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CYFLUTHRIN **Chronic toxicity/carcinogenicity study in rats (83-5, 870.4300)**

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DATA EVALUATION RECORD
Supplement to DER for MRID No. 00137303 Cyfluthrin: Toxicity/Carcinogenicity Rat Study; **This supplement includes a revised executive summary which includes changing NOELs and LOELs to NOAELs and LOAEL.**

STUDY TYPE: Combined Chronic Toxicity/Carcinogenicity Study in Rats
OPPTS Number: 870.4300 OPP Guideline Number: 83-5

DP BARCODE: N/A SUBMISSION CODE: N/A
P.C. CODE: 128831 Tox. chem. No.: 266E

TEST MATERIAL (PURITY): Cyfluthrin (49.7-51.0%); FCR 1272

SYNONYMS: Cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate

CITATION: Suberg, H. and Loeser, E. FCR1272 (Cyfluthrin the active ingredient of Baythroid) chronic toxicity study in rats. (Unpublished report No. 11949 prepared by Bayer AG Institut Fuer Toxikologie for Mobay Chemical Corp., Agr. Chem. Div., Kansas City, MO., dated July 19, 1983.)

SPONSOR: Mobay Chemical Corporation, Agricultural Chemical Division

EXECUTIVE SUMMARY:

In a chronic/carcinogenicity study (MRID No. 00137303), cyfluthrin (49.7-51.0% purity as a premix concentrate in Wessalon S) was administered for 24 months in the diet to Wistar SPF rats (65/sex/dose) at dose levels of 0, 50, 150 or 450 ppm (equivalent to 0, 2.02, 6.19 or 19.20 mg/kg/day in males and 0, 2.71, 8.15 or 25.47 mg/kg/day in females based on food consumption and body weights).

There were no treatment-related deaths and no treatment-related changes noted in the clinical observations, food consumption, hematology, urinalysis, and the gross or microscopic data. No ophthalmologic examinations were performed.

The mean body weights of the high-dose males and females were lower (↓5-10%; $p<0.01$) than the controls throughout the study. The mean body weights of the mid-dose males were also lower than the controls during the first year of the study (↓4-5% ($p<0.05$), with a body weight gain 6% less than controls), but the animals recovered thereafter. Significant ($p<0.05$) increases were observed in the incidences of inflammatory foci of the kidneys in the mid-dose females (7/50 treated versus 1/50 controls) and the high-dose females (7/49 treated) and in hyperplastic nodules of the adrenals in the high-dose animals (males: treated = 20/50, control = 10/48; females: treated = 18/49, control = 4/50; $p<0.05$). Medullary hyperplasia was also observed in high-dose males (14/50 treated vs 4/48 controls). In addition, compared to concurrent controls, the following were observed: (i) increased (↑75%; $p<0.01$) liver N-demethylase activity in the high-dose females after 7 days of dosing; and (ii) increased fluoride levels in the bones of the mid- and high-dose males (11-21%; $p<0.05$) and the high-dose females (19%; $p<0.01$), as well as in the teeth of the high-dose males (20%; $p<0.01$).

The chronic LOAEL is 450 ppm (equivalent to 19.20 mg/kg/day in males and 25.47 mg/kg/day in females) based on decreased body weights (up to 10%) in both sexes. The chronic NOAEL is 150 ppm (equivalent to 6.19 mg/kg/day in males and 8.15 mg/kg/day in females).

Under the conditions of this study, there was no evidence of carcinogenic potential.

This chronic/carcinogenicity toxicity study in rats is classified **acceptable/guideline** for both chronic toxicity and carcinogenicity.

EPA: 68-01-6561
TASK: 90
January 24, 1985

DATA EVALUATION RECORD

CYFLUTHRIN

Chronic Toxicity

CITATION: Suberg, H. and Loeser, E. FCR1272 (Cyfluthrin the active ingredient of Baythroid) chronic toxicity study in rats. (Unpublished report No. 11949 prepared by Bayer AG Institut Fuer Toxikologie for Mobay Chemical Corp., Agr. Chem. Div., Kansas City, MO., dated July 19, 1983.)

