

Aquatic Effects Data

Fomesafen data were originally submitted in the 1980's. As technical fomesafen is only slightly soluble in water, some aquatic tests were conducted with the technical formulation. Some results were expressed in terms of active ingredient (ai), and some were not. The table below is from the spreadsheet used to convert study results for use in the risk assessment. Tables on the following page show the data as reported in the main body of the risk assessment

Fomesafen Aquatic Guideline Data

Rainbow Trout Acute LC50 (MRID103023)

Mean-measured formulation (mg/L)	Conversion to a.i. (X 22.8%)	Mortality (%)
8400	1915	100
6225	1419	100
3355	765	100
2650	604	100
1835	418	100
1470	335	100
1062	242	100
839	191	100
719	164	100
620	141	65
455	104	15
351	80	0
0	0	0

Daphnia Acute LC50 (MRID 103024)

Technical				Formulation			
Test 1		Test 2		Test 1		Test 2	
Mean-measured PP021 (mg/L)	Mortality (%)	Mean-measured PP021 (mg/L)	Mortality (%)	Mean-measured PP021 (mg/L)	Mortality (%)	Mean-measured PP021 (mg/L)	Mortality (%)
0.327	80	0.325	70	3.66	100	3.84	100
0.27	10	0.248	13	1.92	100	1.94	100
0.242	20	0.248	16	0.938	100	0.918	100
0.234	3	0.211	0	0.472	67	0.465	17
0.177	0	0.11	10	0.227	13	0.23	3
0.058	7	0.047	0	0.117	0	0.109	3
0	0	0	0	0.062	0	0.056	3
				0	0	0	0

Statistical Analysis of Aquatic Guideline Data

Data reviews for fomesafen studies were conducted prior to implementation of current format, which includes statistical analysis output. Submitted data were reanalyzed using TOXANAL. Output is shown below.

Rainbow Trout LC50 (MRID 103023)

Formulation Test, Data presented as ppm a.i.

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	4.538912E-02	122.8529	115.8801	130.5561

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.1107277	1	.4267987

SLOPE = 14.60391

95 PERCENT CONFIDENCE LIMITS = 9.744345 AND 19.46347

LC50 = 126.1463

95 PERCENT CONFIDENCE LIMITS = 116.9657 AND 134.5229

LC10 = 103.2551

95 PERCENT CONFIDENCE LIMITS = 89.33874 AND 112.2619

Observed NOAEC 80 ppm a.i.

Observed LOAEC 104 ppm a.i.

Daphnia Formulation (MRID 103024)

Converted to ppm a.i.

Test 1

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
6	2.396329E-02	377.6351	308.34	457.0631

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
9	9.542178E-02	1	.9692729

SLOPE = 5.607484

95 PERCENT CONFIDENCE LIMITS = 3.875308 AND 7.339659

LC50 = 375.9313

95 PERCENT CONFIDENCE LIMITS = 322.9891 AND 437.334

LC10 = 223.1645

95 PERCENT CONFIDENCE LIMITS = 167.035 AND 266.9592

Observed NOAEC 117 ppm a.i.

Observed LOAEC 227 ppm a.i.

Daphnia Test 2

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	4.173839	36.01717	0

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001
SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED
USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 3.668311

95 PERCENT CONFIDENCE LIMITS = -3.826039 AND 11.16266

LC50 = 514.0042

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 231.6107

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

Mysid Acute LC50 (MRID135647)

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.2345372	24.77577	19.11372	38.04456

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	1.863364	2.90676	3.325069E-02

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 2.350842
95 PERCENT CONFIDENCE LIMITS = -.8581767 AND 5.559861

LC50 = 27.19182
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 7.838018
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

Reported Aquatic Effects Data

Species	LC ₅₀ (ppm)	95% C.I. (ppm)	NOAEC (ppm)	Classification ¹ (MRID)
<i>Freshwater Organisms</i>				
Water flea ² (<i>Daphnia magna</i>)	376	323-437	117	Core (163169) Formulation
Rainbow Trout ² (<i>Onchorynchus mykiss</i>)	126	117-135	80	Core (103023) Formulation
<i>Estuarine/ Marine organisms</i>				
Mysid shrimp (<i>Mysidopsis bahia</i>)	25	19-38	ND	Core (135647) Technical
Sheepshead minnow (<i>Cyprinodon varigetus</i>)	>163	ND	>163	Core (135651) Formulation

¹Data are from studies originally reviewed and classified in 1984, some of which used formulated product. ²For purposes of this risk assessment, test concentrations were adjusted for percent a.i. if necessary, and endpoints were re-calculated using TOXANAL software.

