H
OPP

06/ OPP #3414/B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

13PP

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

23 September 1999

MEMORANDUM

SUBJECT: REVISED (PHASE 4) OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR TEMEPHOS (PC Code 059001; DP Barcode D240191-2)

FROM: Jonathan Becker, Ph.D., Environmental Health Scientist 9/29/99
Reregistration Branch II
Health Effects Division (7509C)

TO: Margaret Rice
Reregistration Branch II
Special Review and Reregistration Division (7508W)

THRU: Alan Nielsen, Senior Scientist 9/29/99
Reregistration Branch II
Health Effects Division (7509C)

Please find attached the revised (Phase 4) occupational and residential exposure assessment for Temephos. This chapter uses a streamlined format.

DP Barcode: D240191-2\ D259876

Pesticide Chemical Codes: 059001

EPA Reg Nos: 228-107, 228-118, 228-121, 228-122, 769-678, 769-722, 769-723, 769-724, 769-725, 8329-15, 8329-16, 8329-17, 8329-30, 48273-9, 48273-10, 66733-9, 66733-10, 66733-11.

EPA MRID No.: N/A

PHED: Yes, Version 1.1

1813

Temephos

This is an abbreviated occupational exposure and risk assessment for temephos.

I. Hazard Identification

Table 1 summarizes the critical toxicological information from the Temephos Hazard ID memo (dated 12 May 1998). Results from a recently submitted dermal absorption study (MRID 44756701) are included.

Table 1. Temephos hazard endpoints and uncertainty factors.

Route / Duration	NOEL (mg/kg/ day)	Endpoint	Study	Uncertainty Factors	Comments
Short-term Dermal	0.3	Plasma ChE inhibition	Subchronic feeding study in Rats (MRID # 00001239)	Interspecies: 10x Intraspecies: 10x FQPA: None	38 percent dermal absorption (MRID 44756701).
Short-term Inhalation					No inhalation study is available. Exposure is converted to an oral equivalent dose, combined with the dermal dose, and compared to the oral endpoint.
Intermediate-term and Chronic Dermal					Same endpoint chosen for intermediate-term and chronic as for short-term. See comments above.
Intermediate-term and Chronic Inhalation					No inhalation study available. See comments above.

Temephos is not classified as a carcinogen. Based on the technical formulation, acute oral and dermal toxicity are category II, acute inhalation toxicity is category III, primary eye irritation is category III, and skin irritation is category IV. Temephos is not a dermal sensitizer.

II. Exposure Characterization

Temephos is formulated as a granular (1 to 5 percent active ingredient) and as an emulsifiable concentrate (40 to 45 percent active ingredient). It is used to control mosquito larvae in standing water (tidal areas, woodland pools, shallow ponds, tire and refuse piles). It can be applied by fixed-wing aircraft, helicopter, hand-held sprayers, power backpack blowers, and by spoon. Application rates are based on the organic content of the standing water being treated and range up to 0.5 lb ai per acre for the granular and up to 0.468 lbs ai per acre (1.5 fl. oz. per acre). Areas can be treated multiple times per year, as needed.

2913

Potential occupational exposure routes are dermal and inhalation and may be of short-term (1 to 7 days), intermediate-term (1 week to several months), and chronic durations (more than several months). The largest United States end user of temephos (Lee County Mosquito Control District, Florida) reports that in a "typical" year they apply temephos 5 to 6 days per week from May through October and possibly 2 days per week for the rest of the year (about 160 applications per year). Variation in amount of rainfall in a specific geographical region can greatly prolong or shorten the seasonal duration of required mosquito larvicide treatments. There are no homeowner uses of temephos.

III. Occupational Exposure and Risk Assessment

Application Rates: Temephos may be applied up to 0.5 lbs a.i. per acre for granular formulations and up to 0.0468 lbs a.i. per acre for liquid formulations.

Submitted Studies: HED is not aware of any handler exposure study submitted to the Agency for review.

