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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Prevention, Pesticides, and Toxic Substances

June 17, 1996

MEMORANDUM:

SUBJECT: EFED Text Proposed for the **Profenofos** RED (List B; Case 2540; PC Code 111401)

FROM: David Farrar, RED team coordinator
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

THROUGH: Kathy Monk, Acting Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

TO: Kathleen Depukat, Acting Chief
Accelerated Reregistration Branch
Special Review and Reregistration Division

Attached is text that EFED proposes for the profenofos RED. Risk characterization and recommendations are provided in a separate communication.

Significant gaps in the effects data are absence of chronic toxicity measurements for marine/estuarine organisms, and a fish full life-cycle study. In addition, the EFED is considering the value of toxicity testing for profenofos degradates. The testing to be required for degradates (if any) will be communicated when a conclusion has been reached.

Additional information is needed on environmental fate properties of profenofos and profenofos degradates. The EFED believes that an adequate assessment of environmental fate can be made based on information from an appropriately designed field dissipation study.

If you have questions, contact the EFED RED coordinator, David Farrar (703-305-5721).

cc

EFED RED team (attachment)
Hank Jacoby
Anthony Maciorowski
Ruby Whiters
List B Files

efed.red

EFED Reregistration Team for Profenofos

Joe Sylvester	Reviewing Scientist, EEB
Les Touart	Section Head, EEB
Nelson Thurman	Reviewing Scientist, EFGWB
Jose Melendez	Reviewing Scientist, EFGWB
Mah Shamim	Section Head, EFGWB
Ron Parker	Surface Water Modeler, EFGWB
Henry Nelson	Head of Surface Water Section, EFGWB
David Farrar	Reregistration Coordinator, SACS[1]

[1] 703-305-5721

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Toxicity Data

The Agency has adequate data needed to assess the hazard of profenofos to nontarget terrestrial organisms.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of profenofos to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Avian Acute Oral Toxicity Findings					
Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Study Classification
Mallard	89.4	55.0	41627301 Pedersen, 1990	Moderately Toxic	Core

Avian Subacute Dietary Toxicity Findings					
Species	% A.I.	LC_{50} ppm	MRID No. Author/Year	Toxicity Category	Study Classification
Northern Bobwhite	89.4	57	43107301 Brewer, and Taliaferro, 1994	Highly Toxic	Core
Mallard	89.4	1646	43107302 Brewer and Taliaferro, 1994	Slightly Toxic	Core

These results indicate that profenofos is highly to moderately toxic to avian species ~~on~~ on an acute oral and subacute dietary basis. The guideline requirements are fulfilled, (MRID 43107301, 43107302)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Due to multiple applications of profenofos, avian reproduction studies are required.

Avian Reproduction Findings						
Species	% A.I.	NOEC ppm	LOEC ppm	Endpoints affected	MRID No. Author/Year	Study Classification
Northern Bobwhite	90.6	10	30	egg production	92148004 Fink, 1978	Core
Mallard Duck	90.6	30	100	egg production	92148006 Fink, 1978	Core

The avian reproductive studies indicate that profenofos is highly toxic to birds, and significantly affects reproduction. The guideline requirements are fulfilled. (MRID 92148004, 92148006)

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, findings for small mammals are based on an acute oral LD_{50} determined by the Agency's ~~Office of Pesticide Programs,~~ Health Effects Division.

Based on the review of mammalian toxicity measurements (Section B above) the LD_{50} value used to assess hazard and risk to nontarget small mammals is 300 mg/kg. Profenofos is characterized as moderately toxic according to the Agency classification for hazard assessment for wild small mammals.

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

Nontarget Insect Acute Contact Toxicity Findings					
Species	% AI	LD_{50} μg a.i./bee	MRID No. Author/Year	Toxicity Category	Study Classification
Honey Bee	90.4	0.0953	41627308 Winter, 1990	Highly toxic	Core

There is sufficient information to characterize profenofos as highly toxic to bees. The guideline requirement is fulfilled. (MRID 41627308)

(5) Terrestrial Field Testing for Birds and Mammals

A simulated field study with Curacron was conducted to assess hazard to bobwhite quail, mallard ducks and rabbits (Fink, 1978). Curacron was applied in 6 treatments of 1 lb per acre to broadleaf field crops. During the period of the study, biological effects were not observed that could be attributed to profenofos exposure. The study was not used in assessment of dietary risk because diets were supplemented with untreated food. (MRID 92148007).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings					
Species	% A.I.	LC_{50} ppb a.i.	MRID No.	Toxicity Category	Study Classification
Rainbow trout	90.6	25	92148009 Buccafusco, 1979	Highly Toxic	Core
Bluegill sunfish	90.6	41	92148008 Buccafusco, 1978	Highly Toxic	Core

The results of the 96-hour acute toxicity studies indicate that profenofos is highly toxic to fish. The guideline requirements are fulfilled. (MRID 92148008, 92148009)

Data from fish early life-stage tests are required if the product is applied directly to water or expected to be transported to water from the intended use site and if the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is greater than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days). Each of these criteria is met for profenofos. A study has been submitted and found to be acceptable. Results are shown in the following table.

