afsset agence française de sécurité sanitaire de l'environnement et du travail

Synthèse des données disponibles en matière de propriétés physico-chimiques, toxicologiques et écotoxicologiques et évaluation des risques pour l'Homme et l'Environnement du Téméphos

Dossier réalisé dans le cadre d'une éventuelle demande de dérogation pour usage essentiel (directive biocides 98/8/CE)

Saisine n°2006/001

RAPPORT

Réalisé par la société CEHTRA

Mars 2006

TEMEPHOS

Evaluation for derogation for essential use

DATE

mars 2006

TEMEPHOS

Document content

TEMEPHOS

Summary of Physical-Chemical properties
Environmental information and risk assessment
Ecotoxicological information and risk assessment

DATE

Mars 2006

Temephos is an organophosphate insecticide which is widely used for larval control.

Several formulations are currently used in Europe for this purpose:

Commercial name	Active substance content	Formulation type	Authorised dose
Abate 500 E moustiques	500 g/L	EC	125 g/ha
Larviphos 500 EC	500 g/L	EC	125 g/ha
Abate 1% granule moustiques	500 g/L	EC	125 g/ha

As individual reports were not available to the reviewer, this evaluation is based on reviews previously conducted by different official bodies (references indicated in part I of the reference section). The references of individual studies, when found, are indicated in part II.

1. PHYSICAL CHEMICAL PROPERTIES

Melting point: 30-30.5 ºC
Boiling point: 120-125 ºC
Relative density: 1.32 g/cm^3
Vapour pressure: 7.17 10-6 Pa (20 ºC)
Henry`s law constant: 0.148 Pa m^3 mol -1
Appearance: Analytical grade: white crystalline solid (EPA)
Technical grade: brown, viscous liquid
Solubility in water: 0,03 mg/L (25 ºC)
Solubility in organic solvents: soluble in common organic solvents as diethyl ether, aromatic and chlorinated hydrocarbons. Solubility in hexane is 9.6 g/L.
Partition coefficient n-octanol / water: 4.91 Log Pow
Thermal stability: stable in normal conditions of temperature and pression
Flash point: >93℃ (closed cup)
Explosive properties: Non-explosive
Oxidizing properties: Non-oxidizing potential

2. ENVIRONMENTAL ENDPOINTS

Temephos is dissipated rapidly in soil half life between 12 days (laboratory data, Pesticide Manual) and 30 days (field data, INRA).

According to EPA study, in water-sediment system, half life of temephos has been evaluated to be of 27.2 days as a maximal value (anaerobic system). In water phase, the major identified metabolites were temephos sulphide phenol and temephos sulfone phenol, none of these bear the organophosphate group and have insecticide action. Two others none identified metabolites over passed the threshold of 10% AR in the water phase. In the

sediment phase a single major and non identified metabolite was detected at a level over 10% AR.

In water the main degradation pathway is photolysis with a half life of 15 days. The only major metabolite was temephos sulfoxide with a maximum occurrence of 11% AR.

At the reverse hydrolysis is not a major degradation pathway with a half life of 460 days at pH7. Hydrolysis increased with pH and no major metabolite was formed (EPA study)

Adsorption of temephos on soil is very high with Koc estimation from 8 421 to 31 800. Consistently with this important adsorption on soil and according to the regional approach with Mackay Model III, the major amount of temephos is likely to be encountered in soil (61% of total amount). Calculation of PEC ground water with FocusPELMO 3.3.2 showed that percolation of temephos is not significant. The threshold of 0.1µg/L is never reached.

Instantaneous and average Predicted Environmental Concentrations had been calculated, taking into account 6 applications rate of 125 g as/ha of temephos, with a time interval between 2 applications of 10 days. The results are the following:

	Initial PEC	PEC after last application	Time weighted average PEC	Units
Surface Water	42	114	55 (42 days)	µg/L
Sediment	-	1489	1467(42 days)	µg/kg dry sediment
Soil	0.014	0.050	0.036 (30 days)	mg/kg wet soil
Soil, agriculture	0.014	0.050	0.012 (180 days)	mg/kg wet soil
Soil, grassland	0.028	0.101	0.024 (180 days)	mg/kg wet soil

3. ECOTOXICOLOGICAL INFORMATION

Aquatic toxicity

The toxicity of temephos has been assessed towards various aquatic species.

Temephos shows a wide range of toxicity to aquatic organisms, depending on the formulation. Generally the technical grade active ingredient (TGAI) is moderately toxic and the emulsifiable concentrate (EC) formulations are highly to very highly toxic. The toxicities of the both formulations (EC and CG) are of the same order of magnitude. The formulation EC is slightly more toxic on Daphnia magna and on the pink shrimp.

The most sensitive species is the invertebrate species and *Daphnia magna* is extremely sensitive. Freshwater aquatic invertebrates such as amphipods are highly susceptible to temephos as are some marine invertebrates. The formulation EC is highly toxic to the saltwater species, the pink shrimp (LD_{50} 0.005 mg/l) and the Eastern oyster (LD_{50} 0.014 mg/L). The compound is nearly non-toxic to the bull frog with an LD_{50} of greater than 2000 mg/kg (Extonet PIP).

The most sensitive species of fish is the rainbow trout with a LD_{50} ranging from 0.16 (formulation EC) to 3.49 mg/kg (TGAI). Other LD_{50} values for temephos are close to or higher than 10 mg/L for the TGAI. Other LD_{50} values for formulation EC ranged from 1 to and 7 mg/L.

Temephos has the potential to accumulate in aquatic organisms (log P > 4). The bluegill sunfish accumulated 2,300 times the concentration present in the water. However, the exposure time under

conditions of uses ie in ponds or moving waters is supposed to be very low due to the very high adsorption onto colloids (Koc of ca. 22 000), and the DT_{50} in the water phase is expected therefore to be of few days or less. In addition, nearly 75% of the compound was eliminated from the fish after exposure ended.

Field studies were assessed by the US-EPA (Environmental Protection Agency). The majority of them are conducted in marine environment, which is not representative of the defended essential use: aquatic tested species are different and not always representative of the environment in which the product is applied. The tested doses are lower than the recommended dose. No additional details are available. However, these studies are important because they show that, in systems more complex than the laboratory conditions, there is an important recovery of the medium in the days or weeks which follow the applications.

These aquatic field studies have demonstrated that

1. Non-target aquatic invertebrate populations tend to reestablish to their original population levels within three weeks after application (Fortin, et. al., 1976). In another study, (Liem,et. al., 1976) Cladocerans appeared to be the most sensitive taking 7 days to recover after two applications. The other three representatives tested (copepods, ostracods, and damselflies) reestablished after 48 hours. In another study, (Siefert, et. al., 1986) observed recovery to the zooplankton community, but growth patterns were altered.

2. Ten applications of the granular 2G formulation did not appear to affect survival, growth, or behavior in fish, but growth retarding effects were observed after 4 applications of the liquid Abate 4E formulation (Forgash, et. al., 1976). No acute mortality, growth effects, or acetylcholinesterase inhibition was observed in bluegill (Siefert, et.al., 1981). No acute effects were observed in pinfish, sheepshead minnows, or snook (Pierce, et. al., 1988).

3. A Florida salt marsh field study concluded that there was no acute toxicity to adult fiddler crabs when salt marsh areas were treated three times at 2-week intervals at a rate of 27.7 g/ha (0.031 lb ai/A) (Pierce, et. al., 1989). However, continued work in 1990 concluded that there was a 30% mortality of the fiddler crab larvae (Uca rapax) and a 20% mortality of the mangrove tree crab larvae (Aratus pisonii) six hours after application (Pierce, et. al., 1990). A further 1993 study concluded that concentrations in salt marsh water resulting from an application rate of 27.7 g/ha) is suspected of having adverse effects on the fiddler crab and the mangrove tree crab.

A number of the conducted field studies relating to the fate of temephos under field conditions have verified much of the laboratory data which was reviewed. In addition, much information concerning residue concentrations in various media has been obtained.

Some field studies confirm the laboratory data which characterizes temephos as not persisting in the water column. According to one study temephos was not detectable (although no limit of detection (LOD) was given in the report) in tidal waters for more than 24 hours (Pierce, et. al., 1989). In a 1990 study residues in water after application ranged from 0.6 to 108 µg/L (Pierce et. al., 1990). Temephos concentration after 1 hour ranged from 3 to 10 µ/L at low tide in a mid-marsh site and 1.0 to 1.8 µg/L at high tide 5 hours after application in a 1993 study (Pierce, et. al., 1993).

A study conducted in 1972 by American Cyanamid concluded that temephos was rapidly adsorbed to sediment and converted to temephos sulfoxide. The measured concentration of temephos sulfoxide was 400 µg/L. There was also evidence to show that the liquid temephos formulation was up to 10 times more concentrated at the water's surface (Pierce et. al., 1990). Although not quantified, granular applications resulted in very low sub-surface concentrations (Carey, et. al., 1976).

Residues detected in sediment showed a wide range of results. A 1981 study did not detect temephos in sediment from 1 hour to 14 days (Siefert, et. al., 1986). A study from 1972 showed temephos sediment concentrations of 530 µg/L (American Cyanamide, 1972).

Another study showed a small but consistent amount of temephos in sediment for up to 168 hours (Pierce, et. al., 1989). The most recent study which monitored temephos sediment over a three year period (1995-97), did not detect temephos in the sediment after 24 hours (Pierce, et. al., 1998). Temephos was detected in various media substrates as well as sediment in many of the studies. A 1976 study found that Abate was transferred to surfaces of plant, algae, and other available materials within 24 hours (Carey et. al, 1976). Temephos was also found to remain on leaf surfaces and tidal pools for up to 72 hours, most, however, was dissipated into the estuary by tidal flushing (Pierce, et. al., 1988). Temephos residues found in leaf litter persisted up to 96 hours after application (Pierce, et. al., 1989). Small concentrations of temephos were also recovered from the fiddler crab and mangrove tree crab as well as the coffee bean snail, ribbed mussel, and sheepshead minnow, however quantities were not given (Pierce, et. al., 1990). Temephos residues in Crab ranged from 60 to 3,110

ppb after 2nd treatment (American Cyanamide, 1972). In a 1988 study temephos was not detected in oysters 72 hours after treatment (Pierce, et. al., 1988). Mussels did not accumulate in detectable quantities 24 hours after application in a 1989 study (Pierce, et al., 1989).

Effects of temephos on zooplanctan communities were studied in enclosures in a shallow eutrophic lake (Hanazato et al., 1989). The equivalent of 500 µg active substance was applied as Abate insecticide with 5% of temephos and containing 90% xylene.
In conclusion, the population of cladocerans is severely affected and did not show a recovery under the tested conditions (equivalent of 500µg/L and during maximum of 40 days). Less severe effects were noted for the other populations of copepods and rotiferans.

Risk assessment for aquatic organisms

The most sensitive species is the invertebrate species and *Daphnia magna* is extremely sensitive. Freshwater aquatic invertebrates such as amphipods are highly susceptible to temephos as are some marine invertebrates. EC_{50} = 0.011 µg/L (study conducted on *Daphnia magna* with formulation EC).

However, the size of the assessment factor depends on the confidence with which a $PNEC_{water}$ can be derived from the available data. Data are available for several fish species, for invertebrates, for molluscs and crustacean. Because the substance was tested on various species given information on the inter-species variation, it may lead to a lowered assessment factor :100.

Then, the calculated PNEC is: $PNEC_{temephos} = 1.1.10^{-4}$ µg/L

$PEC_{surface\ water}$ = 0.114 mg/L

PEC/PNEC using these conservative figures indeed would lead to a serious concern to aquatic organisms especially under the proposed conditions of uses. Aquatic invertebrates (or copepods) are considered the most sensitive species, to the exception of larvae of insects and will demonstrate these populations at risks when temephos is used as recommended. Due to its environmental properties (low solubility in water, high adsorption onto colloids, fast dissipation in water phase and in the whole water sediment system) the impact would be limited in time and recuperation was shown to occur within weeks. Therefore a PNEC mesocosm should be a more reliable end point to take into account these properties. Actually under the proposed conditions of use, not all the field data which could be used for a proper mitigation of risks or a refined risks assessment.

Non-target terrestrial animals toxicity

Because Temephos is only applied directly to water, it is not expected to have a direct impact upon terrestrial animals. Birds and mammals are not exposed to the formulation by feeding contaminated plants or plant part. Terrestrial animals may be exposed to temephos via drinking water.
Additionally, due to the tendencies for temephos to bioconcentrate, a piscivorous bird or mammal scenario was proposed to assess the risk to fish-eating birds and mammals.

Toxicity on birds

Tests with various wildlife species were conducted to assess the toxicity of temephos on birds. The toxicity data are reported in the following table. Acute and short-term toxicity data indicate that the bobwhite quail is the most sensitive species and demonstrate that temephos is relatively toxic by ingestion to birds with an acute LD_{50} of 27.4 mg/kg b.w. and a dietaty LC_{50} of 92 ppm mg/kg b.w.

The acute LD_{50} are relatively homogenous: 35.4 mg/kg b.w. for House sparrow, 31.5 mg/kg b.w. for Pheasant, 84 mg/kg b.w. for Japanese quail and 80-2150 mg/kg b.w. for Mallard duck.
The dietary LC_{50} are 50.1 ppm for pigeon, 150-170 ppm for Pheasant, 230-270 ppm for Japanese quail, 894-1400 ppm for mallard duck.

According to a study of oral ADME (adsorption, distribution, metabolism and excretion) in rats and pigs, excretion is complete within 96 h, 65% in faeces mainly as parent compound, 33% in urine, mainly as 4,4'-thiodiphenol.

No acceptable reproductive studies have been submitted, however, field data that has been submitted for review indicate that there is very little, if any, impact on birds.
A data based on the frequency of egg-laying during a long –term study is a NOEL of 1 ppm, i.e. 0.12 mg/kg b.w. (US-EPA database).

Toxicity on terrestrial vertebrates

Temephos is of low acute toxicity with oral LD50 which are all higher than 2000 mg/kg bw. Males are slightly more sensitive than females. According to the US-EPA, a NOEL of 0.3 mg/kg/d could be selected for the long-term risk assessment.

Risk for drinking water

Species that frequent open water bodies are liable to ingest residues of active substances that reach water. The exposure concentration in this case is equal to PECsurface water (0.114 mg/L).
In some situations, some species may obtain all their daily water demand directly from puddles of spray liquid. Because the product is directly applied on the water surface, the exposure concentration is calculated from the applied dose, without dilution or drift.

The daily water intake is calculated allometrically as follows (Calder and Braun 1983). Thus, the daily dose of active substance is calculated as (PECdrinking water * total water ingestion rate) / bodyweight.
The TERs (toxicity to exposure ratio) are calculated for the case of a 1200 g-bird and a 350 g-mammal for which long-term toxicity data are available.