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DATA EVALUATION RECORD

STUDY TYPE: Chronic toxicity.

CITATION: Suberg, H. and Loeser, E. FCR1272 (Cyfluthrin the active ingredient of Baythroid) chronic toxicity study in rats. (Unpublished report No. 11949 prepared by Bayer AG Institut Fuer Toxikologie for Mobay Chemical Corp., Agr. Chem. Div., Kansas City, MO., dated July 19, 1983.)

ACCESSION NUMBER: 072365.

LABORATORY: Bayer AG Institut Fuer Toxikologie, Wuppertal, Federal Republic of Germany.

QUALITY ASSURANCE STATEMENT: Not present for this report.

TEST MATERIAL: The test material was identified as FCR1272, the active ingredient of Baythroid, an insecticide. It was a composite sample of batches received prior to the study and was available as a premix concentrate in Wessalon S, with 49.7 to 51.0% active ingredient. The purity of the technical material was not reported.

PROTOCOL:

1. Male and female Wistar SPF rats were obtained from Winkelmann, Borchen, Federal Republic of Germany. The rats were individually housed in Type II Makrolon cages in rooms maintained at 21-23° C and 50-60% humidity with 12 hour light/dark cycle. The rats were 5-6 weeks of age at the start of the study. Tapwater was available ad libitum.

   It was not reported whether the animals were acclimated to laboratory conditions prior to treatment. Animals were weighed prior to dosing and assigned to 4 groups with initial mean body weights of 80 g for males and 81 g for females.

2. The premix concentrate in Wessalon S, formulation 113, was mixed with pulverized feed to obtain the required concentrations of the active ingredient. The frequency of diet preparation throughout the study was not reported. The control group was fed the basal diet. The concentration, homogeneity, and stability of the diet was determined by gas chromotography at various intervals during the study.

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3. Groups of 65 males and 65 females were fed diets containing 0, 50, 150, and 450 ppm of test material. Dose selection was based on a subchronic feeding study.

4. Animals were observed for clinical signs twice daily and once a day on weekends and holidays.

Individual body weights and group food consumption were determined weekly the first 26 weeks, bi-weekly during week 27 through 74, and then weekly until termination. Food consumption was determined by weighing the unconsumed feed and substracting this value from the amount of food offered.

On day seven of the study 5 rats/sex/group were sacrificed and the activities of N-demethylase and O-demethylase as well as the concentration of cytochrome P_{450} in the liver were determined.

Hematology, clinical chemistry, and urinalysis were performed on 10 rats/sex/group at 6, 12, 18, and 24 months of study. Serum protein electrophoresis was performed at 12 months of study. Blood samples were collected with a Pasteur pipette via the retroorbital venous plexus after ether anesthesia. Blood glucose determinations were performed on blood samples obtained from the tail vein without anesthesia. Blood for thromboplastin time was obtained by cardiac puncture. Urine samples were collected during 16 hr fasting periods.

The following is a list of parameters analyzed: Hematology - erythrocyte count, hemoglobin, hematocrit, red cell indices (MCV, MCH, MCHC), total and differential leukocyte count and thrombocyte count. Clinical chemistry - alkaline phosphatase, SGOT, SGPT, creatinine, urea, glucose, cholesterol bilirubin, total protein, sodium, potassium, and calcium. Urinalyses - glucose, blood, protein, ketone, bilirubin, urobilinogen, pH, specific gravity and total volume.

The fluoride content in bones and teeth of 5 males and 5 females from each group was determined at the 12-month interim and final sacrifices.

Gross examination was performed on rats that died or were sacrificed moribund during the study, interim sacrifice animals, and on all survivors at termination. Rats were anesthetized with ether and sacrificed by exsanguination. At 12 months and termination, 5 rats/sex/group were perfused with 10% buffered formaldehyde, and then examined grossly.

The following organs from each animal were weighed at the interim and terminal sacrifices: heart, testes, lung, liver, spleen, kidneys, adrenals and ovaries. The organs from perfused rats were not weighed.