Fish Early Life-Stage Toxicity Findings							
Species	% A.I.	NOEC (ug/L)	LOEC (ug/L)	MATC (ug/L)	MRID No. Author/Year	Endpoints Affected	Study Classification
Fathead minnow	90.6	2.0	4.4	3.0	92148014 Hoberg & Dean 1979	Survival	Core

These results indicate that profenofos is very highly toxic on a chronic basis. The guideline requirement is fulfilled (MRID 92148014)

The fish life-cycle test is required when an end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site, when any of the following conditions apply: the EEC is equal to or greater than one-tenth of the NOEC in the fish early life-stage or invertebrate life-cycle test; or if studies of other organisms indicate the reproductive physiology of fish may be affected. Each of these criteria is met for profenofos but no fish life-cycle test has been submitted.

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using the first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Freshwater Invertebrate Toxicity Findings				
Species	% A.I.	EC_{50} (ppb)	MRID NO. Author/Year	Study Classification
Daphnia magna	90.4	0.93	41627304 Bellantoni, 1990	Core

There is sufficient information to characterize profenofos as highly toxic to aquatic invertebrates.

The guideline requirement is fulfilled (MRID 41627304).

The criteria for requiring an invertebrate life cycle test are similar to those for requiring a fish early life stage test. These criteria are met for profenofos. An invertebrate life cycle test has been submitted for profenofos and found to be acceptable. The results are summarized in the following table.

Aquatic Invertebrate Life-Cycle Toxicity Findings							
Species	% A.I.	NOEC (ug/L)	LOEC (ug/L)	MATC (ug/L)	MRID No. Author	Endpoints Affected	Study Classification
Daphnia magna	90.6	0.2	0.33	0.26	92148013 Surprenant 1980	Survival	Core

The results indicate that profenofos is highly toxic to invertebrate early life stages. The guideline requirement is fulfilled. (MRID 92148013)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial non-food use of profenofos may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Estuarine/Marine Acute Toxicity Findings					
Species	% A.I.	LC_{50}/EC_{50} (ppb)	MRID No. Author/Year	Toxicity Category	Study Classification
Eastern oyster shell deposition	90.6	280	92148011 Heitmuller, 1980	Highly Toxic	Core
Pink Shrimp	90.6	4.6	92148012 Heitmuller, 1980	Highly Toxic	Core
Pinfish	90.6	7.7	92148010 Heitmuller, 1980	Highly Toxic	Core

There is sufficient information to characterize profenofos as very highly toxic to estuarine/marine organisms. The guideline requirement is fulfilled. (MRID 92148010, 92148011, 92148012).

Chronic estuarine/marine organism testing is required for the same reasons as cited under freshwater organisms. The required tests are a fish (preferably silverside) early lifestage and a mysid life cycle. There are no data available for chronic toxicity of profenofos to estuarine and marine animals. The guideline requirements are not fulfilled.

c. Toxicity to Plants

Tests of toxicity to terrestrial or aquatic plants are not required for profenofos. Testing may be required on a case-by-case basis if there are indications that a pesticide may be phytotoxic. Studies have been submitted and reviewed for soybeans, lettuce, carrot, tomato, cucumber, cabbage, corn oat, ryegrass and onion. Cucumber was apparently the most sensitive species, and the only species that demonstrated a dose response relationship permitting quantification of toxicity. Toxicity data on the technical/TEP material for cucumber are displayed below:

Nontarget Terrestrial Plant Toxicity Findings			
Species	% A.I.	Seedling emergence EC_{25} lbs ai/A	Vegetative vigor EC_{25}
Cucumber (seedling emergence)	90.4	0.13	[Not affected]

The results indicate that profenofos affects seedling emergence at 0.13 lbs ai/A. Vegetative vigor was not affected for any species tested. The guideline requirements are fulfilled. (MRID 41627305)

2. Environmental Fate

a. Environmental Fate Assessment

Available acceptable and supplemental environmental fate studies show that profenofos is not persistent, particularly in neutral and alkaline soils. Hydrolysis is the major route of dissipation. Photolysis is not a major pathway while biotic processes -- aerobic and anaerobic metabolism -- become important after the initial hydrolysis. Profenofos dissipates in neutral to alkaline soils with a half-life of several days. Little data exists for acid soils, although it can be inferred that profenofos dissipates at a slower rate. One of the major degradates, 4-bromo-2-chlorophenol, is persistent in the environment while the fate of another degradate, O-ethyl-S-propyl phosphorthioate, is not well known. Profenofos is not highly mobile and, although the field dissipation studies did not allow for an assessment of the leaching potential, is not expected to leach to ground water under normal use. The mobility and leaching potential of the degradates is unknown. The chemical may reach surface waters through spray drift or runoff.

<u>Persistence</u>. Hydrolysis is the primary route of dissipation. Profenofos hydrolyzes in neutral and alkaline solutions, with half-lives of 104-108 days at pH 5, 24-62 days at pH 7, and 7-8 hours at pH 9 (416273-09, 419390-01). The major degradates are 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate. Photolysis is not a major pathway in the degradation of profenofos in water, soil, or air (418799-01, 419390-02, 416273-10, 420304-01). The UV spectrum of profenofos overlaps slightly with the visible spectrum around 290-295 nm (420304-01). However, the overlap is minimal and extensive photolysis is not expected.

Profenofos metabolizes rapidly in aerobic and anaerobic conditions. In an alkaline (pH 7.8) soil, profenofos degraded with a half-life of 2 days under aerobic conditions (423343-02) and 3 days under anaerobic conditions (423343-03). The rate of metabolism was influenced by hydrolysis and aerobic and anaerobic metabolism in neutral and acid soils is likely to be slower. The major degradates are 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate. 4-Bromo-2-chlorophenol concentrations in both soil metabolism studies did not decline until 60 to 120 days after application. Additional metabolites form slowly. In anaerobic aquatic conditions, profenofos degraded with a half-life of 3 days in an acid (pH 5.1) sediment flooded with neutral (pH 7.3) water (422181-01). The major degradates are 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate. Additional metabolites -- 4-bromo-2-chlorophenyl ethyl ether (BCPEE), cyclohexadienyl sulfate, and phenol complex increased in concentration after 180 days.