Results of the calculation indicate that the amount of temephos that birds would be exposed to through normal water intake is much less than the potentially lethal concentration, and thus not of concern.

Risk for fish-eating birds

A value of log P_{ow} higher than 3 may signify a bioaccumulation risk through the trophic chain. The log P_{ow} of temephos is 4.91. Then the bioaccumulation risk is assessed through two food pathways by birds according the Guidance Document of the European Commission SANCO/4145.

Residues in fish may be estimated from $PEC_{sw, ,twa}$ at 21 days (77 µg/L) and daily doses are calculated for a 1000 g-bird and a 3000 g-mammal, te relevant species recommended by the guidance document (SANCO/4145/2000).

The calculated TERs are widely lower than the trigger value. Therefore, a potential risk for fish-eating birds and mammals is predicted.

However field data (Forgash, 1976; Pierce et al., 1990 Pierce et al., 1989 described in point 1.2.1) that have been submitted for review indicate that there is very little, if any, impact on birds. In fact the mitigation of this calculation includes that the dissipation in water of the active substance is rapid, the depuration of the active substance present in fish tissues is also fast and nearly complete, therefore chronic exposure is not likely to occur limiting the potential for secondary poisoning or effects to fish eating birds as well as mammals. (US-EPA).

Toxicity to bees

The acute contact LD_{50} is 1.55 µg a.s./bee. Because the product is applied directly on water, we consider that the risk for bees is due to the contamination on the adjacent zone of the treated area by

the drift of spraying. the risk towards bees may be assessed with the calculation of hazard quotients (HQ), based on the ratio of the maximum applied dose (in g a.s./ha) to the LD_{50} (in µg a.s./bee).Results showed that there is no potential risk for bee populations.

TEMEPHOS

Summary of toxicological and human exposure information

DATE

mars 2006

Temephos is an organophosphate insecticide which is widely used for larval control.

Several formulations are currently used in Europe for this purpose:

Commercial name	Active substance content	Formulation type	Authorised dose
Abate 500 E moustiques	500 g/L	EC	125 g/ha
Larviphos 500 EC	500 g/L	EC	125 g/ha
Abate 1% granule moustiques	500 g/L	EC	125 g/ha

As individual reports were not available to the reviewer, this evaluation is based on reviews previously conducted by different official bodies (references indicated in part I of the reference section). The references of individual studies, when found, are indicated in part II.

1. TOXICOLOGICAL INFORMATION:

Temephos is an organophosphate insecticide.
Its mechanism of toxicity is primarily by inhibition of the cholinesterase enzymes. This effect is commonly observed in both humans and animals when exposed repeatedly to temephos at sufficient levels.
Temephos was found to be of low acute toxicity with oral and dermal LD50 which are all more than 4000 mg/kg bw with the exception of one by oral (LD50 = 1300 mg/kg bw for rat female) dermal (LD50 = 1300 mg/kg bw for rabbit) or inhalation route (LC50 > 1.3 mg/L). Temephos is slightly irritating to eyes but not irritating to rabbits skin. The compound is not a dermal sensitizer.
It is readily absorbed and rapidly distributed among tissues and eliminated with a half-time of about 10 hours. By dermal application, the absorption of temephos on rat skin is estimated to be 38%.
By repeated exposure, temephos induces an inhibition of the cholinesterase activity. This effect was reported in both human volunteers and laboratory animals at similar levels. The duration of exposure is deemed to have an influence on the occurrence of this effect. When exposed for 44 days, rats exhibited an inhibition of the red blood cell cholinesterase activity at 10 mg/kg bw/d, whereas rats exhibited an inhibition of the same enzyme from 0.9 mg/kg bw/d when exposed for 90 days. Another significant effect reported in the 90-day rat study consisted of a decrease of the liver weight at a dose of 17.5 mg/kg bw/d, but this effect was low in magnitude and was not demonstrated in a 2-year study with rats exposed at a similar level.
In the only performed carcinogenic study, temephos was not found to induce carcinogenic effects in rats. Temephos is not deemed to induce mutagenic effects, but the studies are too few and available results not sufficiently described. The reproduction toxicity studies available did not exhibit any reprotoxic effects of temephos, but these studies are old and found to be not very reliable. In studies performed with hens, which suffered some limitations, temephos was not showed to induce delayed neurotoxicity.

2. OVERALL EVALUATION AND DERIVATION OF RELEVANT DERMAL PENETRATION, RELEVANT NOAEL FOR OPERATOR RISK ASSESMENT

A 38% dermal absorption has been determined in rat. However, no information is available on the tested formulation which is likely to be a solid formulation.

Considering the high level of penetration, the non-GLP character of the study and the fact that only a summary is available, a dermal penetration factor of 50%, based on an expert judgement, is proposed for the operator exposure evaluation.

Operators are likely to be exposed several days per week during several weeks, if not months in case of important outbreak of vector born disease.
The most sensitive adverse effect appears to be RBC ChE inhibition.
One of the most relevant studies is the 28-day human study by oral route (Laws et al.
1967). In this study, no clinical symptoms or RBC ChE inhibition have been reported at a daily dose of 0.9 mg/kg bw/day.
This study is consistent with the 44-day rat study in which the NOAEL is 1 mg/kg bw/day (Gaines et al., 1967) which tends to demonstrate that rat and human are similarly sensitive to ChE inhibition effects of temephos. However, exposure duration may be short compared to expected duration and in the 90-day repeated oral rat study, 0.9 mg/kg bw/day appears to be a LOAEL. In the repeated study (cf p 5), 0.3 mg/kg bw/day is the NOAEL.

NOAEL was fixed at 0.3 mg/kg bw/day.

3. SELECTION OF THE MOST RELEVANT ASSESMENT FACTORS (AF) FOR OPERATOR RISK ASSESSMENT

Assessment factors applied for the calculation of refMOS for subchronic toxicity

Assessment factors	Value
Interspecies	1 Several studies are available in Human. They all indicate that, as for most organophosphate insecticides, rat and human have similar sensitivity)
Intraspecies	5 (workers are considered as a more homogeneous population than the general population. Although there is no indication that some parts of the population are more sensitive to this type of insecticide, a factor of 10 can be used for bystander)
Exposure duration	2 (NOAEL clearly tends to decrease with the duration of the study and exposure of the operators may last more than 90 days)
Route-to-route extrapolation	1 (taken into account by dermal penetration)
Quality of the database	3 (non GLP studies and only summaries available)
refMOS	30

4. HUMAN EXPOSURE INFORMATION

1- Operator

The following conclusions can be drawn for well protected operator (MOS>30 are considered acceptable) and using models available for pesticide uses:

MOS according to the scenario and the model used with the maximum precautions:

Scenario	POEM	BBA	EURO POEM II	PHED
Granules applied with a Spoon	No model	No model	No model	No model
Pre-Pressure Hand Held	0.62	12.3	No model	No model
Air Assisted Spray	0.6	9.6	No model	78.34
Non Air assisted Spray	No model	No model	0.93	20.7
Aerial Application	No model	No model	No model	108.3

The use of risk mitigation measures for occupational handlers (i.e., maximum PPE and engineering controls) results in **MOS greater than the RefMOS of 30 with at least one model** for the following scenarios:

- Air Assisted Spray on quad bike or caterpillar without cab.
- Aerial application

The use of risk mitigation measures form occupational handlers (i.e., maximum PPE and engineering controls) results in **MOS less than the RefMOS of 30 whatever the model used** for the following scenarios:

- Pre-pressure hand held equipment with 5L tank.
- Non air assisted Spray monted on a 4WD pick-up.

The use of risk mitigation measures form occupational handlers (i.e., maximum PPE and engineering controls) could not be evaluated for the following scenario:

- Granules with a spoon.

2- Bystanders

For re-entry exposure, there is probably no exposure with granule and when the product is applied using pre-pressure hand held equipment with 5L tank.
Exposure when using non air assisted Spray mounted on a 4WD pick-up is considered as acceptable.

When using air Assisted Spray on quad bike or caterpillar, the models gives unacceptable exposure but this is mainly due to the use of a very conservative model.

Exposure by direct spray during aerial application is expected to be borderline, then exposure due to simple drift should be acceptable.

TEMEPHOS

Physical and chemical properties

Environmental Risk Assessment

DATE

March 2006

LIST OF ABBREVIATIONS

as	active substance
PEC	Predicted Environmental Concentration
TGD	Technical guidance document
TWA	Time Weighted Average

1. MEMBER STATE

FRANCE

2. ACTIVE SUBSTANCE

2.1. COMMON NAME

Temephos

2.2. EC AND/OR CAS N°

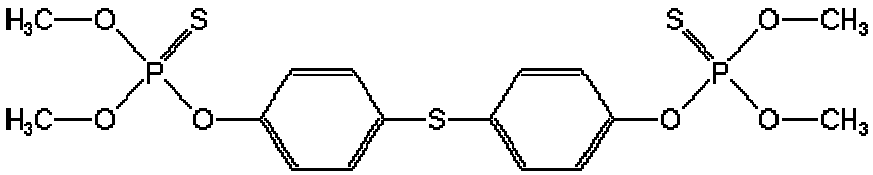
CAS Number: 3383-96-8

EC Number: 222-191-1

2.3. MOLECULAR AND STRUCTURAL FORMULA (INCLUDING DETAILS ON ISOMERIC COMPOSITION) ; MOLECULAR MASS

Molecular formula: $C_{16}H_{20}O_6P_2S_3$
Molecular mass: 466.5 g/mol

Structural formula:



3. PHYSICAL CHEMICAL PROPERTIES IN ACCORDANCE WITH ANNEX IIA POINT III, TO DIRECTIVE 98/8/EC AS APPROPRIATE

3.1. MELTING POINT, BOILING POINT, RELATIVE DENSITY (ANNEX IIA POINT III. 3.1)

According to Pesticide Manual, Thirteenth edition
Melting point: 30-30.5°C for pure active substanc e.
Boiling point: 120-125°C

Relative density: 1.33 at 20°C (BASF)

3.2. VAPOUR PRESSURE (PA) (ANNEX IIA POINT III. 3.2)

Vapour pressure: 9.5 10^{-6} Pa at 25°C (EPA)

Henry constant: 0.148 Pa.m3.mol-1 EPA)

3.3. APPEARANCE (PHYSICAL STATE, COLOUR) (ANNEX IIA POINT III. 3.3)

Physical state:
Analytical grade: white (BASF) crystalline solid (EPA)
Technical grade: brown, viscous liquid (Gharda Chemicals ltd)

Smell: Weak smell (Gharda Chemicals ltd), Typical of mercaptan containing organic chemicals (BASF)

3.4. ABSORPTION SPECTRA (UV/VIS, IR, NMR), AND A MASS SPECTRUM, MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, WHERE RELEVANT (ANNEX IIA POINT III. 3.4)

Intense mass spectral peaks: 466 m/z (100%), 125 m/z (51%), 93 m/z (38%) and 47 m/z (35%) (HSDB)

3.5. SOLUBILITY IN WATER INCLUDING EFFECT OF PH (5 TO 9) AND TEMPERATURE SOLUBILITY, WHERE RELEVANT. (ANNEX IIA POINT III. 3.5)

Solubility in water is very low:
Solubility in water = 0.03 mg/L at 25°C (Pesticide manual, thirteenth edition)
Solubility in water = 0.01 mg/L (EXTOXNET)

Temephos is soluble in common organic solvents, as diethyl ether, aromatic and chlorinated hydrocarbons. Solubility in hexane is 9.6 g/L (Pesticide manual, thirteenth edition)

3.6. PARTITION COEFFICIENT N-OCTANOL/WATER, INCLUDING INFLUENCE OF PH (5 À 9) AND TEMPERATURE (ANNEX IIA POINT III. 3.6)

Temephos partition coefficient, log K_{ow} = log P= 4.91 (Pesticide manual, thirteenth edition)

3.7. THERMAL STABILITY, IDENTITY OF RELEVANT BREAKDOWN PRODUCTS (ANNEX IIA POINT III. 3.7)

Temephos is stable in normal conditions of pressure and temperature. By thermal decomposition oxides of phosphorus and sulphur may be formed. (Gharda Chemical ltd)

3.8. FLAMMABILITY INCLUDING AUTO-FLAMMABILITY AND IDENTITY OF COMBUSTION PRODUCTS (ANNEX IIA POINT III. 3.8)

Temephos may burn, but does not readily ignite (NEW JERSE hazardous Substance Fact Sheet)

By combustion, oxides of phosphorus and sulphur may be formed from temephos (Gharda Chemical ltd).

3.9. FLASH-POINT (ANNEX IIA POINT III. 3.9)

Flash point > 93℃ (closed cup) BASF

3.10. SURFACE TENSION (ANNEX IIA POINT III. 3.10)

Nor required as solubility in water <1 mg/L

3.11. EXPLOSIVE PROPERTIES (ANNEX IIA POINT III. 3.11)

Temephos is not explosive (BASF)

3.12. OXIDISING PROPERTIES (ANNEX IIA POINT III. 3.12)

Temephos is not expected to have oxidising potential (BASF)

3.13. REACTIVITY TOWARDS CONTAINER MATERIAL (ANNEX IIA POINT III. 3.13)

No study available, however no adverse data are existing, demonstrating any specific reactivity towards container materials

4. ENVIRONMENTAL ENDPOINTS

Environmental endpoints presented in this section refer to directive 98/8. Annex IIA – Part VII Points 7.6 to 7.7.

4.1. DEGRADATION (ANNEX IIA – PART VII POINT 7.6)

4.1.1. Biotic (Annex IIA – Part VII Point 7.6.1)

4.1.1.1. Degradation in soil under Aerobic conditions

Information available on aerobic soil degradation is summed up in the table 4.1.1.1-1

Table 4.1.1.1-1: aerobic soil degradation of temephos

Temephos half life in soil	Information source
DT_{50} in soil =**12 days**	Pesticide manual, thirteenth edition,2003
Degradation rate in laboratory under aerobic conditions: **DT_{50} <14 days**	INRA - Agritox
Degradation rate in field conditions: **DT_{50}=30 days**	INRA - Agritox
A half life of **30 days in soil** has been estimated, indicating a low to moderate persistence (Wauchope et al., 1992)	EXTOXNET

The range of values for degradation rate available in soil is 12 to 30 days demonstrating that temephos is dissipated rapidly in soil environment.

4.1.1.2. Degradation in soil under Anaerobic conditions

No reliable data.

4.1.1.3. Aquatic metabolism under anaerobic conditions

According to the EPA study *temephos applied at a concentration of 29.4 µg/g to anaerobic **water/sediment system** underwent degradation. The initial degradation/dissipation half-life was calculated as **12.2 days** (first phase: 0 to 29*

*days) and the terminal, longer degradation/dissipation half-life of **27.2 days** (30 to 121 days and beyond).*

The mean total radioactivity recovered from the water/sediment systems ranged between 89 to 103 % of applied radioactivity.