004285

The following tissues from all animals that died or were sacrificed moribund and all animals sacrificed at weeks 52 and 104, were fixed in 10% formaldehyde:

Aorta	Liver	Thymus (if present)
Eyes	Lung	Uterus
Intestine	Lymph nodes	Gross Lesions
(duodenum, jejunum	Stomach	
ileum, colon and in some	Spleen	
cases cecum and rectum)	Adrenals	
Femur enbloc with	Kidneys	
skeletal musculature	Ovaries	
and* sciatic nerve	Pancreas	
Brain	Prostate	
Urinary bladder	Spinal cord	
Heart	Seminal vesicles	
Testes	Sternum	
Pituitary	Thyroids, esophagus,	
Salivary glands	and trachea enbloc	

Microscopic examination was performed on all the above tissues for each animal on the study.

5. Statistical Methods: The arithmetic mean and standard deviation (STD) for tabular data were calculated and the STD assessed at the 95 and 99% upper and lower confidence limits. The data for dosed groups were compared to the control groups with the significance test (U test) of Mann, Whitney and Wilcoxon at the 5 and 1% significance level. Fisher's exact test was used to compare the mortality of the dosed groups to the controls. An IBM subroutine package was used to generate randomization lists.

RESULTS:

Diet Analysis: There were no data presented or diet analyses for content, homogeneity, and stability of test material.

Clinical Signs: It was stated in the report that there were no differences noted among dosed and control animals in appearance, behavior, activity or condition of coat during the study. However, individual or group data were not presented. Ophthalmologic examinations were apparently not performed.

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* For perfused rats the sciatic nerve was isolated and fixed.

Mortalities: There were no differences in survival among dosed and control animals throughout the two-year study (Table 1).

TABLE 1. Percent Survival of Rats Fed Diets Containing Cyfluthrin for Two Years

Group/Dose (ppm)	Month:	Percent Survival 18	24
Males			
Control		98(49/50)[a]	88(44/50)
50		98(49/50)	88(44/50)
150		100(50/50)	96(48/50)
450		96(48/50)	82(41/50)
Females			
Control		96(48/50)	86(43/50)
50		98(49/50)	90(45/50)
150		100(50/50)	90(45/50)
450		94(47/50)	82(41/50)

[a] Number of animals alive/number of animals in each group.

Body Weights: The mean body weights of males and females receiving the high-dose were significantly lower than control values throughout the study (Table 2). The mean body weights of males receiving the mid-dose was also significantly lower than the control group during the first year of the study, but the animals recovered thereafter. There were no effects on the body weights of animals receiving the low-dose.

Food Consumption: Food consumption was similar throughout the study among compound-treated and control groups (Table 3 and CBI Report Appendix, pp. 63-70). Based on mean food consumption and body weight data, it was reported that the average intake of test compound throughout the study was 2.02, 6.19, and 19.20 mg/kg/day in males and was 2.71, 8.15, and 25.47 mg/kg/day in females for the low-, mid-, and high-dose groups, respectively.

Hematology: There were a few isolated changes in certain hematologic parameters in compound-treated animals as compared to control values, at months 6, 12, 18, or 24 of the study, but none were dose- and/or time-related (CBI Report Tables 3-6). At the end of the study there was a significant decrease in leukocyte count in all dosed male groups.

004285

TABLE 2. Mean Body Weights of Rats Fed Diets Containing Cyfluthrin for Two Years

Group/Dose (ppm)	Week:	Body Weight (g) 0	13	26	51	78	104
Males							
Control		81	320	370	407	420	422
50		81	313	365	405	412	409
150		80	304**	356*	392*	407	407
450		80	295**	346**	378**	391**	382**
Females							
Control		81	199	221	239	261	266
50		81	197	219	238	259	267
150		81	195*	217	234	249*	257
450		81	189**	210**	221**	233**	239**

* Significanly different from control value $p < 0.05$.
** Significanly different from control value $p < 0.01$.