Species	NOAEC (ppm)	LOAEC (ppm)	Endpoints Affected	Classification ¹ (MRID)
<i>Freshwater Organisms</i>				
Water flea (<i>Daphnia magna</i>)	50	100	Reduced growth, Total # of offspring	Core (135642) Formulation
<i>Estuarine/ Marine organisms</i>				
Mysid shrimp (<i>Mysidopsis bahia</i>)	0.7	1.7	Parental mortality	Core (135648) Formulation
Sheepshead minnow ² (<i>Cyprinodon varigetus</i>)	12.2	20.1	Reduced larval survival	Core (135644) Formulation

¹Data are from studies originally reviewed and classified in 1984, some of which used formulated product. ²For purposes of this risk assessment, test concentrations were adjusted for percent a.i.

Aquatic Risk Quotient Calculations

EFED does not currently use an automated program to calculate aquatic RQs. Shown below is the spreadsheet used in the calculation.

Aquatic RQ Calculations for Fomesafen (PDB 10/14/05)

FW Aquatic Invertebrates		(All units in ppm)						
Crop	Peak EEC	LC50	RQ	21-day EEC	NOAEC	RQ	RQ	
Soybean MS 0.375 ai/A	0.0075	376	1.99E-05	0.0071	50	1.42E-04	0.000	
Cotton MS 0.385ai/A	0.0121	376	3.22E-05	0.0114	50	2.28E-04	0.000	
Cotton MS 0.49 ai/A	0.0151	376	4.02E-05	0.0142	50	2.84E-04	0.000	

FW Fish		(All units in ppm)					
Crop	Peak EEC	LC50	RQ	60-day EEC	NOAEC	RQ	RQ
Soybean MS 0.375 ai/A	0.0075	126	5.95E-05	0.0064		#DIV/0!	#DIV/0!
Cotton MS 0.375ai/A	0.0121	126	9.60E-05	0.0101		#DIV/0!	#DIV/0!
Cotton MS 0.49 ai/A	0.0151	126	1.20E-04	0.0126		#DIV/0!	#DIV/0!

FW Alga		(All units in ppm)					
Crop	Peak EEC	LC50	Acute RQ	Peak EEC	NOAEC	ES RQ	ES RQ
Soybean MS 0.375 ai/A	0.0075	0.12	0.063	0.0075	0.023	3.26E-01	0.326
Cotton MS 0.375ai/A	0.0121	0.12	0.101	0.0121	0.023	5.26E-01	0.526
Cotton MS 0.49 ai/A	0.0151	0.12	0.126	0.0151	0.023	6.57E-01	0.657

SW Aquatic Invertebrates		(All units in ppm)					
Crop	Peak EEC	LC50	RQ	21-day EEC	NOAEC	RQ	RQ
Soybean MS 0.375 ai/A	0.0075	25	3.00E-04	0.0071	0.69	1.03E-02	0.010
Cotton MS 0.375ai/A	0.0121	25	4.84E-04	0.0114	0.69	1.65E-02	0.017
Cotton MS 0.49 ai/A	0.0151	25	6.04E-04	0.0142	0.69	2.06E-02	0.021

SW Fish		(All units in ppm)					
Crop	Peak EEC	LC50	RQ	60-day EEC	NOAEC	RQ	RQ
Soybean MS 0.375 ai/A	0.0075	163	4.60E-05	0.0064	12.2	5.25E-04	0.0005
Cotton MS 0.375ai/A	0.0121	163	7.42E-05	0.0101	12.2	8.28E-04	0.0008
Cotton MS 0.49 ai/A	0.0151	163	9.26E-05	0.0126	12.2	1.03E-03	0.0010

FW Diatom		(All units in ppm)					
Crop	Peak EEC	LC50	Acute RQ	Peak EEC	NOAEC	ES RQ	ES RQ
Soybean MS 0.375 ai/A	0.0075	1.51	0.005	0.0075	0.94	7.98E-03	0.008
Cotton MS 0.375ai/A	0.0121	1.51	0.008	0.0121	0.94	1.29E-02	0.013
Cotton MS 0.49 ai/A	0.0151	1.51	0.010	0.0151	0.94	1.61E-02	0.016

Statistical Analysis of Terrestrial Guideline Data

Data reviews for fomesafen studies were conducted prior to implementation of current format which includes statistical analysis output. Submitted data were reanalyzed using TOXANAL. Output is shown below.

Mallard Acute LD50 (MRID) 163168

Group	Dose (ppm)	# Birds	#Birds Died
Control	0	10	0
1	2500	10	1
2	5000	10	1

NO METHOD CAN CALCULATE ANY RESULTS IF THE PERCENT DEAD IS THE SAME AT ALL TESTED CONCENTRATIONS.

