			500	493																		

- (a) Alive animals at 11 weeks, when the first tumour (a mammary adenocarcinoma) was observed.
 (b) Two or more tumours of the same and/or different types (fibroadenomas, carcinomas, sarcomas, carcinosarcomas) may be present in the same animal.
 (c) The percentages are related to the corrected number.
 (d) Average age at the onset of the first mammary tumour per animal detected at the periodic examination or at autopsy.
 (e) The percentages are related to total number of animals bearing mammary tumours.
 (f) The percentages are related to total number of animals bearing mammary tumours, histologically examined.

III/ TABLE 9

Experiment BT 403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF MALIGNANT MAMMARY TUMOURS (CARCINOMAS, SARCOMAS AND CARCINOSARCOMAS) REFERRED TO SPECIFIC CORRECTED NUMBER

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		MALIGNANT MAMMARY TUMOURS				
		Sex	No. at start	Corrected number (a)	No.	% (b)	Average latency time (weeks)	No. of tumours/tumour bearing animals
I	20 mg/Kg	♂	50	49	0	-	-	-
		♀	50	48	7	14.6	72.4	1.1
		♂ and ♀	100	97	7	7.2	72.4	1.1
II	10 mg/Kg	♂	50	48	0	-	-	-
		♀	50	50	7	14.0	73.3	1.0
		♂ and ♀	100	98	7	7.1	73.3	1.0
III	5 mg/Kg	♂	50	49	1	2.0	64.0	1.0
		♀	50	50	4	8.0	114.5	1.0
		♂ and ♀	100	99	5	5.0	104.5	1.0
IV	Olive oil (Control)	♂	100	100	1	1.0	131.0	1.0
		♀	100	99	18	18.2	83.5	1.0
		♂ and ♀	200	199	19	9.5	86.0	1.0
Total			500	493				

(a) Alive animals at 14 weeks, when the first malignant mammary tumour was observed.
(b) The percentages are referred to the corrected number.

SL 100368

IL-III TABLE 10

Experiment BT403: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

LOCALIZATION OF EXTRAHEPATIC ANGIOSARCOMAS ACCORDING TO SITE

GROUP NO.	SEX	NO.	EXTRAHEPATIC ANGIOSARCOMAS
I	♂	0	-
	♀	0	-
II	♂	0	-
	♀	0	-
III	♂	0	-
	♀	0	-
IV	♂	1	1 kidney angiosarcoma
	♀	0	-

SL 100369

II III TABLE II

Experiment BT403: *Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg Kg b.w., once daily, 4-5 days weekly, for 52 weeks. Results after 147 weeks (end of the experiment).*

LOCALIZATION OF EXTRAHEPATIC ANGIOMAS AND FIBROANGIOMAS
ACCORDING TO SITE

GROUP NO.	SEX	NO.	EXTRAHEPATIC ANGIOMAS AND FIBROANGIOMAS
I	♂	0	-
	♀	0	-
II	♂	1	1 soft tissue fibroangioma
	♀	0	-
III	♂	0	-
	♀	0	-
IV	♂	0	-
	♀	0	-

SL 100370

II III TABLE 12

Experiment BT103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF HYPERPLASIA (++, +++) AND DYSPLASIA (++/, +++/) OF ANGIOBLASTIC CELLS LINING HEPATIC SINUSOIDS

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		PROLIFERATION OF HEPATIC CELLS					
		Sex	No. at start	Diffused hyperplasia		Nodular hyperplasia		Neoplastic nodule	
				No.	%	No.	%	No.	%
I	20 mg/Kg	♂	50	1	2.0	0	-	0	-
		♀	50	8	16.0	2	4.0	2	4.0
		♂ and ♀	100	9	9.0	2	2.0	2	2.0
II	10 mg/Kg	♂	50	0	-	2	4.0	0	-
		♀	50	9	18.0	4	8.0	0	-
		♂ and ♀	100	9	9.0	6	6.0	0	-
III	5 mg/Kg	♂	50	3	6.0	1	2.0	0	-
		♀	50	9	18.0	2	4.0	0	-
		♂ and ♀	100	12	12.0	3	3.0	0	-
IV	Olive oil (Control)	♂	100	5	5.0	2	2.0	0	-
		♀	100	10	10.0	0	-	0	-
		♂ and ♀	200	15	7.5	2	1.0	0	-
Total			500						