TABLE 3. Mean Food Consumption Data for Rats Fed Diets Containing Cyfluthrin for Two Years

Group/Dose (ppm)	Mean Food Intake (g/rat/day) at Week									
	1	7	13	20	26	39	51	65	78	104
Males										
Control	12.58	18.30	18.30	17.5	17.2	17.55	16.88	16.32	15.65	16.18
50	12.17	17.91	18.24	17.41	16.52	17.60	16.20	16.31	15.41	11.68
150	11.99	16.42	17.62	16.98	16.41	16.26	16.18	15.97	15.56	14.94
450	9.99	17.46	17.69	17.43	16.15	16.57	16.32	16.06	15.21	10.73
Females										
Control	11.23	13.06	13.44	14.81	13.79	13.47	12.41	13.29	13.34	14.78
50	10.39	12.53	13.85	13.11	12.69	13.26	13.18	13.17	12.77	13.61
150	11.09	12.36	13.36	13.06	12.23	13.59	12.16	13.21	12.42	13.25
450	10.60	12.04	13.43	12.70	12.15	12.57	11.47	13.04	12.65	13.87

Blood Chemistry: There were a few isolated changes in certain parameters in dosed animals as compared to control values, at months 6, 12, 18, or 24 of the study, but none were dose and/or time-related (CBI Report Tables 7-15). At the end of the study there was a significant decrease in plasma protein and cholesterol in females receiving the high-dose and in SGPT activity and calcium in males receiving the high-dose. At 12 months, the relative amounts of protein fractions in the serum were determined by electrophoresis. The results indicated a dose-related increased in alpha-1-globulins; there were no other differences noted between control and compound-treated animals.

Urinalysis: There were no dosed-related differences in urinalysis parameters between treated and control animals at months 6, 12, 18, or 24 of the study (CBI Report Appendix pp. 313-328).

Liver Enzyme Activities and Cytochrome P_{450} Content: The hepatic N- and O-demethylase activities and cytochrome P_{450} content in rats were determined one week after study initiation. There were no differences noted in N- or O-demethylase activities or cytochrome P_{450} levels in treated animals when compared to control values, except for a significant increase in N-demethylase activity in females receiving the high-dose (Table 4).

TABLE 4. Hepatic N-Demethylase Activity in Rats Fed Diets Containing Cyfluthrin for Two-Years

Group Dose (ppm)	N-Demethylase Activity (nmol/g/min)	
	Male	Female
Control	107.8	59.3
50	107.7	69.1
150	108.7	71.3
450	135.4	103.8**

** Significantly different from control at $p < 0.01$.

Fluoride Content in Teeth and Bones: The fluoride content in teeth and bones of treated animals was similar to those of control values at month 12 of the study (CBI Report Table 17). Increased fluoride levels were noted in the teeth and bones of males receiving the high-dose, and in the bones of males receiving the mid-dose and females receiving the high-dose (Table 5).

Gross Examinations: Summary data for gross-findings were not presented. It was stated that "gross examination revealed no changes in any of the rats that could be attributed to treatment." (CBI report p 496 - 1177).

TABLE 5. Fluoride Content in Teeth and Bones of Rats Fed Diets Containing Cyfluthrin for Two Years

Group/Dose (ppm)	Fluoride Content (mg/g ash)	
	Teeth	Bones
Males		
Control	0.097	0.464
50	0.125	0.503
150	0.113	0.514*
450	0.116**	0.560*
Females		
Control	0.144	0.654
50	0.144	0.665
150	0.140	0.698
450	0.164	0.779**

* Significantly different from control at $p < 0.05$
** Significantly different from control at $p < 0.05$

Organ Weights: At interim sacrifice, the mean liver weight (5 rats/sex/group) of males and females receiving the high-dose were significantly lower than control values. The liver to body weight ratios of treated male rats were similar to those of control, but the liver to body weight ratios of treated females were significantly lower than control values (Table 6). There were no other changes noted.