*In the aqueous phase, **parent Temephos** decreased from 59.9% at "day 0" (2 hours after application) to 7.9% by one week and below 1.6% after 90 days. In the sediment phase, Temephos decreased from 31.4% at "day 0" to 2.8% at day 90.*

Formation of CO_2 was not detected at any time during the course of the study.

*In the aqueous phase, **Temephos sulfoxide** increased from 1.3% at "day 0," then decreased to below 1.0% but reached 3.4% after 205 days. **Temephos sulfone** increased from 0.9% at "day 0," reached a maximum of 3.3% by 7-days and remained below 1% throughout the duration of the study. In the sediment phase, these two degradates were detected at below 1% of the applied radioactivity at all times.*

The major identified degradates were Temephos sulfide phenol and Temephos sulfone phenol. None of these two degradates bear the organophosphate group. Therefore they do not have insecticide action.

*In the aqueous phase, **Temephos sulfide phenol** increased steadily from non-detected at "day 0" to a maximum of 13.8% after 373-days. In the sediment phase, this degradate was not detected until 29-days at 1.8% maximum and declined to non-detected afterwards.*

***Temephos sulfone phenol** increased steadily from 0.2% at "day 0" to 28.9% by day 61 and declined steadily to below 10% after 121 days. In the sediment phase, Temephos sulfone phenol was not detected until 7 days post-fortification (3.0%) and reached a maximum of 4.2% by day 15 but steady declined afterwards to 2.2% and 1.8% by days 90 and 121, respectively.*

There is a major uncertainty in the identity of three degradation products labelled as "Metabolite A," "Metabolite B," and "Metabolite C." These degradation products partitioned predominantly to the aqueous phase and not to the sediment, where none of them were detected at concentrations greater than 1.1 % of the applied at all times.

*In the aqueous phase, the degradation product labelled as "**Metabolite A**" was detected first at 1.5 clays after application at 8.9% but declined to 1.0% by day 121 and was not detected afterwards.*

*"**Metabolite B**" was first detected at 1.9 by day 15. It steadily increased to 37.2% by day 373.*

*"**Metabolite C**" was not detected at 0.9% until 29 days post-application. It increased steadily to a maximum of 13.4% by day 121. Beyond 121 days the concentration of this degradation product steadily declined to 5.4% by day 373.*
The higher concentration of these unidentified degradates in the aqueous phase suggests that these degradates do not adsorb strongly to the sediment phase and that they may be associated with polar degradates. Polar degradates may form from oxidation of the sulfide linkage with or without oxidation the sulfur present in the organo-thiophosphate groups. Products containing the organothiophosphate

groups can form by cleavage from parent Temephos with or without replacement their sulfur by oxygen and with or without oxidation of the sulfide linkage (i.e., formation of a sulfoxide or a sulfone).

Details on the anaerobic water sediment study are summed up in the following table:

Table 4.1.1.3-1: details on anaerobic water sediment study from EPA

Temephos DT_{50} (Total system, biphasic degradation)	12.2 days (initial phase) and 27.2 days (terminal phase)
Incubation time	373 days
Recoveries	88.6% to 103.2%
Aqueous phase	Aqueous phase: Max. 37.2% (Day 29)
	Org. phase: Excluding 62.8% (day 0), 23.9- 69.2% (Day 7-373)
Sediment	Org. extract: 32.8-53.4% (Day 0-7) declined to less than 10% (Day 121)
	Non extractable: Max. 3.9% (Day 373)
Volatile org. compounds and $C0_2$	No
Temephos and metabolites in water (%AR)	Temephos: 59.9% (Day 0), 7.9-1.1 (Days 7-373)
	Temephos sulphide phenol: 7-13.8% (Day 205-373)
	Temephos. sulfone phenol: 8.8-28.9% (Day 7-61), 15.6-8.7% (Day 90-160), 5% (Day 373)
	Temephos sulfone <5%
	Temephos sulfoxide: < 5%,
	Unknown A: 8.9% (Day 15), 7.5% (Day 29)
	Unknown B: 14.5-37.3% (Day 61-373)
	Unknown C: 7.3-13.4% (Day 61- 121), 8.1-5.4% (Day 160-373)
Temephos and metabolites in sediment (%AR)	Temephos: 31.4-47.9% (Day 0-7), 37.8-1.5 (Days 15-121)
	Metabolites: < 5%

Conclusion:

Degradation half life of temephos in anaerobic aquatic total system has been evaluated to 12.2 days in the initial phase and 27.2 days in the terminal phase. Temephos in the water phase decreased from 59.9% at day 0 to 7.9% AR at day 7, and reached concentration up to 47.9 % in the sediment at day 7.

There is no major metabolite (>10%) in the sediment phase, whereas in the **aqueous phase 4 major metabolites** were detected (2 identified and 2 none identified).

The major identified degradates were temephos sulphide phenol and temephos sulfone phenol. Temephos sulfone phenol is rapidly formed (8.8% after 7 days), while temephos sulphide phenol is a late metabolite. None of these two degradates bear the organophosphate group; therefore they do not have insecticide action.

Two others major metabolites detected but not identified, named unknown B and C, reached values up to 37.3% AR at day 61 for metabolite unknown B and 13.4% AR at day 121 for metabolite unknown C.

4.1.1.4. Aquatic metabolism under aerobic conditions

According to the EPA study, *temephos applied at a concentration of 31.7µg/g to aerobic water/sediment followed first-order kinetics, with a half-life of* ***17.2 days.***

Mean total radioactivity ranged from 91 to 101% of the applied radioactivity.

Volatile organic compounds and "CO_2 reached 0.2% and 4.6%, respectively, by day 30.

In the aqueous phase, ***Temephos*** *decreased from 33.5% of the applied at day 0 to 0.3% at 30 days. In contrast, Temephos in the sediment phase increased from 51.9% at day 0 to a maximum of 72.9% at day 2, decreasing to 21.7% by day 30. Decrease of Temephos in the aqueous phase parallels partition to the sediment phase and increase in degradation.*

Temephos sulfoxide, Temephos sulfide phenol, and Temephos sulfone phenol were identified in both the water and sediment phases.

Temephos sulfoxide *was found at a maximum of 5.4% in the sediment (day 4) and 3.6% in the water by day 2.*

The maximum ***Temephos sulfone phenol*** *detected in the water phase was 6.3% (day 14) and 5.4% in the sediment (day 1).*

Temephos sulfide phenol *in the sediment increased steadily, reaching a maximum 4.8% at day 30 but remained at 1.7% or below in the water phase at all sampling times shorter than 30 days.*

*An unknown metabolite ("****Unknown 1****") in the sediment reached a maximum of 13.2% on day 14. Uncharacterized degradates in the aqueous phase increased steadily to 17% by day 30 and are presumed to be highly polar, weakly adsorbing products.*

Details on the aerobic water sediment study are summed up in the following table:

Table 4.1.1.4-1: details on aerobic water sediment study from EPA

DT50 (Total system)	17.2 days (1st order kinetics for aqueous phase + org. extr. of sed.)
Incubation time	30 days
Recoveries	101.1% to 80.7% (Days 0-30)
Aqueous phase	Aqueous phase: Max. 17.4% (Day 30);
	Org. phase: 38-9.8% (Days 0-30)
Sediment	Org. Extract: 63.1-79.4% (Days 0-2) and 77.8-42.2% (Days 4-30);
	Non extractable: Max. 6.5% (Day 30)
Volatile org. compounds and CO2	Max 0.2% and 4.6% (Day 30)

Temephos and metabolites in water (% AR)	- Temephos: 33.5-0.3% (Days 0-30) - Temephos sulfoxide: < 5% - Temephos sulphide phenol: < 5% - Temephos sulfone phenol: 5.2-6.3% (Days 4-14) - Unknown 1: < 5% - Unknown 2 (org. extractable): < 5%
Temephos and metabolites in sediment (%AR)	- Temephos: 51.9- 72.9% (Days 0-2), 67-21.7% (Days 4-30) - Temephos sulfoxide: 5.4% at Day 4 - Temephos sulphide phenol: < 5% - Temephos sulfone phenol: 5.4% at Day 1 - Unknown 1: 6.4-13.4% (Days 8-14), 12.9-9.8% (Days 21-30)

Conclusion:

Degradation half life of temephos in aerobic water sediment total system has been evaluated to 17.2 days.

In water, the major fraction is the parent and there is no major metabolite (>10% AR).

In sediment, the major fraction is the parent and there is no major metabolite except one unidentified metabolite detected at maximum level of 13.4% on day 14.

4.1.1.5. Ready biodegradability (Annex IIA – Part VII Point 7.6.1.1)

Temephos is not classified as a ready biodegradable substance.

4.1.1.6. Inherent biodegradability, where appropriate (Annex IIA – Part VII Point 7.6.1.2)

No data available

4.1.2. Abiotic (Annex IIA – Part VII Points 7.6.2)

4.1.2.1. Hydrolysis as a function of pH and identification of breakdown products (Annex IIA – Part VII Point 7.6.2.1)

According to the abiotic hydrolysis study (EPA), *abiotic hydrolysis is not a major degradative pathway for temephos. But there is evidence that there is a pH-related trend in the reported, extrapolated half-lives and pseudo first-order rate constants, with the half-lives decreasing with increasing pH. However, there is a great uncertainty in these calculated half-lives because they are extrapolated well beyond the 30-days duration of the study.*

The only major degradate identified was the oxidation product temephos sulfoxide at less than 10% and only at pH 9.

pH 5 at 25°C DT50=1030 days
k= 0.00067 $days^{-1}$

pH 7 at 25°C DT50=460 days
k= 0.0015 $days^{-1}$

pH 9 at 25°C DT50=86 days
k= 0.0081 $days^{-1}$

Those data are consistent with values published in INRA Agritox database.

4.1.2.2. Photo-transformation in water including identity of the products of transformation (Annex IIA – Part VII Point 7.6.2.2)

According to the study on direct photolysis in water (EPA), direct photolysis is an important degradation route for Temephos in water.

The reported calculated half-life of ^{14}C-Temephos under 24 hours of continuous irradiation (xenon arc lamp) is **15 days** ($k = 4.3 \times 10^{-2}$ days), for 30 µg/L (ppb) of Temephos in unbuffered solutions at pH 6.5 to 7.0 and at 25°C.

The major degradate identified was **temephos sulfoxide at 11%** maximum from 3-days after beginning of exposure and throughout the 14-days duration of the study, in contrast to less than 4% in dark control solutions.

4.2. ADSORPTION/DESORPTION SCREENING TEST (ANNEX IIA – PART VII POINT 7.7)

According to Pesticide manual, thirteenth edition, adsorption of temephos on soil is characterised by:
K_d = 73 in loamy sand
K_d = 244 in silt loam
K_d = 541 in loam
K_d= 130 in sandy loam
Adsorption in organic mater is very high

Values reported in the document by EPA are the same than the values mentioned in the pesticide manual 2003. The K_{oc} mean value we can therefore calculate is **22 770**.

Table 4.2-1: Adsorption values from EPA Study

	Loamy sand	**Sandy loam**	**Silt loam**	**Loam**
pH	6.0	6.4	6.9	7.0
$K_{ads,F}$	73	130	244	541
1/n	0.58	0.62	0.72	0.78
K_{oc}	18 250	16 250	31 800	22 800

No targeted mobility data is available on the major degradation products of temephos but data from the aquatic metabolism studies suggest that oxidized, polar products of temephos may be weakly adsorbed to sediment as these degradates tend to partition into the water phase.

Additionally, BASF reported 2 more data for loamy sand and clay soils. The calculated K_{oc} mean from those data is 22 800, close to the average calculated above from EPA study.

Table 4.2-2: adsorption values from BASF

	Loamy sand	Clay
$K_{ads,F}$	115	1 390
1/n	0.695	0.869
K_{oc}	8 241	37 356

5. ENVIRONMENTAL FATE ASSESMENT

All assessments are made for an application rate of 125g as/ha.

5.1. PRELIMINARY APPROACH

As a first approach, a regional Predicted Environmental Concentration (PEC) can be calculated with the Mackay box model-level III (Fugacity based Environmental Equilibrium Partitioning Model, Mackay, 2001).

A Level III describes a situation where chemical is continuously discharged at a constant rate and achieves a steady state condition in which input and output rates are equal. The loss processes are degrading reactions and advection. Equilibrium between media is not assumed and, in general, each medium is at a different fugacity. A mass balance applies not only to the system as a whole, but to each compartment. Rates of intermedia transport are calculated using default values which contain information on mass transfer coefficients, areas, deposition and resuspension rates, diffusion rates, and soil runoff rates.

The Mackay model Level III had been activated with EPIWIN interface (v3.12). Most of the parameters used in the model are default values from EPIWIN software except for physical and chemical properties and half lives values.

Table 5.1-1: Non default values involved in Mackay level III calculation with EPIWIN

Physical and chemical properties	
Vapour pressure (mm Hg)	$7.17\ 10^{-8}$
Melting point (°C)	30.25
Boiling point (°C)	122.5
Henry law constant 'atm m^3 mole	$1.17\ 10^{-6}$
Log Low	4.91
Water solubility (mg/L)	0.03
Degradation rates (hours)	
Air	0.946
Water	413
Soil	720
Sediment	24000
Adsorption	
Koc	8241

The resulting partitioning between environmental compartments is presented in the table 5.1-2.

Table 5.1-2: of level III fugacity model :	Emission (kg/h)	Mass amount (%)
Air	1000	0.09
Water	1000	21.2
Soil	1000	**61.6**
Sediment	0	17.1

Conclusion: according to the Mackay fugacity model III, at a regional scale, temephos is likely to reach maximal amount in soil.

5.2. ROUTE AND RATE IN AIR

The Focus Air group proposed trigger values of vapour pressure to establish whether a substance is likely to reach the air or not. It is considered that a vapour pressure below 10^{-4} Pa at 20°C, do not allow significant volatilisation of the substance. According to the low vapour pressure reported, 7.17 10-6 Pa (20°C) temep hos volatilisation is not significant.

The Atmospheric Oxidation Program for Microsoft Windows (QSAR) estimates the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic chemicals. It also estimates the rate constant for the gas-phase reaction between ozone and olefinic/acetylenic compounds. The rate constants estimated by the program are then used to calculate atmospheric half-lives for organic compounds based upon average atmospheric concentrations of hydroxyl radicals and ozone.

AOPwin v1.91 software calculation provides the following estimations:
K_{O3}: no ozone reaction
K_{OH} rate =$135.61e^{-12}$ cm^3/molc/sec
DT_{50} in air = 0.948 hours

Even if light volatilisation occurs, degradation rate in air is so important that PEC_{air} is negligible.