Mobility. Profenofos is mobile to somewhat mobile, with Freundlich K_{ads} values of 4.60 for sand, 7.46 for sandy loam, 16.96 for loam, and 89.28 for clay soil samples. Desorption values ranged from 6.24 (sand) to 128.1 (clay). Adsorption generally increased with increasing soil organic matter content, clay content, and CEC. K_{oc} values ranged from 869 to 3162 (416273-11). Additional data is needed on the mobility of the major degradates/metabolites of profenofos, in particular 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate.

Laboratory studies show that some profenofos may be released to the atmosphere through volatilization. Over 30 days, volatility averaged 6.13 x 10^{-3} ug/cm^2/hr and the vapor pressure averaged 3.46 x 10^{-6} mm Hg (419050-01). 4-bromo-2-chlorophenol was the major volatile residue.

Field Dissipation. The submitted field studies do not provide adequate information for more than a rough qualitative assessment of profenofos dissipation in the field. Dissipation rate evaluations are complicated because profenofos degrades during storage, probably due to hydrolysis. Both profenofos and its degradate 4-bromo-2-chlorophenol dissipate from the surface 6 inches of cotton and bareground plots in California and Texas with a half-life of several days (428513-01, 429009-01). Neither profenofos or 4-bromo-2-chlorophenol were detected below 12 inches in either study. However, because the studies were conducted in soil and weather conditions that resulted in a moisture deficit, with little or no excess water available for downward movement through the soil, the leaching potential could not be reliably assessed in the studies.

Accumulation. The bioaccumulation potential of profenofos is relatively low in fish. Profenofos residues accumulate preferentially in the viscera of bluegill sunfish, but the residues depurate rapidly after exposure is terminated.

In the studies submitted to the Agency, profenofos residues accumulated preferentially in the viscera of bluegill sunfish. The maximum bioconcentration factors were 29x in the bodies, 45x in the heads, and 682x in the viscera (000859-52, 921480-59). Profenofos residues depurated rapidly, with concentrations decreasing to 1 ppb in the bodies, 2 ppb in the heads, and 7 ppb in the viscera after 8 days. The dominant chemical identified in the viscera was 4-bromo-2-chlorophenol (33-48% of the recovered radioactivity).

Information Needs. While the existing data base is essentially complete for profenofos, data gaps exist for the major degradates. Information is needed on the mobility of 4-bromo-2-chlorophenol and on the persistence, mobility and dissipation pathways of O-ethyl-S-propyl phosphorthioate. Because of the missing information on the degradates, the *overall* environmental fate assessment must be considered incomplete.

b. Detailed Information on Supporting Environmental Fate Studies

(1) Degradation

161-1 Hydrolysis

In a study submitted, profenofos degraded in sterile aqueous buffered solutions with half-lives of 108 days at pH 5, 62 days at pH 7, and 7.2 hours at pH 9. The solutions were incubated in the dark at 25°C. At pH 5, profenofos declined from 95% of the applied radioactivity to 77% after 30 days; 4-bromo-2-chlorophenol increased to 5% after 30 days. At pH 7, profenofos declined from 96% to 67% after 30 days; 4-bromo-2-chlorophenol increased to 23% after 30 days. At pH 9, profenofos declined to 10% of the applied after 24 hours; 4-bromo-2-chlorophenol increased rapidly to a maximum of 80% after 24 hours. (MRID 416273-09)

In a second study, profenofos degraded in sterile buffered aqueous solutions with calculated half-lives of 104 days at pH 5, 24 days at pH 7, and 8 hours at pH 9. At pH 5, profenofos declined from 98% of the recovered radioactivity at 0 days to 79% after 30 days. O-(2-chloro-4-bromophenyl)-S-n-propyl thiophosphate increased to a maximum of 8% after 30 days. At pH 7, profenofos declined from 97% to 55% after 21 days and 40% after 30 days. 4-bromo-2-chlorophenol increased from 1% to 40% after 21 days and 52% after 30 days. At pH 9, profenofos decreased from 97% to 44% after 8 hours and 13% after 24 hours. 4-bromo-2-chlorophenol continued to increase, from 10% after 1 hour to 54% after 8 hours and 84% after 24 hours. (MRID 419390-01).

While not tracked in either study, O-ethyl-S-propyl phosphorthioate is expected to form in equimolar proportions with 4-bromo-2-chlorophenol. The proposed pathway suggests that this degradate will further hydrolyze into O-ethyl phosphate and 1-propanethiol, although no data is provided in support of this.