TABLE 6. Mean Organ Weight Data of Rats Fed Cyfluthrin for Two-Years

Group/Dose (ppm)	Body Weight (g)	Liver (g)	Liver:BW %	Kidney (g)	Kidney:BW %
		12 Month Sacrifice			
Males					
Control	435	15.61	3.58	2.37	0.543
50	418	14.83	3.55	2.43	0.582
150	385**	13.25	3.43	2.23	0.580
450	371**	12.90**	3.48	2.32	0.627
Females					
Control	234	8.36	3.57	1.54	0.658
50	235	7.31	3.10*	1.58	0.671
150	247	7.51	3.04**	1.58	0.643
450	208*	6.78**	3.26*	1.44	0.692
		24 Month Sacrifice			
Males					
Control	418	14.19	3.42	2.56	0.618
50	408	14.61	3.57*	2.66	0.655*
150	410	14.24	3.47	2.58	0.633
450	382**	12.98**	3.40	2.47	0.650**
Females					
Control	265	9.33	3.53	1.78	0.673
50	266	9.16	3.46	1.79	0.679
150	252*	8.51**	3.40	1.70*	0.679
450	237**	8.33**	3.53	1.65**	0.701

* Significantly different from control value $p < 0.05$.
** Significantly different from control value $p < 0.01$.

At final sacrifice, the mean liver weight of male rats receiving the high-dose was significantly lower than the control value (Table 6). Similarly, the mean liver and kidney weights in females receiving the mid- and high-dose were significantly lower than control values. However,

liver- and kidney-to-body weight ratios in both dosed males and dosed females were similar to control values. There was also an increase in lung- and adrenals-to-body weight ratios in females receiving the high-dose as compared to controls.

Histopathology: At the 12 month sacrifice, pituitary gland adenomas were found in one male receiving the low-dose, one male receiving the high-dose, and in two females receiving the mid-dose. Several non-neoplastic lesions were also observed in the interim sacrifice animals, but the incidences were similar among control and dosed rats. The neoplasms observed most frequently in animals that died or were sacrificed at study termination are summarized in Table 7.

The incidences of all neoplastic lesions observed in dosed animals were comparable to those observed in the control animals. Non-neoplastic lesions observed most frequently are summarized in (Table 8). There were increased incidences of the following histopathologic lesions in dosed animals when compared to controls: inflammatory foci of the kidneys of females receiving the mid- and high-doses; cortical hyperplastic nodules in the adrenals of males receiving the low- and high-doses and females receiving the high-dose; and medullary hyperplasia in the adrenals of males receiving the high-dose. The incidences of other histologic lesions were similar among control and dosed animals.

DISCUSSION:

The authors stated that the only compound-related effects observed in dosed rats were decreased body weights in males receiving the mid- and high-doses and females receiving the high-dose. They concluded that the NOEL was 50 ppm of test material in the diet.

Our evaluation of the data is in agreement with the authors statements, although we identified some additional compound-related histopathologic lesions. These effects include increased incidences of inflammatory foci of the kidneys of females receiving the mid- and high-dose; and cortical and/or medullary hyperplastic nodules in the adrenal gland of males and females receiving the high-dose. In addition, there was a significant increase in hepatic N-demethylase activity in females receiving the high-dose for 7 days, indicating enzyme induction by Cyfluthrin. Increased levels of fluoride in teeth and/or bones were also noted in males and females receiving the mid- and high-doses, but in the absence of metabolic studies the toxicological significance of these findings is unclear. We view effects on liver and kidney weights at the end of the study as being primarily due to decreased body weight, since the organ-to-body weight ratio were similar among control and treated animals. Finally, the incidences of neoplastic lesions in treated animals were similar to those observed in controls.

The following deficiencies were noted: individual clinical observations and eye examinations were not reported; no data were presented for diet analyses and stability.

TABLE 7. Summary of Neoplastic Lesions Most Frequently Observed in Rats Fed Cyfluthrin for Two Years

Lesion	Group:	Males				Females			
		0	50	150	450	0	50	150	450
Liver	N[a]	49	50	49	50	50	50	50	49
carcinoma		0	0	0	1	0	0	0	0
Kidneys	N	49	49	49	50	50	50	50	49
adenoma		0	0	1	0	0	0	0	0
Testes	N	49	49	49	50				
leydig cell tumor		3	5	5	3				
Uterus	N					50	50	50	49
polyp						14	7	20	17
adenocarcinoma						5	4	4	3
Pituitary gland	N	47	49	47	47	49	50	48	48
adenoma		10	11	19	6	14	23	10	12
Thyroid gland	N	49	48	47	48	49	48	49	47
adenoma		4	2	2	1	2	1	1	0
Adrenal glands	N	48	48	49	50	50	49	50	49
pheochromocytoma		4	3	5	6	0	2	1	1
Mammary glands	N					5	5	5	5
fibrosarcoma						5	3	3	3
Skin	N	1	2	0	5	4	10	4	4
fibrosarcoma		0	0	0	2	0	2	1	0

[a] The numbers of tissues examined microscopically.