Mallard Dietary LC50 (MRID 163384)

Nominal Test concentrations (ppm) 1756, 2634, 3951, 5926, 8889, 13,333; 20,000
No mortalities occurred in test concentrations
LC50>20,000 ppm

Bobwhite Quail Dietary LC50 (MRID 103022)

Nominal Test concentrations (ppm) 1756, 2634, 3951, 5926, 8889, 13,333; 20,000
One mortality occurred in 20,000 ppm test concentrations
LC50>20,000 ppm

NOTE TO REVIEWER: THIS DATA SET DOES NOT MEET THE CRITERIA ESTABLISHED BY THE COMMITTEE ON METHODS FOR TOXICITY TESTS WITH AQUATIC ORGANISMS BECAUSE NO PERCENT DEAD IS GREATER THAN 65 PERCENT.

NEITHER THE BINOMIAL TEST NOR THE MOVING AVERAGE METHOD CAN GIVE ANY RESULTS FOR THIS DATA. EITHER THE HIGHEST CONCENTRATION KILLED LESS THAN 50 PERCENT OR THE LOWEST KILLED MORE THAN 50. IF THE PROBIT SLOPE IS NEGATIVE, ENTER DATA AGAIN USING NUMBER ALIVE INSTEAD OF NUMBER DEAD.

Female Guinea Pig LC50 Data (MRID 164900)

CONC.	NUMBER EXPOSED	NUMBER DEAD	NUMBER DEAD	PERCENT	BINOMIAL PROB.(PERCENT)
1950	5	5	100	100	3.125
975	5	1	20	20	3.125
487	5	0	0	0	18.75
244	5	0	0	0	3.125

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 607.0274

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

Reported Terrestrial Guideline Data

Shown below is terrestrial animal guideline data as reported in the main body of the risk assessment.

Acute Studies

Species	LC ₅₀ (ppm)	95% C.I. (ppm)	NOAEC (ppm)	Classification ¹ (MRID)
<i>Acute dose</i>				
Mallard duck	>5,000	ND	<2,500	Core (163168)
Rat	F 1499 M 1858	(1302-1749) (1420-2546)	1219 975	Minimum (164901)
Mouse	F 745 M 766	(512-1286) (525-1341)	487 312	Minimum (164901)
Guinea Pig	F 607	ND	244	Minimum (164901)
<i>Acute dietary</i>				
Bobwhite quail	>20,000	ND	13,333	Core (103022)
Mallard duck	>20,000	ND	20,000	Core (163384)

¹Data are from studies originally reviewed and classified in 1984.

ND-Not determined

Chronic Studies

Species	NOAEC (ppm)	LOAEC (ppm)	Endpoint Affected	Classification ¹ (MRID)
Bobwhite quail	51	ND	None	Core (135640)
Mallard duck	46	ND	None	Core (135639)
Rat	250	1000	Number of pups born live, number of pups surviving	Acceptable (144862)

¹Data are from studies originally reviewed and classified in 1984.

ND-Not determined

Adjustment of Mammalian Endpoints

TREX calculates mammalian risk quotients based on the weight of a standard laboratory rat (350 g). There is currently no method within the spreadsheet to adjust for alternative weights if a different animal is more sensitive. Shown below is the spreadsheet used to determine adjusted LC₅₀s, based on mean weight. Mean weight is the average of the reported weight range for the test animals.

$$\text{Adjusted LC}_{50} = \text{Reported LC}_{50} * (\text{Mean weight/standard weight})^{0.25}$$

Conversion of mammalian data (MRID 16901) for TREX-Fomesafen

Species	Sex	Weight range	Mean Wt	LD50	Adj LC50
rat	M	125 220	172.5	1858	1557
	F	110 215	162.5	1499	1237
mouse	M	25 40	32.5	745	411
	F	20 30	25	766	396
guinea pig	F	305 415	360	607	611

Data From Reported Terrestrial Insect Studies

Fomesafen Effect on Insects (MRID 135656)					
Order	Species	Common Name	Test	% Mortality	
				250 ppm ai*	500 ppm ai
Acarina	Tetranychus urticae		adults	0	0
			nymphs	0	0
			eggs	0	0
Hemiptera	Wilaparvata lugens		adults	0	0
			Aphis fabae	mixed	9
Diptera	Musca domestica		adults	0	1
Lepidoptera	Heliothis virescens		residual	0	0
			growth	0	0
			ovicide	0	0
	Plutella xylostella		residual	4	4
Coleoptera	Diabrotica balteata		larvae	1	1
Nematoda	Melodogyne incognita		larvae	0	NT
* mg ai/L, applied as liquid					
NT-not tested					

Terrestrial Plant Data

The existing data package for fomesafen included efficacy data, but not guideline plant tests. Upon request, the registrant submitted guideline studies. At the time of the risk assessment, these studies had not yet been processed through EFED's Data Evaluation Review. Data taken directly from the submitted study is presented below, and the most sensitive endpoints were used in the risk assessment. Provisional classification of the studies is supplemental. Slight modifications in endpoints due to a different method of statistical analysis are not expected to affect overall risk conclusions.