5.3. ROUTE AND RATE IN WATER

5.3.1. Fate in surface water

The abiotic hydrolysis study from EPA (§ 4.1.2.1) indicates a stability of temephos with a DT_{50} of 460 days at pH7. There is no major metabolite detected.

According to all information available and reported above (§4), we can assess that the main degradation pathways for temephos in water are direct photolysis with a half life of 15 days and biodegradation in aerobic water system with a half life of 17.2 days.

From direct photolysis, the major degradate identified is temephos sulfoxide with a maximum level of 11% of applied radioactivity (AR) between day 3 and 14 of incubation. In the aerobic water system, temephos sulfoxide is not a major metabolite (< 5.4%) but other unknown metabolite is detected in sediment at a level over 10% AR, with a maximum of 13.4%.

Under anaerobic conditions in the water system, 4 metabolites were over passing the threshold of 10% AR during incubation. Two of them were identified as temephos sulphide phenol and temephos sulfone phenol with respective maximum level during incubation of 13.8% and 28.9%. The two others were not identified, called unknown B and C they respectively reached maximum level of 37.3% and 13.4% respectively.

Insecticide Risk assessment for surface water is supposed to be done according to the Technical guidance document (TGD) for biocide. As no Environmental Scenario Document (ESD) was available for insecticide use like temephos therefore EUSES model has not been used and a simplified emission scenario had been considered.

With this simplified emission scenario and from the half lives mentioned above, a predicted environmental concentration (PEC) in surface water can be evaluated according to the document of environmental risk assessment published by toxicity commission, Revision 6.5 of October 2004.

Calculations take into account the maximal application rate for temephos of 125g as/ha and the maximal number of 6 applications with an interval between applications of 10 days; Assuming that 100% of the substance applied reach the water system, PEC in surface water have been calculated.

A stagnant water sediment system of 1 hectare, 30cm depth of water is considered.

$PEC_{1\ application}$ (µg/L) = application dose (as./L) *1/3

$PEC_{after\ last\ application}$ (µg/L) = $PEC_{1appplication}$ + $PEC_{residual\ previous\ applications}$

From the $PEC_{1\ application}$, an average concentration (TWA) is also calculated on a duration including the whole duration of applications, plus 42 days after the last application. This way, the PEC_{twa} takes into account:

- The degradation of the substance
- The number of applications
- The interval between applications

The PEC_{twa} calculation is made according to the following equation:

$PEC_{twa} = PEC * (DT_{50}/d* Ln2)*(1-e^{(-d*Ln2/DT50)})$

Basically, when a dissipation in water phase is occurring the area under the curve is calculated and divided by the number of days and therefore it corresponds to a constant exposure over the timing considered.

The initial PEC in surface water is estimated to be 41.67µg/L after the first application and 114.43µg/L after 6 applications of temephos.

Table 5.3.1-1: parameters involved in the calculation of $PEC_{surface\ water}$

$DT_{50\ water}$:	17.2	days
k :	0.040	$days^{-1}$
Application dose :	125	g as/ha
Effective dose	100	%
Number of applications :	6	-
Interval between applications :	10	days
Water depth :	30	cm

Table 5.3.1-2: results of $PEC_{surface\ water}$ calculation

$PEC_{water,,\ 1\ application}$:	**41.667**	µg/L
$PEC_{water,\ last\ application}$:	**114.429**	µg/L

$PEC_{surface\ water,}$	**Days after last application**	**Actual Concentration (µg/L)**	**Time weighted average Concentration (µg/L)**
Initial	0	114.429	114.429
Short term	1	109.909	112.154
	2	105.568	109.939
	4	97.393	105.682
Long term	7	86.302	99.705
	14	65.089	87.451
	21	49.091	77.206
	28	37.024	68.598
	42	21.060	55.164

5.3.2. Fate in ground water

Temephos application process may entail a drift of temephos on soil. The application mode supposed to generate the maximal drift is the aerial spraying. This scenario has been selected as the drift worst case. According to AgDrift model (SDTF, 1999), a drift percentage of 33.2% is associated to the aerial application.

To assess the leaching potential of Temephos, simulations were conducted using FOCUSPELMO 3.3.2 software model and following the FOCUS working group recommendations. Standard FOCUS groundwater scenarios were used and aimed to

represent a mean case situation. Objective is not to represent specific climatic/soil conditions for Member States, but to provide the prediction of the leaching potential of active substance under widely differing conditions present in Europe, where acceptable scenarios (in terms of Regulatory acceptance) may exist for the proposed uses. If the prediction of the presence of an active ingredient and/or its metabolites in groundwaters is leading to concern, national scenarios should be tested towards regulatory cut-off criteria. The software and the scenarios properties are described in the FOCUS document (FOCUS, 2000). Location of the scenarios and the main properties are shown in the Table below. The input data and the results are indicated below.

Figure 5.3.2-1 Location of the 9 groundwater scenarios (from FOCUS, 200[1])

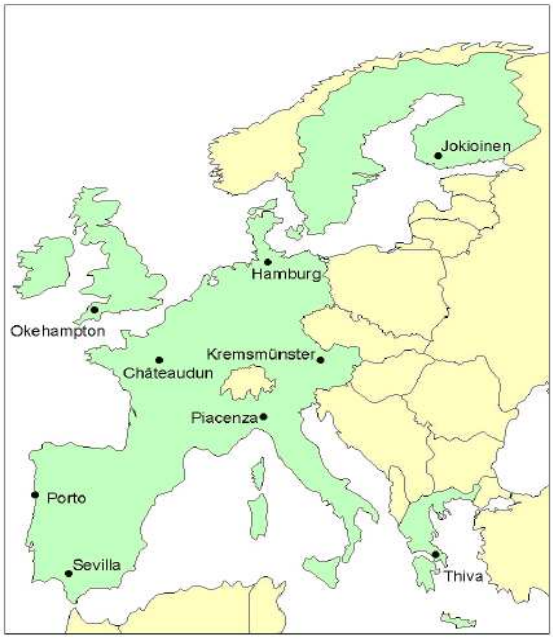


Table 5.3.2-1: Properties of the 9 groundwater scenarios

Location	Mean Annual Temp. (°C)	Annual Rainfall (mm)	Topsoil	Org. matter (%)
Châteaudun	11.3	648 + I*	Silty clay loam	2.4
Hamburg	9.0	786	Sandy loam	2.6
Jokioinen	4.1	638	Loamy sand	7.0
Kremsmünster	8.6	900	loam/silt loam	3.6
Okehampton	10.2	1038	loam	3.8
Piacenza	13.2	857 + I*	Loam	1.7
Porto	14.8	1150	loam	6.6
Sevilla	17.9	493+ I*	Silt loam	1.6
Thiva	16.2	500 + I*	loam	1.3

* I: Irrigation

The PEC_{gw} were calculated with all scenarios.

[1] SANCO/321/2000 rev.2: FOCUS groundwater scenarios in the EU review of active substances.

Table 5.3.2-2: Input parameters for PECgw simulations

Parameters	Temephos
DT_{50} (days) soil max	Field : 30
Koc (Kom) min	8241
Molecular mass (g/mol)	466.5
Vapour pressure (Pa)	9.5 10-6
Water solubility (mg/L)	0.03
Effective applied dose (g as/ha)	125
Scenarios	All
Crop	Grass

PEC_{gw} is expressed as 80th percentile value of the concentrations of compound considered in a water body standing at 1 m depth, after leaching through different soil layers.

Therefore predicted concentrations in soil have been evaluated taking into account a 33.2% drift as the worst case. Adsorption on soil is very high with a lower K_{oc} value of 8241 (worst case from BASF, see § 4.2).

An evaluation of PEC in ground water with FocusPELMO 3.3.2 software provided the following results:

Table 5.3.2-3: results of PECgw (µg/L) with FOCUSPELMO 3.3.2

Location	Temephos PECgw (µg/L)
Châteaudun	<0.001
Hambourg	<0.001
Jokioinen	<0.001
Kremsmunster	<0.001
Okehampton	<0.001
Piacenza	<0.001
Porto	<0.001
Sevilla	<0.001
Thiva	<0.001

Therefore percolation of temephos in soil is not significant.

5.4. ROUTE AND RATE IN SEDIMENT

5.4.1. Calculation method

Considering the same water stagnant system (100*100*0.3m^3) with a sediment layer of 5 cm depth and 0.8 g/cm^3 density, PEC in sediment have been evaluated according to the recommendation of the toxicology commission (revision 6-5 of October 2004):

$$PECsed(t),(mg/kg) = \frac{PEC_{ini,sw} * V_{sw} * P_{sed}(t)}{V_{sed} * bd_{sed} * 100}$$

With :

PECini,sw:	PEC initial in surface water
Vsw :	water volume (300L)
Psed(t):	% of active substance in sediment at time t
Vsed:	sediment volume (5cm depth: 5000cm^3)
Bdsed:	sediment density: 0.8g/cm^3

5.4.2. Parameters involved

The parameters involved in the PEC sediment calculation are the following:

Table 5.4.2-1: Parameters involved in PEC_{sed} calculation

Substance	Temephos	
PECwater, 1 application :	41.667	µg/L
% max in sediment (EPA study):	79.4	%
DT_{50} in sediment (default value)	1000	days

5.4.3. Results

Taking into account, a default value for the degradation rate in sediment of 1000 days, the PECsed have been evaluated. PECsed is estimated to be 1488.75µg/kg of dry sediment after the last application and 1467 µg/kg after 21 days.

Table 5.4.3-1: results of PEC_{sed} calculation

$PEC_{sed,\ initial}$:	1488.75	µg/kg of dry sediment

PECsed	Days after last application	Concentration (µg/kg dry sediment)	Average Concentration (µg/kg dry sediment)
Initial	0	1488.75	1488.75
Short-term	1	1487.72	1488.23
	2	1486.69	1487.71
	4	1484.63	1486.69
Long-term	7	1481.54	1485.14
	14	1474.37	1481.55
	21	1467.23	1477.96
	28	1460.13	1474.39
	42	1446.03	1467.28

5.5. ROUTE AND RATE IN SOIL

5.5.1. Calculation method for local PEC soil

Predicted Concentrations have been assessed according to the Technical Guidance Document (TGD). Therefore 3 PEC_{soil} have been calculated for 3 different endpoints:

- Terrestrial ecosystem
- Crops for human consumption
- Grass for cattle

Instantaneous concentration ($PEC_{soil,t}$) and time weighted average concentration ($PEC_{soil,twa}$) were determined for each endpoint. Considering a first-order degradation kinetics, $PEC_{soil,t}$ and $PEC_{soil,twa}$ are determined following the formula :

$PEC_{soil,\ t} = PEC_{ini,n}\ e^{(-kt)}$,

and to obtain time the average concentrations ($PEC_{twa,soil}$) over the time the area under the curve is calculated and divided by the number of days :

$$PEC_{twa,soil} = PEC_{ini,n} \cdot \frac{DT50}{t_i \cdot \ln(2)} (1 - e^{(-t_i \cdot \ln(2)/DT50)})$$

Where:
$PEC_{soil,\ i}$ = initial predicted environmental concentration (mg/kg)
DT_{50} = half-life of dissipation in soil (days)
t_i = considered time period for averaging (days)

In case of multiple applications, the PEC after last application is calculated following the formula:

$$PEC_{ini,n} = \frac{PEC_{ini,1}(1-e^{-nki})}{(1-e^{-ki})}$$

Where:
$PEC_{ini,n}$ is the initial PEC after n applications (mg/kg soil),
$PEC_{ini,1}$ the initial PEC after the first application (mg/kg soil),
n the number of applications spaced by i days,
k the rate constant of the degradation of the active substance (d^{-1}).

5.5.2. Parameters involved

Temephos application process may entail a drift of temephos on soil. The application mode supposed to generate the maximal drift is the aerial spraying. This scenario has been selected as the drift worst case. According to AgDrift model (SDTF, 1999), a drift percentage of 33.2% is associated to the aerial application.

From documents available, the maximal value reported for field degradation rate in soil is 30 days (according to INRA-Agritox database, see § 4.1.1.1).

Considering the worst case of a maximal DT_{50}, and a maximal drift of 33.2% PECs soil have been evaluated. The results are presented in § 5.4.3.

Table 5.5.2-1: Parameters involved in temephos PEC_{soil} calculation

Parameter	Value	Units
DT_{50} in soil:	30	days
k:	0.023	days-1
Application rate:	125	g/ha
Drift (worst case)	33.2	%
Effective application rate:	41.5	g/ha
Applications number:	6	-
Time between applications:	10	days
Soil density (wet soil)	1.5	g/cm^3

Table 5.5.2-2 Soil depth and averaging time for the 3 PEC_{soil} calculated

	Soil depth (m)	Averaging time for PEC_{twa} (days)	Endpoint
PEClocal, soil	0.20	30	Terrestrial ecosystem
PEClocal, agr, soil	0.20	180	Crops for human consumption
PEClocal, grassland	0.10	180	Grass for cattle

5.5.3. Results

Table 5.5.3-1: results for the 3 PEClocal soil

PEC (mg/kg of wet soil)	PEC initial	PEC_{soil} after last application	PEC_{twa}
$PEC_{local,\ soil}$	0.014	0.050	0.036
$PEC_{local,\ agr,\ soil}$	0.014	0.050	0.012
$PEC_{local,\ grassland}$	0.028	0.101	0.024

Table 5.5.3-2: detailed results of $PECl_{ocal\ soil}$ calculation with a soil depth of 0.20m

$PEC_{soil,\ 1application,\ ini}$:	**0.014**	mg/kg
$PEC_{soil,\ last\ application,\ ini}$:	**0.050**	mg/kg

PEC	Days after last application	Actual Concentration (mg/kg wet soil)	Average concentration (mg/kg wet soil)
Initial	0	0.050	0.050
Short-term	1	0.049	0.050
	2	0.048	0.049
	4	0.046	0.048
Long-term	7	0.043	0.046
	21	0.031	0.040
	30	**0.025**	**0.036**
	100	0.005	0.020
	180	**0.001**	**0.012**

Table 5.5.3-3: detailed results of PEClocal $_{soil}$ calculation with a soil depth of 0.10m

$PEC_{soil, 1application, ini}$:	**0.028**	mg/kg
$PEC_{soil, last application, ini}$:	**0.101**	mg/kg

PEC	Days	Actual Concentration (mg/kg wet soil)	Average concentration (mg/kg wet soil)
Initial	0	0.101	0.101
Short-term	1	0.098	0.099
	2	0.096	0.098
	4	0.092	0.096
Long-term	7	0.086	0.093
	21	0.062	0.080
	30	0.050	0.073
	100	0.010	0.039
	180	**0.002**	**0.024**

CONCLUSION

Temephos is dissipated rapidly in soil half life between 12 days (laboratory data, Pesticide Manual) and 30 days (field data, INRA).