Handler Exposure Scenarios: HED has identified the potential for occupational exposure for 14 major scenarios, as follows: (1) mixing / loading liquids for aerial application; (2) mixing / loading liquids for rights-of-way sprayer; (3) loading granulars for aerial application; (4) applying liquids using fixed-wing aircraft; (5) applying liquids using helicopter; (6) applying liquids using rights-of-way sprayer; (7) applying granulars using fixed-wing aircraft; (8) applying granulars using helicopter; (9) flagging during aerial application of liquid sprays; (10) flagging during application of granulars; (11) mixing / loading / applying sprays with a backpack sprayer; (12) loading / applying granulars with a power backpack blower; (13) loading / applying granulars with belly grinder; and (14) applying granulars by spoon.

Occupational handler dermal and inhalation exposures for all durations (developed using PHED Version 1.1 surrogate data) are presented in Tables 4 and 5. The assumptions and the formulae that were used in the exposure / risk calculations are as follows:

- Daily exposure (mg/day) = Unit exposure (mg/lb ai) * Application rate (lb ai/acre) * Acres treated.

- Acres treated are 350 to 700 acres per day for aerial application, 40 acres per day for rights-of-way sprayer, and 5 acres per day for backpack sprayer. Based on flight logs from 1996 supplied by the Lee County Mosquito Abatement District, a greater number of acres may be treated by air on some occasions, for example 1024 acres treated in 4.5 hours by a single applicator on May 23, 1996 and 1482 acres treated in 5.3 hours by a single applicator on August 8, 1996.

3713

- Daily dose (mg/kg/day) = Daily exposure (mg/kg) / Body weight (70 kg).

- MOE = NOEL (mg/kg/day) / Daily dose (mg/kg/day).

- Body weight for an adult handler is assumed to be 70 kg.

- PHED clothing and risk mitigation scenarios are as follows: Baseline - long sleeved shirt, long pants, no respirator; Maximum PPE - coveralls over long pants, long sleeved shirt, chemical-resistant gloves, organic vapor respirator; Engineering Controls - long pants, long sleeved shirt, no gloves in an enclosed cab or cockpit, closed mixing/loading.

- Data from PHED for helicopter application of sprays and granulars are based on a very limited number of replicates. Instead of assessing this exposure scenario using inadequate data, data from PHED for fixed-wing application of sprays were used in accordance with HED Science Advisory Council of Exposure Policy Number 5 (May 7, 1998).

Handler Exposure Scenario Results: Results for the occupational handler scenarios are presented in the attached spreadsheet and are summarized below in Table 2.

Table 2. Highest estimated MOE for each temephos exposure scenario for all exposure durations.

Exposure Scenario	Range of MOEs		
	Baseline	Maximum PPE	Engineering Controls
Mixer/Loader			
Mixing / loading liquids for aerial application	0.58 - 1.2	97 - 190	190 - 380
Mixing / loading liquids for rights-of-way sprayer	10	1,700	3300
Loading granulars for aerial application	12 - 25	41 - 82	610 - 1,200
Applicator			
Applying liquids using fixed-wing aircraft	No data	Scenario not feasible	330 - 650
Applying liquids using helicopter	No data	Scenario not feasible	No adequate data
Applying liquids using rights-of-way sprayer	22	100	Scenario not feasible
Applying granulars using fixed-wing aircraft	No data	Scenario not feasible	31 - 63
Applying granulars using helicopter	No data	Scenario not feasible	No data
Flagger			
Flagging during aerial application of liquid sprays	140 - 280	170 - 330	7,700 - 14,000
Flagging during application of granulars	49 - 99	96 - 190	2,500 - 4,900
Mixer/Loader/Applicator			
Mixing / loading / applying sprays with a backpack sprayer	91	150	Scenario not feasible
Loading / applying granulars with a power backpack blower	No data	No data	Scenario not feasible
Loading / applying granulars with belly grinder	2.2	2.7	Scenario not feasible
Applying granulars by spoon (by hand used as a surrogate)	66	120	Scenario not feasible

Postapplication Exposure Scenarios: HED believes that postapplication exposures would be minimal. This belief is based on the low application rate (0.5 lb ai per acre for granular formulations and 0.04688 lb ai per acre for liquid formulations) of temephos, the short duration spent by the worker in a treated area (typically a few minutes), and the low exposure activity of

5813

the worker (typically dipping water from a temporary pool with a long handled dipper and examining the collected water for mosquito larvae).