SL 100371

II III TABLE 13

Experiment BT103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF DIFFUSED HYPERPLASIA, NODULAR HYPERPLASIA AND NEOPLASTIC NODULES OF LIVER PARENCHYMA

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 5 weeks old at start)		PROLIFERATION OF ANGIOBLASTIC CELLS OF HEPATIC SINUSOIDS					
		Sex	No. at start	→		→→		→→→	
				No.	%	No.	%	No.	%
I	20 mg/Kg	♂	50	0	-	0	-	0	-
		♀	50	1	2.0	0	-	0	-
		♂ and ♀	100	1	1.0	0	-	0	-
II	10 mg/Kg	♂	50	0	-	0	-	0	-
		♀	50	3	6.0	0	-	0	-
		♂ and ♀	100	3	3.0	0	-	0	-
III	5 mg/Kg	♂	50	0	-	0	-	0	-
		♀	50	0	-	0	-	0	-
		♂ and ♀	100	0	-	0	-	0	-
IV	Olive oil (Control)	♂	100	1	1.0	0	-	0	-
		♀	100	0	-	0	-	0	-
		♂ and ♀	200	1	0.5	0	-	0	-
Total			500						

SL 100372

II III TABLE 14

Experiment BT 103. *Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg Kg b.w., once daily, 4-5 days weekly, for 52 weeks.*
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF FORESTOMACH EPITHELIAL TUMOURS ACCORDING TO HISTOTYPE

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)			FORESTOMACH EPITHELIAL TUMOURS	
		Sex	No. at (Corrected start number/a)		Papillomas and scanthomas	Carcinomas
I	20 mg/Kg	♂	50	49	0	0
		♀	50	48	2	0
		♂ and ♀	100	97	2	0
II	10 mg/Kg	♂	50	48	0	0
		♀	50	50	1	0
		♂ and ♀	100	98	1	0
III	5 mg/Kg	♂	50	49	0	0
		♀	50	50	0	0
		♂ and ♀	100	99	0	0
IV	Olive oil (Control)	♂	100	100	1	0
		♀	100	99	3	1
		♂ and ♀	200	199	4	1
Total			500	493		

(a) Alive animals at 14 weeks, when the first tumour (a mammary adenocarcinoma) was observed.

SL 100373

II III TABLE 16

Experiment B F 103: Exposure by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

DISTRIBUTION OF ENCEPHALIC TUMOURS (OTHER THAN NEUROBLASTOMAS)
ACCORDING TO HISTOTYPE

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)			ENCEPHALIC TUMOURS		
		Sex	No. at start	Corrected number (a)	Ependymomas	Meningiomas	Oligodendro- gliomas
					No.	No.	No.
I	20 mg/kg	♂	50	49	0	0	0
		♀	50	48	0	0	0
		♂ and ♀	100	97	0	0	0
II	10 mg/kg	♂	50	48	0	0	1
		♀	50	50	0	0	0
		♂ and ♀	100	98	0	0	1
III	5 mg/kg	♂	50	49	1	1	0
		♀	50	50	0	1	0
		♂ and ♀	100	99	1	2	0
IV	Olive oil (Control)	♂	100	100	0	1	1
		♀	100	99	0	3	0
		♂ and ♀	200	199	0	4	1
Total			500	493			

(a) Alive animals at 14 weeks, when the first tumour (a mammary adenocarcinoma) was observed.

SL 100374

II III TABLE 17

Experiment B F 103. *Exposure* by ingestion (stomach tube) to Vinylidene Chloride in olive oil, at 20, 10, 5 mg/Kg b.w., once daily, 4-5 days weekly, for 52 weeks.
Results after 147 weeks (end of the experiment).

INCIDENCE OF TOTAL MALIGNANT TUMOURS

GROUP NO.	DOSE	ANIMALS (Sprague-Dawley rats, 9 weeks old at start)		TOTAL MALIGNANT TUMOURS	
		Sex	No. at start	No.	% (n)
I	20 mg/Kg	♂	50	4	8.0
		♀	50	9	18.0
		♂ and ♀	100	13	13.0
II	10 mg/Kg	♂	50	9	18.0
		♀	50	13	26.0
		♂ and ♀	100	22	22.0
III	5 mg/Kg	♂	50	8	16.0
		♀	50	10	20.0
		♂ and ♀	100	18	18.0
IV	Olive oil (Control)	♂	100	18	18.0
		♀	100	31	31.0
		♂ and ♀	200	49	24.5
Total			500		

(a) The percentages are referred to the number at start.

SL 100375