According to EPA study, in water-sediment system, half life of temephos has been evaluated to be of 27.2 days as a maximal value (anaerobic system). In water phase, the major identified metabolites were temephos sulphide phenol and temephos sulfone phenol, none of these bear the organophosphate group and have insecticide action. Two others none identified metabolites over passed the threshold of 10% AR in the water phase. In the sediment phase a single major and non identified metabolite was detected at a level over 10% AR.

In water the main degradation pathway is photolysis with a half life of 15 days. The only major metabolite was temephos sulfoxide with a maximum occurrence of 11% AR.

At the reverse hydrolysis is not a major degradation pathway with a half life of 460 days at pH7. Hydrolysis increased with pH and no major metabolite was formed (EPA study)

Adsorption of temephos on soil is very high with Koc estimation from 8 421 to 31 800. Consistently with this important adsorption on soil and according to the regional approach with Mackay Model III, the major amount of temephos is likely to be encountered in soil (61% of total amount). Calculation of PEC ground water with FocusPELMO 3.3.2 showed that percolation of temephos is not significant. The threshold of 0.1µg/L is never reached.

Instantaneous and average Predicted Environmental Concentrations had been calculated, taking into account 6 applications rate of 125 g as/ha of temephos, with a time interval between 2 applications of 10 days. The results are the following:

	Initial PEC	PEC after last application	Time weighted average PEC	Units
Surface Water	42	114	55 (42 days)	µg/L
Sediment	-	1489	1467(42 days)	µg/kg dry sediment
Soil	0.014	0.050	0.036 (30 days)	mg/kg wet soil
Soil, agriculture	0.014	0.050	0.012 (180 days)	mg/kg wet soil
Soil, grassland	0.028	0.101	0.024 (180 days)	mg/kg wet soil

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TEMEPHOS

Ecotoxicological risk assessment

DATE

Mars 2006

1. ECOTOXICOLOGICAL STUDIES

Data on the toxicity of temephos to aquatic or terrestrial organisms are presented in the following paragraphs. These data are issued from the assessment of temephos by the US-Environmental Protection Agency (EPA), from literature data, from private companies as well as from data pertaining to website INRA/Agritox (Regulatory Body in France).

Data were provided from studies conducted with the active ingredient or with various formulations reported in the following table.

Formulation name	Type	Concentration
-	EC	43%
Abate	EC	90%
Abate 4-E	EC	46.1%
Abate 4EC	EC	45.1%
5-CG	CG	5.7%
Abate 2CG	CG	2%

Risk assessments for aquatic and terrestrial organisms are based on these available data.

1.1. EFFECTS ON AQUATIC ORGANISMS - TOXICITY EXPOSURE RATIO VALUES

Toxicity of temephos to aquatic organisms

The toxicity of temephos has been assessed towards various aquatic species.

Temephos shows a wide range of toxicity to aquatic organisms, depending on the formulation. Generally the technical grade active ingredient (TGAI) is moderately toxic and the emulsifiable concentrate (EC) formulations are highly to very highly toxic. The toxicities of the both formulations (EC and CG) are of the same order of magnitude. The formulation EC is slightly more toxic on Daphnia magna and on the pink shrimp.

The most sensitive species is the invertebrate species and *Daphnia magna* is extremely sensitive. Freshwater aquatic invertebrates such as amphipods are highly susceptible to temephos as are some marine invertebrates. Because the compound is an insecticide and is used effectively to control the aquatic larval stages of mosquitos, black flies and midges, the toxic nature to these organisms is not surprising.

The formulation EC is highly toxic to the saltwater species, the pink shrimp (LD_{50} 0.005 mg/l) and the Eastern oyster (LD_{50} 0.014 mg/L). The compound is nearly non-toxic to the bull frog with an LD_{50} of greater than 2000 mg/kg (Extonet PIP).

The most sensitive species of fish is the rainbow trout with a LD_{50} ranging from 0.16 (formulation EC) to 3.49 mg/kg (TGAI). Other LD_{50} values for temephos are close to or higher than 10 mg/L for the TGAI. Other LD_{50} values for formulation EC ranged from 1 to and 7 mg/L.

Temephos has the potential to accumulate in aquatic organisms (log P > 4). The bluegill sunfish accumulated 2,300 times the concentration present in the water. However, the exposure time under conditions of uses ie in ponds or moving waters is supposed to be very low due to the very high adsorption onto colloids (Koc of ca. 22 000), and the DT_{50} in the

water phase is expected therefore to be of few days or less. In addition, nearly 75% of the compound was eliminated from the fish after exposure ended.

1.1.1. Laboratory study

Table 01: Data on the toxicity of temephos to aquatic organisms

Species	Test type	LC/EC_{50} (mg a.s./L)	Reference
Fish			
Rainbow trout	24 h; TGAI (86.2%)	3.49	US-EPA RED Extonet
Rainbow trout	s.a., 96 h	31.8	MSDS Abate 500E , Bayer E. S.
Rainbow trout	48 h	9.6	Agritox
	96 h	9.6	Pesticide Manual
Guppy *Lebistes reticulatus*	24 h	> 200	Agritox
Gambusia *Gambusia affinis*	72 h	> 200	Agritox
Largemouth Bass *Micropterus salmoides*	24 h	> 200	Agritox
Channel catfish	96 h, TGAI	> 10	Extonet
Atlantic salmon	96 h, TGAI	21	Extonet
Bluegill sunfih *Lepomis macrochirus*	TGAI (86.2%), 96 h	21.8	US-EPA RED Memorandum Agritox, Extonet
Bluegill sunfih *Lepomis macrochirus*	^{14}C temephos	BCF = 2300 (whole fish)	BASF Doc ID TM-519-002
Bluegill sunfih *Lepomis macrochirus*	^{14}C temephos	Several major and minor metabolites identified, rapid decline during depuration phase	BASF Doc ID TM-519-001
Invertebrates			
Stonefly *Pteronarces spp*.	TGAI (86.2%)	0.01	US-EPA RED
Mollusc			
Eastern oyster *Crassostrea virginica*	TGAI (86.2%), 96h	0.22	US-EPA RED Memorandum

Table 02: Data on the toxicity of the formulation EC to aquatic organisms

Species	Test type	LC/EC_{50} (mg a.s./L)	Reference
Fish			
Rainbow trout	24 h; formulation EC (43%)	0.158	Extonet US-EPA RED
Rainbow trout	Formulation Abate (90%)	> 8.6	BASF Doc ID TM-560-001
Sheepshead minnow	Formulation 4-E 46.1% a.s., saltwater, 96 h, GLP	4.7	BASF Doc ID TM-560-008
Bluegill sunfih *Lepomis macrochirus*	Formulation EC (43%)	1.14	US-EPA RED Memorandum Extonet
Coho salmon	96 h, formulation EC	0.35	Extonet
Atlantic salmon	96 h, formulation EC	6.7	Extonet
Largemouss bass	96 h, formulation EC	1.44	Extonet
Channel catfish	96 h, formulation EC	3.23	Extonet
Invertebrates			
Daphnia magna	Formulation 4-E 46.1% a.s., 48 h, GLP	$0.011.10^{-3}$	US-EPA RED Memorandum BASF Doc ID TM-560-005
Mollusc			
Eastern oyster *Crassostrea virginica*	Formulation EC 43%, 96h	0.17	US-EPA RED Memorandum
Eastern oyster *Crassostrea virginica*	Formulation 4-E, 96 h, GLP	0.014	BASF Doc ID TM-560-013
Crustacean			
Pink shrimp *Penaeus duorarum*	Formulation EC 43%, 96h	0.0053	US-EPA RED Memorandum

Table 03: Data on the toxicity of the granular formulation to aquatic organisms

Species	Test type	LC/EC_{50} (mg a.s./L)	Reference
Fish			
Sheepshead minnow	Formulation 5-CG 5.7% a.s., 96 h, GLP	5.4	BASF Doc ID TM-560-009
Invertebrates			
Daphnia magna	Formulation 5% G, 48 h	$0.054.10^{-3}$	US-EPA RED Memorandum
Mollusc			
Eastern oyster *Crassostrea virginica*	Formulation 5-CG 5.7% a.s., 96 h, GLP	0.015	BASF Doc ID TM-560-006
Crustacean			
Pink shrimp *Penaeus duorarum*	Formulation 5-CG 5.7% a.s., 96 h, GLP	0.014	BASF Doc ID TM-560-007

"The low solubility of 0.030 mg/L and the relatively high Koc of 22 000 might suggest that some laboratory sediment toxicity testing should be performed. However, measurements of residues in sediment from field studies generally concluded that temephos tends to rapidly adsorb to organic media and further degrade to low or undetectable concentrations. The most recent field study, which monitored temephos in sediments over a three year period, (1995-1997) did not detect temephos in the sediment after 24 hours" (RED Temephos US-EPA). However, no limit of detection is given in this evaluation.
As a result of these field data, a sediment toxicity study will not be necessary at this time. In addition under laboratory conditions, temephos was shown to rapidly degrade with a measured DT_{50} of ca 17 days in the whole water sediment system.

1.1.2. Field study

The following studies were assessed by the US-EPA (Environmental Protection Agency). Theses studies were summarised in the Revised Environmental Fate and Effects Assessment of the Reregistation Eligibility Document for Temephos.

They are reported in the following paragraphs. The majority of them are conducted in marine environment, which is not representative of the defended essential use: aquatic tested species are different and not always representative of the environment in which the product is applied. The tested doses are lower than the recommended dose. No additional details are available.

However, these studies are important because they show that, in systems more complex than the laboratory conditions, there is an important recovery of the medium in the days or weeks which follow the applications.

01/

Report :	Sanders, Herman O. and Walsh, David O., and Campbell. 1981.; Abate: Effects of the Organophosphate Insecticide on Bluegills and Invertebrates in Ponds. U.S. Fish and Wildlife Service. Technical Bulletin 104.

Tested Substance
Abate EC (45.1% ai)

Description of Study

The objective of this study was to determine if Bluegill and aquatic invertebrates are adversely affected. Six 0.04 ha earthen ponds were used in this study, and had an average depth and volume of 0.88 m and 311 m^3, respectively. Three applications were applied at 40 and 4 µg ai/L at approximately one month interval between applications.

Findings

No acute bluegill mortality

02/

Report :	Siefert, et. al. 1986. Effects of Abate® (Temephos) on Non-Target Aquatic Organisms in a Natural Pond Undergoing Mosquito Control Treatment. U.S. EPA Environmental Research Laboratory Progress Report, Duluth. 105 pp.

Tested Substance
Abate EC (45.1% ai)
Abate 1% granular

Description of Study

Two applications were applied at 89.2 g/ha at approximately 14 days interval between applications.
Two reference ponds (0.567 and 0.729 haA) and one treatment pond (0.405 ha = 1 A) were monitored to obtain field data on the effects of mosquito larvicide applications to non-target aquatic organisms. Environmental conditions including dissolved oxygen, temperature, pH, precipitation, rainfall, and outlet stream flow were monitored prior to, during and after the study. Water and sediment samples were also collected and analyzed.

Findings

- No bluegill mortality
- Fewer fry at higher rates (40 µg ai/L)
- AchE (acetylcholinesterase activity) not affected
- Not detected in sediment from 1 hr to 14 days
- Lab tests suggest acute toxicity 5-20X greater than TGAI
- Several changes in zooplankton community. Recovery occurred, but growth patterns altered.
- Macro invertebrates increased in densities

- Cladocerans and Chaoborus very sensitive
- Short-lived in water and toxic at detection limit (<0.7 ppb)

03/

Report :	Abate®: Abate and Abate Sulfoxide Residues in Environmental Samples - Water, Sediment and Four Aquatic Species (Chrisfield, MD and Newark, DE). American Cyanamide Company, Report No. C-333, November, 1972.

Tested Substance
Abate 4EC (45.1%)

Description of Study

The objective of this study was to determine the effects of Abate on marine organisms in relation to the ecological food chain. Measurement of residue data was used to give insight into persistence.

Four marine species (killifish, grass Shrimp, Blue Claw Crab, and American oyster) were exposed to dosages of Abate® 4E under field conditions in the Chrisfield, Maryland (MD) study. Samples were taken 3 days after treatment for the first three treatments and daily for two weeks after the final treatment. Sizes of treatment areas (test plots) were not reported. In addition, raw data and tables were not included. The Newark, Delaware (DE) site conducted experiments in “micro-marsh” testing pools in which natural salt-marsh conditions were simulated (details not given). Killifish and grass shrimp composite samples were taken 7 days after the final treatment. Water and sediment samples were taken for 4 weeks after treatment.
The rates of application were:
MD: Five appl. at timing of 14, 28, 28 and 14 days respectively at rates of 13.3, 26.8, 80.3, 160.7 and 321.4 g/ha
DE: Four appl. at 14 and 28 days respectively at a rate of 80.3 g/ha.

Findings

- Highest residue accumulation in oysters (concentrations not reported)
- Crab residues from 0.06 to 3.11 ppm after 2nd treatment
- Maximum Abate sediment concentrations was 0.53 ppm
- Maximum Abate Sulfoxide concentration was 0.4 ppm
- Rapid adsorbing to sediment and conversion to Abate Sulfoxide

04/

Report :	Carey, W.E. and R. Iadevaia. 1976. Abate Residues in Salt Marsh substrates. Proceedings of the 63rd Annual Meeting of the NJ Mosquito Control Commission, pp. 186-193.

Tested Substance
Abate 2CG
Abate 4EC (45.1%).

Description of Study

Ten granular applications at a rate of 89.3 g/ha at 2 week intervals.
Four liquid applications at 28.5 g/ha at 2 weeks intervals.

This study was conducted as a field study to measure residues of Abate in salt marsh substrates.
In 1973 a 0.6075 ha plot near Tuckerton, New Jersey was treated at 2-week intervals with 10 granular applications of Abate 2CG as described above.
In addition, in 1974 a 3.04 ha salt marsh plot near Manahawkin was treated with 4 liquid applications of Abate 4E at 28.5 g ai/ha at 2-week intervals.
At the Tuckerton site water was monitored on an hourly basis for Abate residues in 5 potholes. The following year 3 of the 5 potholes were monitored.
Three potholes were monitored at the Manahawkin site after the applications.
Algae, grass, and soil samples were taken at the same potholes on day 1 and weeks 1 and 2 after application. Samples were also collected at control plots where Abate was not detected.

Findings

- Granular applications result in very low subsurface concentrations
- Abate 4EC applied to the surface is transferred to surfaces of plant, algae, and other available materials within 24 hours.
- *S. Alterniflora*, a sparse grass which was subjected to flooding had greater soil exposure than S. patens, a dense grass not subjected to flooding.