Cholinesterase Monitoring: The Lee County Mosquito Control District has submitted limited monitoring data from their cholinesterase testing program to the Agency. Data were submitted for four job categories – inspector, aircraft mechanic, mixer/loader, and pilot. Each job category is represented by one individual. Blood samples were taken at intervals of approximately six months to one year from 1993 to 1995 yielding three or four samples per individual. Plasma and red blood cell cholinesterase levels were measured and expressed as a percentage of the reference range. For plasma cholinesterase "normal" values range from 42 to 158 percent and for red blood cell cholinesterase "normal" values range from 71 to 130 percent of the reference level. Summarized results for these four individuals are presented in Table 3.

Table 3. Results of cholinesterase sampling of four individuals (1 or 2 samples per year) representing four different job categories.

Job Category	Number of Samples	Sample Years	Plasma ChE (% of Reference Range)	Red Blood Cell ChE (% of Reference Range)
Inspector	4	1993 – 1995	115 – 125	106 – 120
Aircraft Mechanic	3	1993 – 1995	78 – 85	96 – 104
Mixer / Loader	3	1993 – 1994	70 – 114	98 – 114
Pilot	3	1993 - 1994	80 – 98	114 – 124

The data in Table 3 show that the cholinesterase levels of the four individuals tested from 1993 to 1995 were within the reference range for the general population in the United States for all samples. These data have limited utility in addressing the cholinergic effects of organophosphate pesticides, specifically temephos, on the workers for the following reasons:

- Representativeness of four individuals to other member of the same job category is not established.

- Complete occupational exposure history to organophosphate pesticides is not known. A detailed description of how, when and for how long the pesticide was handled/applied prior to sample collection is not provided. Information such as percent active ingredient, formulation, dilution factors, concentrations of all impurities, inerts or other added ingredients is not known.

- Complete non-occupational exposure history to other cholinesterase inhibiting chemicals is not known. Examples of these other chemicals are organophosphates used in and around the home.

- Baseline plasma and red blood cell cholinesterase levels were not established for each individual. While the cholinesterase levels in Table 3 are within the range of that for the general United States population, each individual has their own unique normal range. Comparisons between a given individual's plasma cholinesterase level and the reference population mean value is uninformative. For example, the mixer/loader in Table 3 had a plasma cholinesterase level of 70 percent of the reference level. This value could be interpreted as a 30 percent depression (as compared to the reference level), or as a normal value (if the individual's pre-exposure baseline level is lower than the reference level).

- The health histories of subjects are not know. Confounding variables such as smoking status, diet or medication use or other exposures are not addressed. Further, the subjects were not assessed for possible clinical signs (symptoms of cholinergic effects) following pesticide activity such as a self-reporting questionaires and more quantifiable measures (e.g., blood pressure, heart rate).

- A non-exposed group (control) group of individuals were not sampled. While it is important to establish the pattern of individual baseline (pretreatment) blood levels, a separate control group need to be established to compare values as well as to provide statistical comparisons.

IV. Residential Exposure Assessment

Residential Handler Exposure: There are no residential uses of temephos. Because of the areas in which temephos is aerially applied (e.g., tidal marshes) and the presumed large droplet size of the spray, it is unlikely that significant exposure via spray drift would occur. However, because of the diversity of sites that temephos may be used, HED remains concerned that bystander spray drift exposure may occur in some situations. HED reserves the decision concerning the magnitude of bystander spray drift exposure and the required buffer zone until data can be supplied.

Residential Postapplication Exposure: Although temephos may be used in areas (e.g., temporary pools along the side of the road, standing water in discarded tires, and refuse piles) that may occasionally be visited by the general population, HED believes that it is unlikely that significant postapplication exposure would occur. This belief is based on the low application rate, the likelihood of a brief duration spent in such environments, and the probability of low exposure activities of the residents.