161-2 Photodegradation in Water

In a study submitted, profenofos applied at 10 ppm to a pH 5 buffer solution and irradiated continuously with a xenon arc lamp at 25°C for 360 hours, degraded with a half-life of 51 days (adjusted to 12-hour photoperiods), compared to 60 days for dark controls. The rates of degradation between irradiated and dark control solutions were not statistically different. Profenofos declined from 92% of the recovered radioactivity to 60% in the irradiated samples, and from 92% to 63% in the dark controls. O-(2-chloro-4-bromophenyl)-S-n-propyl thiophosphate, the degradate found in the pH 5 hydrolysis study, was detected in both the irradiated and dark control solutions at 19-20% of the recovered radioactivity after 360 hours. (MRID 418799-01)

In a second study, profenofos applied at 11.6 ppm to a pH 5 buffer solution and irradiated on 12-hour light:dark cycles with a xenon arc lamp at 25°C for 30 days, degraded with a half-life of 75 days (adjusted to 12-hour photoperiods), compared to 104 days in the dark control. Profenofos declined from 98% of the recovered radioactivity to 89% at 14 days and 74% after 30 days. In the dark controls, profenofos declined to 79% after 30 days. Two hydrolysis degradates -- O-(2-chloro-4-bromophenyl)-S-n-propyl thiophosphate and 4-bromo-2-chlorophenol -- comprised less than 9% of the recovered after 30 days in both the irradiated and dark control solutions. (MRID 419390-02).

161-3 Photodegradation on Soil

In a marginally acceptable study, profenofos degraded more rapidly in the dark control samples (half-life of 7 days) than on a pH 7.5 sandy loam soil irradiated on 12 hour light:dark cycles with a xenon arc lamp (half-life of 28 days). Problems with the experimental design or analytical procedures may have led to these atypical results. However, the results do indicate photolysis on soil is not an important route of dissipation and are in line with the results of aqueous and air photodegradation studies. (MRID 416273-10).

161-4 Photodegradation in Air

While this supplemental study was not designed to adequately distinguish between photolysis in the air and in the condensate, EPA recognizes the difficulties inherent in this procedure (EPA, 1993). Since no photolysis was evident in the combined samples, an additional study is not required. The UV spectrum of profenofos overlaps slightly with the visible spectrum around 290-295 nm. The overlap is minimal and extensive photolysis would not be expected. (MRID 420304-01)

(2) Metabolism

162-1 Aerobic Soil Metabolism

In a study submitted, profenofos applied at 10.9 ppm to a pH 7.8 sandy loam soil, degraded with a half-life of 1.9 days. Profenofos concentrations declined to 56% of the applied radioactivity at 2 days, 36% at 3 days, and 9% at 9 days. The major metabolites were: (1) 4-bromo-2-chlorophenol, increasing from 11% at 1 day to a maximum concentration of 79% at 120 days before declining to 32% at 270-360 days; (2) BCPEE [4-bromo-2-chlorophenol ethyl ether], increasing from 2% at 5 days to 13% at 90 days and 42% at 270-360 days; and (3) THPME [2-thioethylenecarboxy-4-hydroxyphenyl methyl ether], reaching a maximum of 10% at 180-270 days. Although not tracked in this study, O-ethyl-S-propyl phosphorothioate is expected to form in equimolar proportions with 4-bromo-2-chlorophenol. Volatilized profenofos residues totaled over 50% of the applied by 30 days posttreatment.

The concentrations of profenofos and 4-bromo-2-chlorophenol at 2 days were similar in the non-sterile and sterile samples, suggesting that processes other than metabolism may be at work. The major degradates are the same as in the hydrolysis studies, which could be expected since profenofos hydrolyzes rapidly under alkaline conditions and the soil used in the study was alkaline. At the end of the study (360 days), 4-bromo-2-chlorophenol comprised 94% of the applied radioactivity in the sterile soils, compared to 32% in the non-sterile samples. Aerobic metabolism may be important in the formation of subsequent 4-bromo-2-chlorophenol metabolites. (MRID 423343-02)

162-2 Anaerobic Soil Metabolism

In a study submitted, profenofos degraded with a half-life of 3 days when incubated anaerobically in a pH 7.8 sandy loam soil for 60 days following 2 days of aerobic incubation. Profenofos declined to 58% of the applied radioactivity after 2 days of aerobic conditions. Under anaerobic conditions, it declined to 20% after 3 days, 10% after 7 days, and 1.5% after 60 days. The major degradate, 4-bromo-2-chlorophenol, increased from 35% at the start of anaerobic conditions to 82.5% at 60 days. O-ethyl-S-propyl phosphorothioate will be formed in equimolar proportions with 4-bromo-2-chlorophenol. Other degradates were 4-bromo-2-chlorophenol ethyl ether (BCPEE), cyclohexadienyl sulfate, and phenol and/or its conjugate.

The major degradates are the same as in the hydrolysis studies, which could be expected since profenofos hydrolyzes rapidly under alkaline conditions and the soil used in the study was alkaline. (MRID 423343-03)

162-3 Anaerobic Aquatic Metabolism

In a study submitted, profenofos degraded with a half-life of 3.2 days in an anaerobic sandy loam soil (pH 5.1) flooded with creek water (pH 7.3). Profenofos concentrations declined from 98% of the applied at 0 days to 66% at 3 days, 23% at 6 days, and <0.1% after 60 days. The major degradate, 4-bromo-2-chlorophenol, increased from 29% at 3 days to a plateau of 68 to 81% between 6 and 180 days before declining to 3% at 360 days. After 180 days, additional degradates increased in concentration: 4-bromo-2-chlorophenol ethyl ether (BCPEE) from 7% to 20%, cyclohexadienyl sulfate from 5% to 47%, and phenol complex from 4% to 28% (270 days).

Profenofos and CGA-55960 were detected in both the soil and water fractions. While greater concentrations of profenofos occurred in the soil fraction, CGA-55960 was found in greater concentrations in the water. BCPEE was detected in the soil and volatile fractions. Cyclohexadienyl sulfate and the phenol complex were associated primarily with the water fraction. (MRID 422181-01)

162-4 Aerobic Aquatic Metabolism

These data are not required for terrestrial uses.