05/

Report :	Forgash, A.J. 1976. A Summary of Studies of the Impact of Temephos and Chlorpyrifos on the Salt Marsh Environment. Proceedings of the 63rd Annual Meeting of the NJ Mosquito Control Commission, pp. 94-98.

Tested Substance
Abate 2CG
Abate 4EC (45.1%)

Description of Study

The objective of this study was to determine the impact of temephos (Abate) on a salt marsh ecosystem.
Ten granular applications at a rate of 89.3 g/ha at 2 week intervals.
Four liquid applications at 28.5 g/ha at 2 week intervals.
This study was conducted as a field study to determine the impact of temephos (Abate) on a salt marsh ecosystem. In 1973, 4 0.405 ha plots (2 treated and 2 control) near Tuckerton, New Jersey were marked out for the measurement of effects of temephos to bird species. Two additional plots (1 treatment and 1 control) were marked for grass productive, non-target organisms, and .residues studies. Ten granular applications of Abate 2CG were applied as described above. In addition, in 1974, five 3.04 ha salt marsh plots near Manahawkin were treated with 4 liquid applications of Abate 4E at 28.5 g/ha at 2-week intervals. Two of the five plots were used as controls, one for the Abate 4EC treatment, one for a Dursban (Chlorpyrifos) treatment, and one as a bird control plot. Although the details of the studies are not given, observations and measurements were said to be made at frequent, periodic intervals before, during and after treatment.

Findings
- Salt marsh grasses (*S alterniflor and S. patens*), isopods, amphipods, and snails, and birds species tested not affected.
- Did not appear to effect survival, growth, or behaviour in fish for Abate 2G.

- Growth retarding effects to fish observed with Abate 4EC
- Abate 2G reduces the density of natural fiddler crab populations
- Crab activity was impaired by sublethal doses making larvae susceptible to bird predation.

06/

Report :	MD Department of Agriculture. A Study of the Effects of Abate, Applied for Mosquito Larvae Control on Non-Target Organisms in a Maryland Tidal Marsh. 1977. Unpublished Report. 9 pp.

Tested Substance
Abate 4EC (45.1%)

Description of Study

The objective of this study was to determine the acute toxicity of Abate 4EC to estuarine organisms found to be most sensitive under laboratory conditions.

One application at 42.8 g/ha
This study was conducted in August 1977 on the salt marshes at the Deal Island Wildlife Management Area on the Eastern Shore of Maryland. Abate 4EC was applied to 101.2 ha at a rate of 42.8 g ai/ha. An additional control plot about 2 miles south was not treated. The selected four test species of non-target organisms indigenous to salt marshes included the eastern oysters (70 individuals), the blue crab (10 individuals), the grass shrimp (140 individuals) and the mallard duck (10 individuals). Observations were made for mortality prior to and 24 and 48 hours after application.

Findings

- Negligible 48-hour mortality to the four salt marsh organisms tested.

07/

Report :	Liem, K.K., and R.N. LaSalle. 1976. Effects of Abate 2G® and Abate 4E® Mosquito Larvicides on Selected Non-Target Organisms Coexisting with Mosquito Larvae in Woodland Depressions. Mosquito New 36(2): 202-203.

Tested Substance
Abate 2CG
Abate 4EC (45.1%)

Description of Study

The objective of this study was to establish the effects of granular and flowable temephos formulations on non-target organisms under field conditions.
One application Abate 2G at 4.46 kg/ha and one application of Abate 4EC at 27.7 g ai /ha.
The non-target organisms used in this study were representatives of the cladocerans, copepods, ostracods, and damselfly. The breeding sites were observed daily and 10 dips of water were taken at each site and poured through a plankton net. Population estimates were determined and recorded for a period of 5 days before treatment and 10 days after the treatment. The pre-treatment dips were used as the controls to record the natural development of untreated populations.

Findings

- Most non-target populations returned to original population levels after 48 hours of application.
- Cladocerans were most susceptible (7 days for recovery needed)

08/

Report :	Fortin, C., A. Maire, and R. LeClair. 1987. The Residual Effect of Temephos (Abate® 4E) on Non-Target Communities. Journal of the American Mosquito Control Association. 3(2): 282-288.

Tested Substance

Abate 4EC (45.1%)

Description of Study

The objective of this study was to study the impact of temephos on non-target organism in relation to the time of recovery of these populations.

One application Abate 4EC at 2.23 kg ai/ha.
Three man made ponds were treated to assess the impact of temephos (Abate 4E) on non-target organisms. The first pond was untreated and served as a control pond, while the second and third were treated at a rate of 2.23 kg ai/ha on May 14, 1982. The first and the third pond contained about the same water volume, shape, surface area, and depth, while the second pond differed enough to have a direct effect on the thermal regimen of the ponds. Three samples of 5 liters were collected at predetermined transects at each pond, filtered, and fixed in a 5% formaldehyde solution. Beginning on May 4, 1982, the ponds were sampled 3 times prior to application, then at 3 or 4 day intervals for the 2 weeks after application, then on a weekly basis throughout the season. The ponds were also sampled 5 times the following summer. Physicochemical characteristics were also measured at each sampling time.

Findings

- Non-target populations recovered 3 weeks after the application.
- Temephos did not persist in treated water

09/

Report :	Pierce, R.H., Henry, M.S., Proffitt, L.S., and Evans, R.K. 1989. Impact Assessment of Mosquito Larvicides on Non-Target Organisms in Costal Wetlands. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance

Abate 4EC (45.1%)

Description of Study

The objective of this study was to measure the impact of Abate (temephos) applications on coastal shorebird populations and their prey under field conditions

Three aerial applications of Abate were made 2-week intervals (on 8/27/88, 9/10/88, and 10/28/99) at an average rate of 27.7 g ai/ha to 3 sites plus 1 control site. Crabs and mussels were collected from the St. Jude area of Lee County, Florida up to 24 hours after application. Larvicide residue field collections included residue monitoring on mangrove leaves, water pools, leaf littler/detritus, fiddler crabs, and mussels. Residues on mangrove leaves were determined by collecting 30 leaves from each site. Leaf litter/detritus were obtained by collecting a composite sample from each site. Residues in water were collected in a 1-L water sample at each site. Residues in mussels and fiddler crabs were determined by collecting at least 12 individuals from each site.
Three sites were also chosen for bird study sites. An additional control site was located in the mangrove and salt marsh fringes of Charlotte Harbor. The method used to monitor birds was to routinely visit predetermined points and recording bird species seen and/or heard for three 5-minute intervals. The primary purpose of these recordings were to provide insight into the within group variation between observational periods at each point.

Findings

- No acute toxicity was observed in adult fiddler crabs
- Tidal water did not retain larvicides in detectable amount for greater than 24 hours
- Mussels did not accumulate Abate in detectable quantities
- Fiddler crabs retained Abate in concentrations similar to that found in leaf litter. Possible internal bioaccumulation or physical adsorption to the crab shell
- Abate residues found in leaf litter persisted up to 96 hours after application
- Sediment samples contained a small but consistent amount of Abate for up to 168 hours
- At least 13 species of listed birds were observed at or near the habitat typically sprayed
- In total, 115 bird species were documented during the study period
- Most wading birds make heavy use of the isolated ponds upland of the saltern habitat, as well as the salterns, when standing water is present.

10/

Report :	Pierce, R.H., Henry, M.S., Levi, M.R., and Lincer, J.L. 1990. Impact Assessment of Mosquito Larvicides on Non-target Organisms in a Salt Marsh Community and on Selected Listed Species of Marsh and Shore Birds of the Southwest Florida Coast. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance

Abate 4EC (45.1%)

Description of Study

The objective of this study was to

1) Assess the impact of temephos on larvae and juveniles of non-target salt marsh organisms during a 15-month period (July 1, 1989 to September 30, 1990).

2) Determine what levels of temephos were in the eggs and/or young of selected species at various distances from the study area; and determine where these birds were feeding.

Three applications at 2-week intervals at a rate of 27.7 g ai/ha.

The objective of the first study was to assess the impact of temephos on larvae and juveniles of non-target salt marsh organisms during a 15-month period (July 1, 1989 to September 30, 1990). Five field applications were made with temephos (Abate 4-E) at the rate of 27.7 g ai/ha on 7/21/89, 8/18/89, 9/14/89, 8/7/90, and 9/7/90. The primary organism of study was the larvae of the marsh fiddler crab (Uca rapax). However, the mangrove tree crab (Aratus pisonii) and the marsh crab (Sesarma sp.) were also tested as well as the snook fry (Centropomus undecimalis), the adult specimens of the invertebrate (Mysidopsis bahia), and the sheepshead minnow (Cyprinodon variegatus). In addition, two field sites were monitored on July 7 and September 6, 1990 as field controls without a temephos application to assess the survival of the marsh fiddler crab (Uca rapax), the mangrove tree crab (Aratus pisonii), and snook fry (Centropomus undecimalis) larvae. All were compared to the mortality rate of the target salt marsh mosquito larvae Aedes taeniarhynchus. To measure temephos distribution and persistence at the surface glass fiber filter pads were placed at ground level and collected one hour after application. Water samples were also taken before and after application to measure exposure to aquatic organisms. The amount of temephos remaining in the mangrove canopy was established by analysis of mangrove leaves at various time intervals after application.

The second study was a follow-up of a previous avian one year study in which over 115 bird species were documented as having used the marsh study areas. Thirteen of these species were listed species. The objective of this study was to 1) determine what levels of temephos were in the eggs and/or young of selected species at various distances from the study area; and 2) determine where these birds were feeding. Key bird species and rookery sites were selected for the study in accordance with availability and abundance as well as their likelihood of representing the top level of the food web. (It was pointed out that a limited number of osprey and possibly great blue heron eggs were collected and broader geographic coverage of colonies were limited because many of the key species occupied the centers of the colonies and were, therefore, unobservable.) Eggshell thicknesses for collected eggs were measured, and the only conclusion that could be made was that temephos could not be detected in any of the 40 eggs or 8 prey items that were analyzed.

Findings

- Temephos residues in water after application ranged from 0.6 to 108 µg/L (ppb).
- Small concentrations of temephos were recovered from the Uca and Aratus crabs as well as the coffee bean snail, ribbed mussel, and sheepshead minnow, indicating a potential for accumulation in the food chain.
- Temephos was observed to be almost 10 times more concentrated at the water's surface indicating that organisms in contact with the water surface are more vulnerable.
- The 1990 studies concluded that there was a 30% mortality of Uca crabs and a 20% mortality of Aratus crabs 6 hours after application. However, the mosquito larvae experienced a 100% mortality.
- The crab larvae were not frequently present when mosquito larvae are developing. Better timing of temephos applications could avoid exposure to crab larvae.

11/

Report :	Pierce, R.H., Brown, R.C., Henry, M.S., Hardman, K.R., and Palmer, C.L.P. 1988. Fate and Toxicity of Abate® Applied to an Estuarine Environment. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance
Abate 4EC (45.1%)

Description of Study

The objective of this study was to investigate the fate and toxicity of Abate (temephos) in a mangrove system following mosquito larvicide application to intertidal mangrove-fringed estuarine areas.

Five applications in 3 episodes at a rate of 27.7 g ai/ha (0.031 lb ai/A) for each application:
1) Two applications at 4-day interval
2) One application.
3) Two applications at 3-day interval.

One control and one test area were studied. Three separate application episodes of Abate® 4EC were monitored at a rate of 27.7 g ai/ha. The first episode was a 96-hour period where 2 applications were applied at 4 day interval (June 13 and June 17) with sample collections for residue analysis and toxicity monitoring of caged organisms at intervals of 1 hr, 6 hrs, 24 hrs, and 48 hrs after each application. The second episode was a 24-hour period where 1 application was applied on July 24 with sample collections and toxicity monitoring at 1 hr, 3 hrs, and 24 hrs after application. The final episode was a 96-hour period where 2 applications were applied at a 3-day interval (September 29 and October 2) with sample collection and toxicity monitoring at 1 hr, 2 hrs, 4 hrs, 7 hrs, 24 hrs, and 72 hrs after the first application, and 1 hr, 2 hrs, 4 hrs, 7 hrs, and 24 hrs after the second application.

The objective of the study was "determining the distribution and persistence of temephos applied to an estuarine environment during routine applications and to establish the acute toxicity to select marine organisms under normal larvicide application conditions."

Residue data was collected on the surface water, mangrove leaves, sediment, and oysters. For field toxicity tests, 6 estuarine species were observed for behavior and mortality. These species are Ampelisca abdita, Eohaustorius estuarius, Leptocheirus plumulosus, or Rhepoxynius abronius. The six species tested in this field test were the mysid shrimp (Mysidopsis bahia, snook (Centropomis undeimalis), brown shrimp (Panaeus aztecus), grass shrimp (Palaemonetes pugio), sheepshead minnow (Cyprinodon variegatus), and pinfish (Lagodon rhombiodes).

Findings

- Brown shrimp and pinfish not acutely affected.
- 14% mortalities in mysid shrimp. No acute toxicities for sheepshead minnows, snook, and grass shrimp.
- Temephos not detected in oysters after 72 hours.
- No residues observed after in water 1-2 hrs due to tidal flushing

- Temephos remained on leaf surfaces and tidal pools up to 72 hrs.
- Negligible amounts of temephos found in sediment samples
- Potential problems in static pools and upper salt marshes due to lack of tidal flushing in these areas.

12/

Report :	Pierce, R.H. 1993. Effects of the Mosquito Larvicide, Temephos, to Non-target Organisms in a Salt marsh Community. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance
Abate 4EC (45.1%)

Description of Study
The aim of this study was to assess the impact of temephos on non-target salt marsh organisms with an ultimate goal to determine whether the use of temephos creates an unacceptable risk to non-target organisms within a south Florida salt marsh.

Two series of five applications at a rate of 13.4 g ai/ha (0.015 lb ai/A) for each application. (Each series were sprayed at different locations.)
First Series: 3 applications with 4 week interval between applications.
Second Series: About 6 weeks after last application of first series 2 more applications with 7 day interval.
One control and one test area were studied for mortality monitoring at the St. Jude area site.
Three applications of Abate® 4EC were applied at a rate of 13.4 g ai/ha on 6/5, 7/31, and 8/28/92. Ten Aratus spp. Crab larvae were placed in each of 6 cylinders in floating trays. Additionally, 10 mosquito larvae were placed in each of three nytex cylinders. Two trays were used at each site, one with a cylinder of mosquito larvae and 3 cylinders of Aratus larvae and the other with 2 cylinders of mosquito larvae and 3 of Aratus larvae. Two cylinders at each site were used to return to the lab for long-term observation after the 6-hour field exposure period.
The second test site at Bonita Springs area was similarly set up to study the effect of a reduced larvicide dosage on mortality of the freshwater mosquito larvae, Culex migripalpas. Applications were made on 10/16 and 10/23/92.
Temephos concentrations were analyzed from the surface and mid-depth water to assess the distribution and persistence of temephos. Filter pads were also placed at the larval exposure sites, the control site, and in the open marsh area and collected 1 hour after application to measure the amount of temephos settling in the marsh.
The laboratory toxicity tests were conducted for the Aratus crabs using both static and water exchanges systems on 4/21/92, 5/4/92, 5/19/92, and 6/9/92. The Uca crabs were tested on 7/15/92, 9/4/92, and 9/29/92. These studies were said to follow EPA protocols, but complete details and the raw data of these studies did not appear in the report.