V. Incident Data

A search for incident data by Jerome Blondell (OPP/HED/CEB2) did not identify any cases of temephos related illnesses or injuries. This may be due to the relatively small amount of temephos used (as compared to other organophosphate pesticides).

VI. Conclusions

Based on the above occupational exposure and risk assessment, HED concludes:

- The use of risk mitigation measures for occupational handlers (i.e., maximum PPE and engineering controls) results in **MOEs greater than 100** for the following scenarios: mixing / loading liquids for aerial application, mixing /loading for rights-of-way sprayer, loading granulars for aerial application, applying liquids using fixed-wing aircraft, applying liquids using a rights-of-way sprayer, flagging during aerial application of granulars and liquid sprays, mixing / loading / applying sprays with a backpack sprayer, and applying granulars by spoon.

- The use of risk mitigation measures for occupational handlers (i.e., maximum PPE and engineering controls) results in **MOEs less than 100** for the following scenarios: applying granulars using fixed-wing aircraft, and loading / applying granulars with belly grinder.

- Two scenarios lack exposure data that are needed to assess risk to temephos handlers. These scenarios are applying granulars using a helicopter and loading / applying granulars with a power backpack blower. A power backpack blower is frequently the method of choice for applying granulars to tire piles. Further, this scenario has the highest application rates for the chemical.

- HED remains concerned that bystander spray drift exposure may occur in some situations and requests supporting data concerning bystander spray drift exposure from the registrant.

VII. Summary

Temephos, formulated as a granular and as an emulsifiable concentrate, is used as an insecticide for the control of mosquito larvae. Based on HED's occupational and risk assessment, MOEs are less than 100 for two exposure scenarios. Exposure scenarios with MOEs greater than 100 include: mixing / loading liquids for aerial application, mixing /loading for rights-of-way sprayer, loading granulars for aerial application, applying liquids using fixed-wing aircraft, applying liquids using a rights-of-way sprayer, flagging during aerial application of

8913

granulars and liquid sprays, mixing / loading / applying sprays with a backpack sprayer, and applying granulars by spoon. Two exposure scenarios could not be assessed because of the lack of exposure data. HED also requests supporting data concerning bystander spray drift exposure from the registrant.

cc: Nicole Paquette (OPP/HED/RRB2)
HED Exposure Assessment Files

9813

Table 4: Occupational Handler Dermal and Inhalation Exposures to Temephos with Baseline Clothing.

Exposure Scenario	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader						
Mixing / loading liquids for aerial application	2.9	1.2	0.046875	350	48	0.020
				700	95	0.039
Mixing / loading liquids for rights-of-way sprayer	2.9	1.2	0.046875	40	5.4	0.0023
Loading granulars for aerial application	0.0084	1.7	0.5	350	1.5	0.30
				700	2.9	0.60
Applicator						
Applying liquids using fixed-wing aircraft	No data	No data	0.046875	350	—	—
				700	—	—
Applying liquids using helicopter	No data	No data	0.046875	350	—	—
				700	—	—
Applying liquids using rights-of-way sprayer	1.3	3.9	0.046875	40	2.4	0.0073
Applying granulars using fixed-wing aircraft	No data	—	0.5	350	—	—
				700	—	—
Applying granulars using helicopter	No data	—	0.5	350	—	—
				700	—	—

10813

Exposure Scenario	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Flagger						
Flagging liquid sprays	0.0011	0.35	0.046875	350	0.18	0.0057
				700	0.36	0.011
Flagging granulars	0.0028	0.15	0.5	350	0.49	0.026
				700	0.98	0.053
Mixer /Loader / Applicator						
Mixing / loading / applying sprays with a backpack sprayer	2.5	30	0.046875	5	0.59	0.007
Loading / applying granulars with a power backpack blower	No data	—	—	—	—	---
Loading applying granulars with a belly grinder	10	62	0.5	5	25	0.16
Applying granulars by spoon (by hand used as a surrogate)	71	470	0.5	0.023	0.82	0.0054

[a] Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab.

[b] Baseline inhalation exposure represents no respirator.

[c] Application rates are the maximum single application rates.

[d] Daily acres treated values are based on EPA HED estimates of acreage that could be treated in a single day for each exposure scenario of concern.