(3) Mobility

163-1 Leaching and Adsorption/Desorption

In a study submitted, profenofos was somewhat mobile to mobile, with Freundlich K_{ads} values of

4.60 (n = 0.965) for sand (2% clay; 0.5% organic C), 7.46 (n = 1.509) for sandy loam (6% clay; 0.3% organic C), 16.96 (n = 1.012) for loam (11% clay; 0.7% organic C), and 89.28 (n = 1.097) for clay (42% clay; 2.8% organic C) soil samples. Freundlich K_{des} values ranged from 6.24 (sand) to 128.1 (clay). Adsorption generally increased with increasing soil organic matter content, clay content, and CEC. K_{oc} values calculated by the registrant ranged from 869 to 3162.

This study provides information on the mobility of profenofos in soils. Additional data is needed on the mobility of the major degradates/metabolites of profenofos, in particular 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate. (MRID 416273-11)

163-2 Volatility -- Laboratory

The results of a supplemental study show that some profenofos may be released to the atmosphere as a result of volatility. The average rate of volatilization for profenofos decreased with time from an average 10.62 x 10^{-3} ug/cm^2/hr after 1 day to 2.93 x 10^{-3} ug/cm^2/hr after 30 days. For the entire study, volatility averaged 6.13 x 10^{-3} ug/cm^2/hr and the vapor pressure averaged 3.46 x 10^{-6} mm Hg. After 30 days, over 90% of the volatilized [^{14}C]residues were 4-bromo-2-chlorophenol, which forms as a result of hydrolysis. 4-bromo-2-chlorophenol was also the major degradate identified in the soil extracts. Because of the high degree of variability in duplicate samples, "mean" results are of questionable value and should be interpreted with caution. (MRID 419050-01)

(4) Field Dissipation

164-1 Terrestrial Field Dissipation

Two studies submitted provide supplemental information about the terrestrial field dissipation of profenofos. Neither meet Subdivision N guidelines because profenofos appears to have degraded during storage and because the site conditions were not conducive to assessing the potential of profenofos and its degradates/metabolites to leach. However, both provide a qualitative assessment of the dissipation of profenofos and 4-bromo-2-chlorophenol. Because of potential storage stability problems, the half-life values should be interpreted with care. While actual dissipation rates may be longer, they should be within the same order of magnitude. The leaching potential could not be reliably assessed in the studies.

Profenofos was applied as Curacron 8E to the cotton plots in 6 applications of 1 lb ai/A each in 4-7 day intervals and to the bareground plots at 6 lb ai/A. Profenofos dissipated rapidly on bareground and cotton test plots situated on a sandy soil (a slightly acid pH and low organic matter content) located near Madera, California (428513-01). The registrant-calculated half-life for the upper 6 inches of soil was 2 days on the cotton plot and 3 days on the bareground plot. In Terry, Texas, profenofos also dissipated rapidly on bareground and cotton test plots situated on an alkaline (pH 7.6) soil (429009-01). The registrant-calculated half-life for the upper 6 inches of soil was approximately 2 days for both test plots. Neither profenofos or 4-bromo-2-chlorophenol were detected below 12 inches in either study. (MRID 428513-01, 429009-01)

In boilerplate — change 5. spray drift to accumulation

164-2 Aquatic Field Dissipation

These data are not required for terrestrial uses.

(5) Accumulation

165-4 Accumulation in Fish

A study submitted partially fulfills environmental fate data require
information on the bioaccumulation and depuration of profenofos residues in bluegill sunfish. Profenofos residues accumulated preferentially in the viscera of bluegill exposed to profenofos at 1 ppb for 28 days in a flow-through aquarium. The maximum bioconcentration factors were 29x (25 ppb) in the bodies, 45x (38 ppb) in the heads, and 682x (580 ppb) in the viscera. Chemicals identified in the viscera tissue included profenofos (1-4% of the recovered radioactivity), 4-bromo-2-chlorophenol (33-48%), 4-bromo-2-chlorophenol sulfate (6%) and two aqueous-soluble unknowns (10 and 29%). Profenofos residues depurated rapidly, with concentrations decreasing to 1 ppb in the bodies, 2 ppb in the heads, and 7 ppb in the viscera after 8 days. Two degradates comprising 10 to 29% of the recovered radioactivity were not identified. Degradate identification could have been facilitated by analyzing whole-fish tissues rather than just viscera and by using a larger dose rate (1 ppb was 3% of the LC50 of 30 ppb; concentrations up to 10% of the LC50 could have been used). (MRID 000859-52, 921480-59)

c. Water Resources

(1) Ground Water

While laboratory mobility data suggest that profenofos is not likely to leach to ground water under normal use, a terrestrial field dissipation study conducted under potential leaching conditions is needed to confirm this. The mobility and leaching potential of the degradates is unknown. In EPA's National Pesticides in Ground Water Database, profenofos was not detected in any of the 188 well sampled in a Texas study (1987-88). No other study included in the database analyzed for profenofos.

(2) Surface Water

Profenofos can contaminate surface water at application via spray drift. However, substantial fractions of applied profenofos should be available for runoff for only a few days post-application because of its relatively rapid dissipation in soil (aerobic soil metabolism half-life of 1.9 days; terrestrial field dissipation half-lives of 2, 2.2, 3.1, and 1.8 days). The somewhat intermediate soil/water partitioning of profenofos (K_{oc}s of 869, 2540, 2400, and 3160; K_{ads}s of 4.6, 7.5, 20, and 89; K_{des}s of 6.2, 7.6, 23, and 128) suggests that substantial portions of runoff will occur via both dissolution in runoff water and adsorption to eroding soil. Although soil/water partition coefficients greater than 1 indicate that concentrations in soil will be greater than concentrations in runoff water, the normally much greater mass of runoff water than eroding soil should ensure that both pathways generally contribute significantly to runoff.