Findings

- Temephos concentrations in salt marsh water of 27.7 g ai/ha are suspected of having adverse effects on Aratus spp. and Uca spp. larvae.
- Reduction of temephos to 13.4 g ai/ha reduced field concentrations below acute toxicity levels for Aratus spp.
- Lab tests showed temephos more highly toxic to Aratus than Uca.
- Uca spp present in the mid-marsh, and therefore not as susceptible as Aratus spp.
- 48 hr LC50 ranged from 6.4 to 49.8 µg/L for Aratus spp.

- Uca 96 hour LC_{50}s ranged from 5.6 to 14.9 µg/L. 48-hour LC_{50}s ranged from 56 to >67µg/L.

13/

Report :	Pierce, R.H. 1993. Temephos Distribution and Toxicity in a South Florida Salt marsh Community. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance
Abate 4EC (45.1%)

Description of Study

The objective of this study was to determine if aerial application of temephos is detrimental to non-target organisms in a South Florida mangrove fringing salt marsh community.

The experimental approach was to assess the environmental exposure and follow-up with an evaluation of the environmental hazard to representative salt marsh organisms based on laboratory toxicity tests. The final outcome was to propose application conditions which would reduce the risk to non-target organisms while providing effective control of mosquito larvae.
To assess the environmental exposure an aerial application of temephos was applied to upper and mid-marsh areas on September 2, 1993 where the most abundant crab species (Uca rapax and Aratus pisonii) were known to occur. The application rate was not specified in the actual report, however, the summary indicated a rate of 13.4 g ai/ha (0.015 lb ai/A). Water samples at the surface and mid-level depths were collected prior to and at 1 and 5 hours after application. A second application was applied on September 17 to the upper marsh area only at low tide and water samples were collected prior to and at 1, 4, 5, and 6 hours after application.
Samples were again collected at surface and mid-depth at the upper, middle, and lower marsh sites.

The environmental hazard evaluation was determined by comparing the EECs from the field studies to the Estimated Toxic Threshold (ETT) determined from both laboratory and field toxicity tests. The ETT was defined as the concentration of temephos exposure at which there was no difference in percent survival between test and control larvae through two days past the first molt. Laboratory toxicity tests for determination of the ETT were performed for both the Uca and Aratus crab larvae with both the technical form of the active ingredient and the product formulation (Abate®).

The larvae for the toxicity tests were used 1 to 2 days after enclosure, and to simulate tidal flushing the exposure water was exchanged at 70% at 6 hours, 50% at 24 hours and 50% every 48 hours thereafter. Three replicate sets of 20 larvae at 5 concentrations and 2 replicate sets of controls, one in salt marsh water and one set in water plus methanol which was used as a dispersant. The test concentration levels for temephos were 2.5, 5, 10, 15, and 20 µg/L. For the Abate formulation the test concentrations were 2.5, 5, 7.5, and 10 µg/L, based on the amount of temephos in the water.

Field toxicity tests were also conducted in the salt marshes by exposing mosquito and crab larvae (Aratus ppisonii) for 6 hours (5 hours for the 1993 study), then removing them from the marshes. They were promptly returned to the laboratory and monitored

for a period of 12 days. The objective of these tests was to establish effects on survival through the first molt. The tests run in 1992 utilized Aratus crab larvae and mosquito larvae. The 1993 tests run the Uca crab larvae and the saltwater mosquito larvae, Aedes thaeniorhynchus.

Findings

- Temephos concentration after 1 hour ranged from 3 to 10 µg/L at the low tide mid-marsh Uca site. The concentrations ranged from 1.0 to 1.8 µg/L temephos at high tide five hours after application. None was detected in the lower marsh
- After second application to upper marsh area only, no temephos was detected in middle or lower marshes during out-going tide.
- Lab tests showed no difference in crab larvae toxicity between the technical and Abate.
- 1992 field test concluded no immediate concern, but significant mortality through first molt
- 1993 field test showed increased mortality during first molt for Uca larvae in mid-marsh, but no effect for Aratus in lower marsh.
- Study concludes that when applications are restricted to upper marsh areas risks to crab larvae is reduced or eliminated.

14/

Report :	Pierce, R.H. Henry, M.S., and Culter, J.K. 1998. Ecological Impact Assessment of Abate® on Florida State Lands/Salt Marsh communities. Mote Marine Laboratory, Sarasota, Fl.

Tested Substance
Abate 4EC (45.1%)

Description of Study

The objective of this study was to address the concern for possible adverse effects from applications of the mosquito larvicide abate (temephos) on State-owned salt marsh lands along the intertidal regions of Cape Coral, Florida.

Both control and application areas were designated for monitoring the benthic infauna and temephos concentrations before and after the applications benthic macroinfauna were monitored to account for the extreme environmental conditions due to the monthly variations from wet to dry. Another component to the study was the application of adulticides (malathion or baytex) over residential areas as needed after adult mosquitoes emerged. Therefore, the drift from these adulticides was also monitored.

Temephos was aerially applied three times in 1995 (5/1, 5/22, and 6/6), 1996 (6/14, 7/3, and 7/20), and 1997 (5/14, 6/25, and 7/17) at a rate of 0.5 fl. oz./A (0.015 lb ai/A). For adequate replication of samples the number of test and control sites were increased from two to four pairs of sites for 1996 and 1997. Samples were collected at each site at the water (surface micro layer and mid-depth), surface sediment, and at glass-fiber filter pads to monitor the amount of larvicide deposition to the marsh surface. The monitoring included collections at pre-application, 2 hours, 24 hours, and 96 hours post-application for the 1995 applications. Filter pads were retrieved 1 hour post-application for 1996 and 1997. Invertebrate samples were collected pre-application and 96 hours post-application at each study site, and a Hester Dendy invertebrate settlement collector was added in 1996 and 1997 sampling to reduce the

natural habitat variability from one site to another. Snail mesocosm studies were also established to assess the impact on natural populations of marsh invertebrates. One control site and one test site was used and monitored 96 hours after the 6/1/95 application and during final field collection on 10/11/95.

Findings

- 1995 data conclude that no temephos was detected at the surface water and very little in mid-depth after 96 hours. None detected in sediment surface water after 24 hours.
- 1996 data showed no detectable levels of temephos residue in sediment.
- 1997 data concluded that no detectable temephos levels were found in control areas. Temephos not detected in surface sediment samples.
- 1995 benthic data concluded no long-term exposure or accumulation. Greater species diversity at control sites.
- 1996 benthic data showed high level of temporal and spatial variation.

General conclusion

Although these studies do not yield toxic endpoints required, they have a benefit in that they show results under more realistic field conditions. The data summarized in these aquatic field studies have demonstrated the following conclusions regarding risk to non-target aquatic organisms.

1. Non-target aquatic invertebrate populations tend to reestablish to their original population levels within three weeks after application (Fortin, et. al., 1976). In another study, (Liem,et. al., 1976) Cladocerans appeared to be the most sensitive taking 7 days to recover after two applications. The other three representatives tested (copepods, ostracods, and damselflies) reestablished after 48 hours. In another study, (Siefert, et. al., 1986) observed recovery to the zooplankton community, but growth patterns were altered.

2. Ten applications of the granular 2G formulation did not appear to affect survival, growth, or behavior in fish, but growth retarding effects were observed after 4 applications of the liquid Abate 4E formulation (Forgash, et. al., 1976). No acute mortality, growth effects, or acetylcholinesterase inhibition was observed in bluegill (Siefert, et.al., 1981). No acute effects were observed in pinfish, sheepshead minnows, or snook (Pierce, et. al., 1988).

3. A Florida salt marsh field study conducted in 1989 concluded that there was no acute toxicity to adult fiddler crabs when salt marsh areas were treated three times at 2-week intervals at a rate of 27.7 g/ha (0.031 lb ai/A) (Pierce, et. al., 1989). However, continued work in 1990 concluded that there was a 30% mortality of the fiddler crab larvae (Uca rapax) and a 20% mortality of the mangrove tree crab larvae (Aratus pisonii) six hours after application (Pierce, et. al., 1990). A further 1993 study concluded that concentrations in salt marsh water resulting from an application rate of 27.7 g/ha) is suspected of having adverse effects on the fiddler crab and the mangrove tree crab.

Laboratory studies revealed that the mangrove tree crab with a 48-hour LC50 range of 6.4 to 49.8 µg/L was found to be more sensitive than the fidler crab (LC50 = 56 to >67 µg/L). The mangrove tree crab inhabits the lower marsh areas which are not being treated, and exposure to this species was greatly reduced. Further, when the application was reduced to 13.4 g/ha and sprayed in the upper and mid-marsh areas where the fiddler crab is found, the exposure concentrations were reduced to below the fiddler crab acute toxicity level while still killing 100% of the mosquito larvae (Pierce, et. al., 1993).

Further field toxicity studies were conducted to establish the effects of larval survival through the first molt (Pierce, et. al., 1993). The results of the 1992 study showed significant mortality through the first molt (almost 50% in one test). The 1993 study showed increased mortality for the Uca rapax (fiddler crab) in the mid-marsh, but no effect to the Aratus pisonii (mangrove tree crab) in the lower marsh. The net conclusions of these studies are when minimum application rates 13.4 g ai/ha are restricted to upper marsh areas, risk to crab lavae are reduced or eliminated. It is also interesting to note that the laboratory results showed no difference in crab larvae sensitivity between the technical temephos and the formulated product (Abate 4EC). In contrast, the acute toxicity data available for fish indicate that the formulated product is much more toxic than the technical. The rainbow trout LC_{50} for the technical is 3,490 ppb, and 158 ppb for the formulated product. No data related to the toxicity on Daphnia magna are available.

A number of the conducted field studies relating to the fate of temephos under field conditions have verified much of the laboratory data which was reviewed. In addition, much information concerning residue concentrations in various media has been obtained.

Some field studies confirm the laboratory data which characterizes temephos as not persisting in the water column. According to one study temephos was not detectable (although no limit of detection (LOD) was given in the report) in tidal waters for more than 24 hours (Pierce, et. al., 1989). In a 1990 study residues in water after application ranged from 0.6 to 108 µg/L (Pierce et. al., 1990). Temephos concentration after 1 hour ranged from 3 to 10 µ/L at low tide in a mid-marsh site and 1.0 to 1.8 µg/L at high tide 5 hours after application in a 1993 study (Pierce, et. al., 1993).

A study conducted in 1972 by American Cyanamid concluded that temephos was rapidly adsorbed to sediment and converted to temephos sulfoxide. The measured concentration of temephos sulfoxide was 400 µg/L. There was also evidence to show that the liquid temephos formulation was up to 10 times more concentrated at the water's surface (Pierce et. al., 1990). Although not quantified, granular applications resulted in very low sub-surface concentrations (Carey, et. al., 1976).

Residues detected in sediment showed a wide range of results. A 1981 study did not detect temephos in sediment from 1 hour to 14 days (Siefert, et. al., 1986). A study from 1972 showed temephos sediment concentrations of 530 Fg/L (American Cyanamide, 1972).

Another study showed a small but consistent amount of temephos in sediment for up to 168 hours (Pierce, et. al., 1989). The most recent study which monitored temephos sediment over a three year period (1995-97), did not detect temephos in the sediment after 24 hours (Pierce, et. al., 1998). Temephos was detected in various media substrates as well as sediment in many of the studies. A 1976 study found that Abate was transferred to surfaces of plant, algae, and other available materials within 24 hours (Carey et. al, 1976). Temephos was also found to remain on leaf surfaces and tidal pools for up to 72 hours, most, however, was dissipated into the estuary by tidal flushing (Pierce, et. al., 1988). Temephos residues found in leaf litter persisted up to 96 hours after application (Pierce, et. al., 1989). Small concentrations of temephos were also recovered from the fiddler crab and mangrove tree crab as well as the coffee bean snail, ribbed mussel, and sheepshead minnow, however quantities were not given (Pierce, et. al., 1990). Temephos residues in Crab ranged from 60 to 3,110 ppb after 2nd treatment (American Cyanamide, 1972). In a 1988 study temephos was not detected in oysters 72 hours after treatment (Pierce, et. al., 1988). Mussels did not accumulate in detectable quantities 24 hours after application in a 1989 study (Pierce, et al., 1989).

15/

Report :	Metge G., Franquet E. and Ponel P. La mise au pont d'une méthodologie d'évaluation de l'impact de deux insecticides sur des milieux temporaires colonisés par les Aedes ; 2001, 2002 Programme Life-Environnement, EID LIFE 99 ENV/F/00489 University of Aix-Marseille III, France

Tested Substance
Abate

Description of Study

The objective of this study is to define the impact of temephos on various ecological levels and to determine the most sensitive taxonomic group. Only the last application was relevant to conclude on the impact of temephos.
Application of 102.4 g/ha (11/07/2001)
Application of 125 g/ha (02/09/2002)

Findings
- July 2001: Chironnomid, Cyclopoid, Baetidae, Calopterigydae. These taxonomic groups appeared after the treatments from the 13/07, they are not affected by the treatment
- September 2002: Cyclopoid, Batidae (Scm-Phc) : the treatment led to a decrease of populations. Calopterigydae. On the ecological levels Scm-Phc and Phc: the treatment led to a decrease of populations on 04/09 and 09/09. The population recolonise the environment on 16/09.

16/

Report :	Hanazato T., Iwakuma and Yasuno M. (1989) Effects of Temephos on Zooplankton Comminities in Enclosures in a Shallow Eutrophic Lake Environmental Pollution 59, 305-314

Tested Substance
Abate 5%

Description of Study

Large volume enclosure was constructed in Lake Suwa (Japan) to determine the influence of temephos onto the different species of zooplankton communities. Enclosures were constructed at a 4.2 m deep with a surface area of 25m^2 open to the lake sediment. Volume of each enclosure (4 in total ie two treated and two controls) is of 105 m^3. In august 1986 the equivalent of 500 µg active substance was applied as Abate insecticide with 5% of temephos and containing 90% xylene.