[e] Daily dermal exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/acre) * Acres treated.

[f] Daily inhalation exposure (mg/day)= Unit exposure (µg/lb ai) * (1mg/1000 µg) Unit conversion * Application rate (lb ai/A) * Acres treated.

Table 5. Occupational Handler Risks from Temephos with Baseline Clothing, Maximum PPE, and Engineering Controls.

Exposure Scenario	Baseline Clothing		Maximum PPE		Engineering Controls	
	Total Daily Dose (mg/kg/day) [a]	MOE[b]	Total Daily Dose (mg/kg/day)[c]	MOE[d]	Total Daily Dose (mg/kg/day)[e]	MOE[f]
Mixer/Loader Exposure						
Mixing / loading liquids for aerial application	0.26	1.2	0.0015	190	0.00079	380
	0.52	0.58	0.0031	97	0.0016	190
Mixing / loading liquids for rights-of-way sprayer	0.030	10	0.00018	1,700	0.00009	3,300
Loading granulars for aerial application	0.012	25	0.0037	82	0.00025	1,200
	0.024	12	0.0073	41	0.00049	610
Applicator Exposure						
Applying liquids using fixed-wing aircraft	No data	—	Scenario not feasible	—	0.00046	650
	No data	—	Scenario not feasible	—	0.00092	330
Applying liquids using helicopter	No data	—	Scenario not feasible	—	No adequate data	—
Applying liquids using rights-of-way sprayer	0.013	22	0.003	100	Scenario not feasible	—
Applying granulars using fixed-wing aircraft	No data	—	Scenario not feasible	—	0.0048	63
	No data	—	Scenario not feasible	—	0.0095	31
Applying granulars using helicopter	No data	—	Scenario not feasible	—	No adequate data	—

12/15

Exposure Scenario	Baseline Clothing		Maximum PPE		Engineering Controls	
	Total Daily Dose (mg/kg/day) [a]	MOE[b]	Total Daily Dose (mg/kg/day)[c]	MOE[d]	Total Daily Dose (mg/kg/day)[e]	MOE[f]
Flagger Exposure						
Flagging liquid sprays	0.0011	280	0.0009	330	0.00002	14,000
	0.0021	140	0.0018	170	0.00004	7,000
Flagging granulars	0.003	99	0.0016	190	0.00006	4900
	0.006	49	0.0031	96	0.00012	2500
Mixer / Loader / Applicator						
Mixing / loading / applying sprays with a backpack sprayer	0.0033	91	0.0021	150	Scenario not feasible	—
Loading / applying granulars with a power backpack blower	No data	—	No data	—	Scenario not feasible	—
Loading / applying granulars with a belly grinder	0.14	2.2	0.11	2.7	Scenario not feasible	—
Applying granulars by spoon (by hand used as a surrogate)	0.0045	66	0.0025	120	Scenario not feasible	—

[a] Baseline dose represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab, and no respirator. Baseline total daily dose (mg/kg/day) = Baseline dermal daily dose (mg/kg/day) + Baseline inhalation daily dose (mg/kg/day).

[b] Baseline total MOE = NOAEL (mg/kg/day) / Baseline total daily dose (mg/kg/day).

[c] Maximum PPE represent coveralls over long pants, long sleeved shirt, chemical-resistant gloves and organic vapor respirator. Maximum PPE total daily dose(mg/kg/day) = Maximum PPE dermal daily dose (mg/kg/day) + Maximum PPE inhalation daily dose (mg/kg/day).

[d] Maximum PPE total MOE = NOAEL (mg/kg/day) / Maximum PPE total daily dose (mg/kg/day).

[e] Engineering Controls represent long pants, long sleeved shirt, no gloves in an enclosed cab or cockpit. Engineering Controls total daily dose (mg/kg/day) = Engineering Controls dermal daily dose (mg/kg/day) + Engineering Controls inhalation daily dose (mg/kg/day).

[f] Engineering Controls total MOE = NOAEL (mg/kg/day) / Engineering Controls total daily dose (mg/kg/day).

13913