The persistence of profenofos in the water column may vary substantially depending upon the pH, the microbiological activity and the hydrologic residence time of the water body. The rapid hydrolysis of profenofos in alkaline waters (hydrolysis half-life of 8.2 hours at pH 9) and its apparent susceptibility to biodegradation indicate that it will not persist in alkaline waters or in waters with much lower pHs that have substantial microbiological activity. However, the substantial increase in its hydrolysis half-life with decreasing pH (23.8 days at pH 7 and 104 days at pH 5) coupled with a low susceptibility to direct photolysis (irradiated half-life of 75 days) and relatively low potential for volatilization from water (Henry's Law constant of 3.34 X 10^{-7} atm·m^3/mol) indicate it will be somewhat more persistent in neutral to acidic waters with low microbiological activities and long hydrologic residence times. An anaerobic soil metabolism half-life of 2.9 days and an anaerobic aquatic metabolism half-life of 3.2 days indicate that it will probably not persist in normally anaerobic sediments.

The intermediate soil/water partitioning of profenofos indicates that significant portions of profenofos in surface water will be dissolved in the water column and adsorbed to suspended and bottom sediment. Although soil/water partition coefficients greater than 1 indicate that concentrations adsorbed to suspended and bottom sediment will probably be greater than concentrations dissolved in the water column, the mass of water in the water column will generally be much greater than the suspended and bottom sediment available for binding profenofos. Reported BCFs for the bluegill sunfish of 45X, 682X, and 29X for head, viscera, and the whole fish, respectively indicate that the bioaccumulation potential of profenofos is relatively low.

The major primary degradates of profenofos under both aerobic and anaerobic conditions in soil are also its major hydrolysis degradates: 4-bromo-2-chlorophenol and O-ethyl-S-propyl phosphorthioate. A major secondary degradate under both aerobic and anaerobic conditions is 4-bromo-2-chlorophenyl ethyl ether (BCPEE). A major tertiary degradate under anaerobic conditions is cyclohexadienyl sulfate.

Except for O-ethyl-S-propyl phosphorothioate for which there is no direct fate data, the major degradates listed above all appear to be substantially more persistent than profenofos. Consequently, substantial amounts of those degradates in terms of fractions of applied should remain available for runoff for longer periods than for profenofos. The presence of hydrolyzable groups on the O-ethyl-S-propyl phosphorothioate indicate that it may be less persistent than some of the other major degradates, but its actual persistence was not determined.

Although no direct soil/water partitioning data are available for the major degradates, a greater partitioning of both 4-bromo-2-chlorophenol and cyclohexadienyl sulfate into water than profenofos in the aquatic anaerobic metabolism study suggests they may exhibit substantially lower soil/water partitioning than profenofos. If so, runoff of those degradates may occur primarily by dissolution in runoff water as opposed to adsorption to eroding soil, and most of their mass in receiving waters may be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment.

EFGWB does not have any data on the concentrations of profenofos in surface water. Also, no entries for profenofos in surface water were found in the STORET database.

Surface Water Modeling. The Agency has modeled contamination of surface water resulting from profenofos use on cotton, using the models PRZM2 and EXAM II. The site modeled was a hydrologic Group C silt loam soil in Yazoo County, Mississippi. It was assumed that a 10 hectare cotton field drains into a body of water at the edge of the field with 1 hectare surface and depth 2 meters. The Agency believes that these assumptions represent a reasonable high-runoff and high-erosion scenario.

The site was modeled over 36 years. One in 10 year peak, maximum 96-hour average, maximum 21-day average, maximum 60-day average, and maximum 90 day average estimated environmental concentrations in the pond were 5.9 ug/L, 2.6 ug/L, 1.1 ug/L, 0.75 ug/L, and 0.50 ug/L, respectively. These results are used in Section C.3 above as estimates of exposure to nontarget aquatic organisms.

For the profenofos loaded into the body of water, 84% was transported as spray drift and 16% in runoff water (15% dissolved and 1% adsorbed to particles).

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g., the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g., the LC_{50}. The acute effect levels typically are:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and Associated Risk Presumptions	
Mammals and Birds	
Criterion	**Presumption when Criterion Met**
Acute RQ ≥ 0.5	High acute risk.
Acute RQ ≥ 0.2	Risk that may be mitigated through restricted use.
Acute RQ ≥ 0.1	Endangered species may be affected acutely.
Chronic RQ ≥ 1	Chronic risk, endangered species may be affected chronically.

Fish and Aquatic Invertebrates	
Acute RQ ≥ 0.5	High acute risk.
Acute RQ ≥ 0.1	Risk that may be mitigated through restricted use.
Acute RQ ≥ 0.05	Endangered species may be affected acutely.
Chronic RQ ≥ 1	Chronic risk, endangered species may be affected chronically.
Plants	
RQ ≥ 1	High risk.
RQ ≥ 1	Endangered plants may be affected.
For plants, there are not separate criteria for restricted use or chronic effects.	