Fomesafen Guideline Tests (provisional data, not yet reviewed (PDB 11/22/05))					
Species	Common	Class	Vegetative vigor (MRID 46673802)		
			EC ₂₅ (lb ai/A)	NOAEC (lb ai/A)	Endpoint
<i>Raphanus sativus</i>	radish	D	0.0016	0.00098	height
<i>Lactuca sativa</i>	lettuce	D	0.0017	NR	biomass
<i>Brassica napus</i>	oilseed rape	D	0.0034	0.002	biomass
<i>Beta vulgaris</i>	sugarbeet	D	0.16	0.063	biomass
<i>Lycopersicon esculentum</i>	tomato	D	0.25	0.063	biomass
<i>Glycine max</i>	soybean	D	>0.50	0.5	none affected
<i>Echinochloa crus-galli</i>	barnyard grass	M	0.31	0.25	biomass
<i>Allium cepa</i>	onion	M	>0.50	0.5	none affected
<i>Avena sativa</i>	oat	M	>0.50	0.5	none affected
<i>Zea mays</i>	field corn	M	>0.50	0.5	none affected
NR- not reported					
Species	Common	Class	Seedling emergence (MRID 46673801)		
<i>Raphanus sativus</i>	radish	D	EC ₂₅ (lb ai/A)	NOAEC (lb ai/A)	Endpoint
<i>Lactuca sativa</i>	lettuce	D	0.11	0.13	survival
<i>Brassica napus</i>	oilseed rape	D	0.23	0.25	biomass
<i>Beta vulgaris</i>	sugarbeet	D	0.079	0.13	survival
<i>Lycopersicon esculentum</i>	tomato	D	0.37	0.5	survival
<i>Glycine max</i>	soybean	D	0.005	0.16	survival
<i>Echinochloa crus-galli</i>	barnyard grass	M	>0.50	0.5	none affected
<i>Allium cepa</i>	onion	M	>0.50	0.5	none affected
<i>Avena sativa</i>	oat	M	0.089	0.13	biomass
<i>Zea mays</i>	field corn	M	>0.50	0.5	none affected
NR- not reported					

Fomesafen Terrestrial Plant Testing (MRID 135656)						
Species (Common)	Latin	Class	Percent damage			
			pre-emergence		post-emergence	
			0.25 kg a.i./ha	1.0 kg a.i./ha	0.25 kg a.i./ha	1.0 kg a.i./ha
Soybean	<i>Glycine max</i>	D	0-20	0-20	0-20	0-20
Sticky-willy	<i>Galium aparine</i>	D	21-40	80-9	41-60	100
Cotton	<i>Gossypium hirsutum</i>	D	41-60	100	41-60	80-99
Prostrate knotweed	<i>Polygonum aviculare</i>	D	61-80	81-99	21-40	81-99
Java bean	<i>Cassia obtusifolia</i>	D	81-99	100	41-60	61-80
Morning-glory	<i>Ipomoea spp.</i>	D	81-99	100	0-20	81-99
Lambsquarters	<i>Chenopodium album</i>	D	TF	TF	81-99	100
Common groundsel	<i>Senecio vulgaris</i>	D	100	100	100	100
Indian mallow	<i>Abutilon theophrasti</i>	D	100	100	41-60	100
Pigweed	<i>Amaranthus retroflexus</i>	D	100	100	61-80	100
Rape	<i>Brassica napus</i>	D	100	100	61-80	100
Spiny cocklebur	<i>Xanthium spinosum</i>	D	100	100	81-99	100
Sugarbeet	<i>Beta vulgaris</i>	D	100	100	41-60	81-99
Blackgrass	<i>Alopecurus myosuroides</i>	M	21-40	61-80	0-20	41-60
Couchgrass	<i>Agropyron repens</i>	M	41-60	81-99	0-20	21-40
Nutgrass	<i>Cyperus rotundus</i>	M	41-60	81-99	0-20	21-40
Wild oat	<i>Avena fatua</i>	M	61-80	81-99	21-40	41-60
Barnyard grass	<i>Echinochloa crus-galli</i>	M	81-99	100	41-60	100
Hairy crabgrass	<i>Digitaria sanguinalis</i>	M	81-99	100	0-20	80-99
Johnson grass	<i>Sorghum halepense</i>	M	81-99	100	81-99	100
Maize	<i>Zea mays</i>	M	81-99	81-99	41-60	61-80
Rice	<i>Oryza sativa</i>	M	81-99	100	0-20	21-40
Winter wheat	<i>Triticum aestivum</i>	M	81-99	81-99	0-20	41-60
Green bristlegrass	<i>Setaria viridis</i>	M	100	100	61-80	100
TF-test failed						