TABLE 8. Summary of Non-Neoplastic Lesions Most Frequently Observed in Rats Fed Cyfluthrin for Two-Years[a]

Lesion	Group:	Males				Females			
		0	50	150	450	0	50	150	450
Heart	N	49	50	49	50	50	50	50	49
myocardial fibrosis		25	27	27	32	34	17	15	27
myocarditis		11	-	9	4	7	1	0	3
Trachea	N	49	50	47	50	49	49	50	48
chronic tracheitis		5	15	10	11	6	2	6	5
Lungs	N	49	50	49	50	50	50	50	49
macrophage		9	9	16	11	11	6	4	4
perivascular cuffing		18	22	16	9	8	13	10	9
Liver	N	49	50	49	50	50	50	50	49
inflammation		24	21	17	14	16	13	11	6
bile duct proliferation		31	34	32	29	14	8	8	13
clear cell foci		33	34	32	29	10	3	1	3
Kidneys	N	49	49	49	50	50	50	50	49
inflammatory foci		3	4	9	1	1	1	7*	7*
chronic nephropathy		38	43	45	38	29	35	34	17
Urinary bladder	N	48	48	49	50	50	49	48	49
cystitis		14	17	14	12	6	6	17	8
urothel. hyperplasia		2	1	2	2	0	2	2	4
Testes	N	49	49	49	50				
tubular atrophy		15	16	15	19				
leydig cell hyperplasia		8	11	12	7				
Prostate	N	49	49	49	50				
inflammation		4	3	2	2				
Ovaries	N					50	50	49	49
cyst						21	24	21	26
stromal hyperplasia						3	6	9	9
Uterus	N					50	50	50	49
cystic hyperplasia						10	9	10	5
Thyroid gland	N	49	48	47	48	49	48	49	47
follicular cyst		23	36	42	38	37	27	29	44
nodular hyperplasia		8	13	19	10	11	14	3	9
Adrenal glands	N	48	48	49	50	50	49	50	49
altered cell foci		23	23	23	17	10	24	30	14
cort. hyperpl. nodule		10	21*	14	20*	4	9	11	18*
medull. hyperplasia		4	8	8	14*	5	4	1	4
Spleen	N	49	48	49	50	50	50	50	49
hemopoiesis		28	14	15	18	33	23	17	23
Lymph nodes	N	49	49	46	50	50	47	48	49
hyperplasia		13	18	10	15	13	8	15	12
Eyes	N	49	47	49	50	49	49	47	49
retinal atrophy		16	13	9	14	23	15	16	25

* Statistically different from control value at $p < 0.05$.

[a] Statistical analyses conducted by the reviewers, using the Fisher Exact test.

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CONCLUSIONS:

Under the conditions of this 2-year feeding study, Cyfluthrin was not oncogenic to male and female Wistar CRF rats. There was a compound-related effect on body weight of males receiving the mid- and high-doses and females receiving the high-dose. In addition, increased incidences of inflammatory foci of the kidneys of females receiving the mid- and high-doses and hyperplastic nodules of the adrenals of males and females receiving the high-dose were observed. There were no other effects noted except for increased levels of fluoride in teeth and/or bones of male and females receiving the mid- and high-doses and increased liver N-demethylase activity in females receiving the high-dose. Hence, the NOEL and LEL for chronic toxicity based on mean body weights of male rats were 50 and 150 ppm, respectively.

CORE CLASSIFICATION: Minimum for both chronic toxicity and oncogenicity.

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R058534

Chemical:	**Cyfluthrin**
PC Code:	**128831**
HED File Code	**13000 Tox Reviews**
Memo Date:	**02/16/2001 12:00:00 AM**
File ID:	**00000000**
Accession Number:	**412-04-0046**

HED Records Reference Center
03/25/2004