Risk to nontarget organisms has been assessed based on the assumption that the product Curacron 8E is applied at a rate of 1 lb active ingredient per acre. The maximum application rate per season is 3 qts Curacron per acre. Curacron 8E contains 8 lbs active ingredient per gallon.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Estimation of the potential for adverse effects to wild birds is based upon the Agency's draft 1995 Standard Evaluation Procedure for risk assessments and methods used by Hoerger and Kenaga (1973) as modified by Fletcher et.al. (1994) for terrestrial EEC determinations.

Residues found on dietary food items following one application may be compared to LC_{50} values to predict hazard. The maximum concentration of residues of profenofos which may be expected to occur on selected avian or mammalian dietary food items following a single application rate is provided in the table below, where the EEC is the Estimated Environmental Concentration, RQ equals EEC/LC50 for acute risk and EEC/NOEC for chronic risk; and LC50 equals 57 ppm and NOEC equals 10 ppm (for Northern Bobwhite Quail).

Estimated Environmental Concentrations (EECs) and Risk Quotients			
Food items	EEC (ppm)	RQ acute	RQ chronic
Range Grasses (short)	240	4.21	24.00
Fruit/Vegetable Leaves (other than legumes)	125	2.19	12.5
Forage Legumes and Insects	58	1.02	5.8
Seeds	12	0.21	1.20
Fruits	7	0.12	0.70

Risk quotients exceed Levels of Concern for endangered and non-endangered species of birds and mammals. High acute and chronic risk may be presumed for these species with profenofos.

(b) Mammals

Estimation of the potential for adverse effects to wild mammals is based upon the Agency's draft 1995 Standard Evaluation Procedure for mammalian risk assessments. Those sources indicate the estimated environmental concentrations (EECs, mg ai/kg food) to be used in calculation of risk quotients. A risk quotient is determined by dividing the EEC by an estimate of the LC_{50} value. The LC_{50} is estimated by conversion of an LD_{50} measurement as follows:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}} = \frac{LD_{50}}{\%BWC}$$

where %BWC is the mass of food consumed per day, as a fraction of body mass.

Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each assumed to consume four different kinds of food (grass, forage, insects, and seeds). The acute risk quotients for broadcast applications of nongranular products are tabulated below.

Mammalian (Herbivore/Insectivore) Acute Risk Quotients for Single Application of Nongranular Products (Broadcast).

Site, Application Rate	Body Weight (g)	% Body Weight Consumed (%BWC)	LD_{50} mg/kg	Estimated Environmental Concentration (EEC, mg/kg)			Acute Risk Quotient (RQ)[1]		
				Short Grass	Forage & Small Insects	Large Insects	Short Grass	Forage & Small Insects	Large Insects
Forage and Insects; 1 lb ai/A	15	95	300	240	58	15	0.76	0.18	0.05
	35	66					0.53	0.13	0.03
	1000	15					0.12	0.03	0.01

[1] $RQ = EEC / (LD_{50} / \%BWC)$

Certain risk quotients exceed Levels of Concern for small mammals exposed to profenofos. Presumption of high risk is indicated for this chemical for small mammals exposed to short grasses, and risk to endangered mammals exposed to forage and small insects.

(c) Insects

Based on the proposed use and toxicity studies, profenofos can be characterized as highly toxic to insects.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: Profenofos displays very high toxicity to most aquatic organisms tested to date. The Agency has calculated refined exposure estimates based on the PRZM and EXAM models (Section 2(c)2. above).

The following are the inputs used and the PRZM/EXAM EEC's which were calculated:

Crop cotton
Application method aerial/ground spray
One maximum application 1.0 lb ai/A
Maximum seasonal application 6.0 lb ai/A
Field half-life 1.9 days
Water solubility of profenofos at 20 C: 28.0
Percent spray drift assumed 5%
Incorporation depth: 0 inches
Hydrolysis half-life: 62 days maximum
Photolysis half-life: 75 days maximum
Combined pond half-life 61.59 days

The resulting PRZM/EXAM EECs for a one in 36 year event (which is the maximum number calculated in each category and is an EEC that is expected to be met or exceeded less than 3% of the time) are:

Instantaneous:	41.74
Average 4 day:	15.07
Average 21 day:	4.04
Average 60 day:	2.12

The one in ten year EEC's (the EEC that is expected to be met or exceeded 10% of the time) as calculated by PRZM/EXAM are:

Instantaneous:	5.93
Average 4 day:	2.59
Average 21 day:	1.15
Average 60 day:	0.75

Toxicity measurements used in the following calculations are reviewed in Section C.1.a above. The EEC's used in these calculations are one in ten year EEC's.

(a) Freshwater Fish

For freshwater fish, the risk quotient (RQ) for acute risk is given by EEC/LC_{50} with EEC = 5.93 ppb (instantaneous exposure) and LC_{50} = 25 ppb (based on rainbow trout). The RQ for chronic risk is EEC/MATC where EEC = 1.15 ppb (21-day average exposure) and MATC = 3.0 ppb (based on fathead minnow).

Risk Quotients (RQ) for Freshwater Fish			
Crop/application rate	Species	Acute RQ (Instantaneous)	Chronic RQ (21-day)
Cotton @ 1.0 lb ai/A	Rainbow trout	0.24	-
	Fathead minnow	-	0.38

Freshwater fish Levels of Concern (LOCs) are not exceeded using the one in ten year EEC's but are exceeded when calculated using the one in 36 year EEC's.

(b) Freshwater Invertebrates

For freshwater invertebrates, the risk quotient (RQ) for acute risk is given by EEC/EC_{50} with EEC = 5.93 ppb (instantaneous exposure) and EC_{50} = 0.93 ppb. The RQ for chronic risk is EEC/MATC where EEC = 1.15 ppb (21-day average exposure) and MATC = 0.26 ppb.

Risk Quotients (RQ) for Freshwater Invertebrates			
Crop/application rate	Species	Acute RQ (Instantaneous)	Chronic RQ (21-day)
Cotton @ 1.0 lb ai/A	*Daphnia magna*	6.38	4.42

Risk Quotients exceed the LOCs for aquatic invertebrates. Presumption of high acute and chronic risk to endangered and non-endangered freshwater invertebrates is indicated for this chemical.

(c) Estuarine and Marine Animals

Risk quotients (RQ) for estuarine and marine animals are given by EEC/LC50, where the instantaneous EEC = 5.93 ppb and the LC50's for acute exposure are 4.6 ppb for pink shrimp, 280 ppb for eastern oyster, and 7.7 ppb for pinfish.

Risk Quotients (RQ) for Estuarine and Marine Organisms		
Crop/application rate	Species	Acute RQ Instantaneous
Cotton @ 1.0 lb ai/A	Pink Shrimp	1.29
Cotton @ 1.0 lb ai/A	Eastern Oyster	0.02
Cotton @ 1.0 lb ai/A	Pinfish	0.77

The risk quotients for pink shrimp and pinfish exceed the high risk LOC for estuarine and marine animals exposed to profenofos.

The Agency has no data on chronic toxicity to estuarine and marine animals. Based on risk identified for freshwater organisms, estuarine organisms would likely be at high risk. Presumption of high acute and chronic risk to endangered and non-endangered species is indicated for this chemical.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Non-target terrestrial plants inhabit non-aquatic areas. Non-target "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and semiaquatic plants are exposed to pesticides from runoff, drift, or volatilization.

Exposure by runoff is based on one acre to one acre sheet runoff for terrestrial plants and on channelized runoff from 10 acres to one acre for terrestrial and semiaquatic plants. Exposure from spray drift is calculated by assuming 5% of the pesticide application will drift over to an adjacent acreage or to a much longer distance.

The following EECs have been determined for non-target plants that are exposed from the labeled application of 1.0 lb ai/A:

One acre to one acre sheet runoff: 0.05 lb ai/A
Ten acre to one acre channelized runoff: 0.50 lb ai/A
Spray drift plus runoff: 0.10 lb ai/A
Spray drift: 0.05 lb ai/A

The EC_{25} value for the most sensitive species in the seedling emergence study is used with the runoff exposure to determine the risk quotient. If the chemical is very persistent (as indicated by the aerobic soil metabolism half-life), the value can also be used with drift exposure to emerging non-target plants. The EC_{25} value of the most sensitive species in the vegetative vigor study is used with the drift exposure. Cucumber seedling emergence EC_{25} = 0.13 lb ai/A.

RQ and EEC Values for Terrestrial and Semi-aquatic Plant Species

Use Site	Maximum Application Rate	Type of EEC	EEC (lbs a.i./A)	Risk Quotient
Cotton	1.0	sheet runoff	0.05	0.38
		channel runoff	0.50	3.85
		drift + runoff	0.10	0.77
		spray drift	0.05	0.38

Levels of Concern are not exceeded for terrestrial and semi-aquatic plant species, except for channel runoff at a maximum application rate of 1.0 lb ai/A of profenofos. High acute risk is indicated for channel runoff.

(4) Endangered Species

Profenofos presents a high acute and chronic risk to endangered species of birds, mammals and organisms.

When the Endangered Species Protection Program becomes final, limitations of the use of profenofos may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

(5) Discussion of Risk to Nontarget Species

The risk of profenofos use to nontarget species was assessed based on an assumed application rate of 1 lb active ingredient per acre.

Profenofos is highly to moderately toxic to birds on an acute oral and subacute dietary basis. Avian reproduction studies indicate that this chemical is highly toxic on a chronic basis and significantly affects reproduction. The available mammalian data indicates that profenofos is moderately toxic to small mammals on an acute oral basis. This chemical is also highly toxic to insects.

Profenofos is highly toxic to freshwater aquatic species including fish and invertebrate adults and sub-adults. This chemical is very highly toxic to estuarine and marine organisms on an acute basis. There are no data available for chronic toxicity of this chemical to estuarine and marine organisms. A fish full life cycle study is required because the EEC exceeds the early life stage NOEC by over seven fold. This study will assist in further defining a fish chronic level of concern.

Risk Quotients exceed estimated levels of concern for birds, small mammals, and aquatic organisms, in freshwater, marine and estuarine habitats. Presumption of high acute and chronic risks to endangered and non-endangered species is indicated for profenofos.

b. Water Resources Risk Implications for Human Health.

(1) Ground Water

As discussed in Section C.2.c the information available to EFED does not suggest that Profenofos poses a risk to ground water quality. However, confirmatory information is needed on fate properties of profenofos and profenofos degradates.

(2) Surface Water

Profenofos may contaminate surface water by spray drift or runoff. Primary treatment employed by most surface water source supply systems may be only moderately effective in removing profenofos and profenofos degradates with intermediate soil/water partitioning.

Profenofos is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, water supply systems are not required to analyze for profenofos and no Maximum Contaminant Level (MCL) has been established. In addition, no Health Advisory Levels (HALs) have been established for it by the USEPA Office of Drinking Water. However, profenofos is of possible concern with respect to dietary risks to humans due to its inclusion on the list of "Apparent Exceeders (Chronic effects and Cancer)" maintained by the Agency's Office of Pesticide Programs, Health Effects Division.

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