Findings

In the studied systems, cladocerans and copepods showed a slight (if any) recovery after being absent for 26 days and 40 days respectively in the two treated enclosure. Cladocerans were found to be very sensitive to temephos as expected. As the residual concentration of temephos in the system were close to or higher than LC50 values of the most sensitive species of cladocerans (*Daphnia pulex* from unpublished information

of the authors i.e. LC50 of 0.07-0.09 µg/L), no recovery of cladocerans was expected. Cladocerans were found more sensitive than copepods by a factor estimated at 10 by the authors of the study. In addition to these populations, rotiferan communities were also affected although to a lesser extent and in addition, temporary disappearing of predators like cladocerans influenced the growth of rotiferan community. The application of temephos also altered the composition of this community showing within that group different sensitivity of the individual species.

In conclusion, the population of cladocerans is severely affected and did not show a recovery under the tested conditions (equivalent of 500µg/L and during maximum of 40 days). Less severe effects were noted for the other populations of copepods and rotiferans.

1.1.3. Risk assessment for aquatic organisms

A PNEC is regarded as a concentration below which an unacceptable effect will most likely not occur. In principle, the PNEC is calculated by dividing the lowest short-term L(E)C50 or long-term NOEC value by an appropriate assessment factor. The assessment factors reflect the degree of uncertainty in extrapolation from laboratory toxicity test data for a limited number of species to the 'real' environment. Assessment factors applied for long-term tests are smaller as the uncertainty of the extrapolation from laboratory data to the natural environment is reduced.

Initial risk assessment

The most unfavourable data from the laboratory studies is the endpoint for *Daphnia magna* (study conducted with the formulation EC).
EC_{50} = 0.011 µg/L
The most sensitive species is the invertebrate species and *Daphnia magna* is extremely sensitive. Freshwater aquatic invertebrates such as amphipods are highly susceptible to temephos as are some marine invertebrates.

According to the recommendations of the TGD (Technical guidance Document) and because only short-term toxicity data are available, an assessment factor of 1000 must be applied on the lowest $EC_{50.}$
However, the size of the assessment factor depends on the confidence with which a $PNEC_{water}$ can be derived from the available data. Data are available for several fish species, for invertebrates, for molluscs and crustacean. Because the substance was tested on various species given information on the inter-species variation, it may lead to a lowered assessment factor :100.
Then, the calculated PNEC is: $PNEC_{temephos} = 1.1.10^{-4}$ µg/L

$PEC_{surface\ water}$ = 0.114 mg/L

PEC/PNEC using these conservative figures indeed would lead to a serious concern to aquatic organisms especially under the proposed conditions of uses. Aquatic invertebrates (or copepods) are considered the most sensitive species, to the exception of larvae of insects and will demonstrate these populations at risks when temephos is used as recommended. Due to its environmental properties (low solubility in water, high adsorption onto colloids, fast dissipation in water phase and in the whole water sediment system) the impact would be limited in time and recuperation was

shown to occur within weeks. Therefore a PNEC mesocosm should be a more reliable end point to take into account these properties. Actually under the proposed conditions of use, not all the field data which could be used for a proper mitigation of risks or a refined risks assessment.

1.2. NON-TARGET TERRESTRIAL ANIMALS

Because Temephos is only applied directly to water, it is not expected to have a direct impact upon terrestrial animals. Birds and mammals are not exposed to the formulation by feeding contaminated plants or plant part. Terrestrial animals may be exposed to temephos via drinking water.
Additionally, due to the tendencies for temephos to bioconcentrate, a piscivorous bird or mammal scenario was proposed to assess the risk to fish-eating birds and mammals.

1.2.1. Toxicity on birds

Tests with various wildlife species were conducted to assess the toxicity of temephos on birds. The toxicity data are reported in the following table. Acute and short-term toxicity data indicate that the bobwhite quail is the most sensitive species and demonstrate that temephos is relatively toxic by ingestion to birds.

According to a study of oral ADME (adsorption, distribution, metabolism and excretion) in rats and pigs conducted by BASF/ ADME (BASF DocID TM-440-001), excretion is complete within 96 h, 65% in faeces mainly as parent compound, 33% in urine, mainly as 4,4'-thiodiphenol.

Table 04: Summary of the avian toxicity of Temephos

Species	Conditions	Endpoint	Result	Reference
Acute single oral				
Mallard duck	-	LD_{50}	80 mg/kg b.w.	Agritox
Mallard duck	Temephos technical	LD_{50}	2150 mg/kg b.w.	BASF Doc ID TM-505-004
Japanese quail	-	LD_{50}	84 mg/kg b.w.	Agritox
Pheasant	-	LD_{50}	31.5 mg/kg b.w.	Agritox
Bobwhite quail	Temephos technical	LD_{50}	25.2 mg/kg b.w.	BASF Doc ID TM-505-005
Bobwhite quail	Temephos technical (94.7%)	LD_{50}	27.4 mg/kg b.w.	US-EPA RED Memorandum
House sparrow	-	LD_{50}	35.4 mg/kg b.w.	Agritox
Short-term dietary				
Mallard duck	-	LC_{50}	> 1400- < 1600 ppm	Agritox

Species	Conditions	Endpoint	Result	Reference
Mallard duck	Temephos technical (86.9%)	LC_{50}	894 ppm	US-EPA RED Memorandum
Japanese quail	-	LC_{50}	> 230-< 270 ppm	Agritox
Pheasant	-	LC_{50}	> 150-< 170 ppm	Agritox
Bobwhite quail	Temephos technical (86.9%)	LC_{50}	92 ppm	US-EPA RED Memorandum
Bobwhite quail	-	LC_{50}	> 90-< 110 ppm	Agritox
Pigeon	-	LC_{50}	50.1 ppm	Agritox
Long-term reproduction				
Mallard duck		Mallards fed diets containing moderate amounts of temephos showed no changes in reproduction except in the frequency of egg-laying		Extonet PIP Temephos
Mallard duck	45 d, frequency of egg-laying	NOEL	1 ppm i.e. 0.12 mg/kg bw/d*	US-EPA database

* Conversion by considering the worst case where the daily dose eaten by a bird during reproduction studies correspond to 12% of its bodyweight

No acceptable reproductive studies have been submitted, however, field data that has been submitted for review indicate that there is very little, if any, impact on birds.

1.2.2. Toxicity on mammals

The acute toxicity data on mammals are reported in the following table.

Tableau 05 : Oral acute toxicity study in the rat

Species	Endpoint	Result	Reference
Rat (male-female)	LD_{50}	3410-5247 mg/kg b.w.	MSDS Temephos technical Charda Chemicals Ltd
Rat (male-female)	LD_{50}	2030-2330 mg/kg b.w.	
Rat (male-female	LD_{50}	4204-> 10000 mg/kg b.w.	BASF Doc ID TM-410-002
Rat	LD_{50}	3100 mg formulation/kg b.w.	FDS Temephos 500 g/L SC Gharda Chemicals Ltd

According to the US-EPA, a NOEL of 0.3 mg/kg/d could be selected for the long-term risk assessment. This endpoint is based on inhibition of cholinesterase in the red blood

cells of rats of both sexes at 0.9 mg/kg/d (LOAEL) in a 90-day feeding study. The toxic effect was observed within one week after initiation of treatment, and thus is considered to be appropriate for a short term (1-7 day) assessment. Use of this same endpoint for the chronic assessment is supported by similar doses and endpoints seen in another subchronic toxicity study in rats, as well as a chronic study in dogs where red blood cell and plasma cholinesterase inhibition occurred from one week onward.

1.2.3. Risk for drinking water

Species that frequent open water bodies are liable to ingest residues of active substances that reach water. The exposure concentration in this case is equal to $PEC_{surface\ water}$, obtained from the environmental fate section.

$PEC_{surface\ water}$= 0.114 mg/L after the last application

In some situations, some species may obtain all their daily water demand directly from puddles of spray liquid. Because the product is directly applied on the water surface, the exposure concentration is calculated from the applied dose, without dilution or drift.

The daily water intake is calculated allometrically as follows (Calder and Braun 1983):

For the birds: Total water ingestion rate (L /day) = $0.059W^{0.67}$

For the mammals: Total water ingestion rate (L/day) = $0.099W^{0.90}$

Where W is the body weight in kg. Thus, the daily dose of active substance is calculated as ($PEC_{drinking\ water}$ * total water ingestion rate) / W.

The TER are calculated for the case of a 1000 g-bird and a 350 g-mammal for which long-term toxicity data are available.

Table 06: TER after drinking water

species	Weight (kg)	Total water ingestion rate (L /day)	Daily dose (mg ai/kg bw/d)	NOEL (mg ai/kg bw/d)	TER	Trigger value
Mallard duck	1.20	0.067	$6.4.10^{-3}$	0.12	18.8	> 5
Rat	0.35	0.038	$4.3.10^{-3}$	0.3	69	

Results of the calculation indicate that the amount of temephos that birds would be exposed to through normal water intake is much less than the potentially lethal concentration, and thus not of concern.

1.2.4. Risk for fish-eating birds

A value of log P_{ow} higher than 3 may signify a bioaccumulation risk through the trophic chain. The log P_{ow} of temephos is 4.91. Then the bioaccumulation risk is assessed through two food pathways by birds according the Guidance Document of the European Commission SANCO/4145. The following models were provided by works of Jager (1998) and Crocker et al. (2002).

A study performed with bluegill sunfish revealed a bioconcentration factor (BCF) of 2300 for the whole fish (see aquatic risk assessment).

1.2.4.1. Bioaccumulation in fish

A 28-day dynamic exposure of 120 acclimated fish to a concentration of ^{14}C-Temephos of 0.65 ± 0.12 µg/l indicated rapid uptake of radioactivity by the fish. Daily bioconcentration factors for fillet, whole fish, and viscera ranged from 63-970, 99-2300, and 150-3900, respectively. The uptake concentrations of ^{14}C-Temephos in tissues ranged from 50-630 ppb, 78-1500 ppb, and 120-2500 ppb for fillet, whole fish, and viscera, respectively. No mortality or abnormalities were observed in the Temephos-exposed fish.

The 14-depuration phase indicated 75, 75, and 78 percent depuration from fillet, whole fish and viscera, respectively and indicated a gradual decrease through the depuration phase. The ^{14}C-Temephos residues in the 28-day uptake phase dropped from 630 ppb to 160 ppb (fillet), 1500 ppb to 380 ppb (whole fish), and 2500 ppb to 560 ppb by the end of the 14-day depuration period.

The uptake rate constant (K_1), the depuration rate constant (K_2) the depuration half-life ($t_{1/2}$), the [steady state] bioconcentration factor (BCF), and the time to reach 90% of steady state were calculated using the non-linear BIOFAC kinetic modeling program. The standard deviation of each estimated parameter was use as a measure of variability. The results are summarized as follows:

$K_{1(uptake)}$ *= 200(±16);*
$K_{2(depuration)}$ *= 0.086(±0.0073);*
$_{1/2(depuration)}$ *= 8(±0.68) days*
$BCF_{steady\ state}$ *= 2300(±270)*
Steady state$_{90\%}$ *= 27(±2.3)days*

The metabolic fate of ^{14}C-Temephos in the fish was determined by characterizing the chemical nature of residues in fillet, whole fish, and viscera at 21 and 28 days exposure. The extracted residues (methanol:methylene chloride, 1:1 v/v; 95% extraction efficiency) were cochromatographed (2-dimensional thin layer chromatography) with authentic standards of parent and suspected metabolites.
Parent Temephos was the major residue identified in fillet, whole fish, and viscera in 21 and 28 day samples. In fillet, whole fish and viscera Temephos was found at 490, 1700, and 1000 ppb, respectively in 21-day samples. In 28-day samples, 630, 2500, and 1500 ppb were respectively present in fillet, whole fish and viscera. The percent of applied Temephos found as intact Temephos was: (1) fillet, 79% at 21 days and 86% at 28 days; (2) whole fish, 73.6% at 21 and 28 days; viscera, 82% at 21 days and 59% at 28 days.

Temephos sulfoxide was the major metabolite. In terms of applied radioactivity, Temephos sulfoxide accounted for: (1) fillet, 5.1% at 21 days, and 4.5% at 28 days; whole fish, 6.8% at 21 and 28 days; viscera, 9.2% at 21 days and 12.8% at 28 days. Other minor hydrolytic and oxidative metabolites, each at equal or less than 4%, were also found. One of the metabolites, 4,4'-thiodiphenol, are the result of losing both phosphorothioate groups from the parent metabolite. The two other metabolites, phosphorothioic acid,O-p-(p- hydroxyohenylthio) phenyl, O,O'-dimethyl ester and phosphoric acid, O-p-(p-hydroxyphenylthio)phenyl dimethyl ester, contains only one

organophosphate group; in the latter metabolite, the sulfur group in the phosphorothioate group was replaced by oxygen. All of these three metabolites preserve the sulfide linkage, that is, they are not a sulfoxide or a sulfone. Non-identified metabolites (2 to 9) were present at 4 to 13% and were mostly present in the viscera.

1.2.4.2. Risk for fish-eating birds

There is a potential risk for predators feeding on contaminated prey for a prolonged period of time, and this risk must be assessed. The relevant species recommended by the guidance document (SANCO/4145/2000) are a 1000 g-bird and a 3000 g-mammal, even if observed species in this environment have various size and weight: mallard duck, Greater Flamingo, slender-billed gul, gull-billed tern cattle egret by example for birds and Eurasian otter or Europan pond turtle for terrestrial vertebrates.

Residues in fish may be estimated from $PEC_{sw, ,twa}$ at 21 days (77 µg/L)

PEC_{fish} = BCF * $PEC_{sw,twa}$ (21 d) in mg/kg food

PEC_{fish} = 2300 x 0.077 = 177 .1 mg/kg fish

Applying a factor of 0.21 (1000-g bird eating 206 g fresh fish per day, as recommended by guidance document SANCO/4145/2000), the daily dose eaten by a fish-eating bird may be 0.21*PEC_{fish} in mg temephos/kg bw/day.

Applying a factor of 0.13 as recommended by guidance document SANCO/4145/2000), the daily dose eaten by a fish-eating mammal may be 0.13*PEC_{fish} in mg temephos/kg bw/day.

Daily dose = 0.21 x 177.1 = 37.2 mg/kg bw/d for birds

Daily dose = 0.13 x 177.1 = 23.0 mg/kg bw/d for mammals

The comparison of daily dose to the NOEL value leads to a toxicity to exposure ratio.

Table 07 : TER for fish-eating birds and mammals after use of temephos

Species	$PEC_{sw, 21\ d, twa}$ (µg/L)	PEC_{fish}	ETE (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER	Acceptable TER value
Bird	0.077	177.1	37.2	0.12	0.003	> 5
Mammal	0.077	177.1	23.0	0.3	0.01	

The TERs are widely lower than the trigger value. Therefore, a potential risk for fish-eating birds and mammals is predicted.

However field data (Forgash, 1976; Pierce et al., 1990 Pierce et al., 1989 described in point 1.2.1) that have been submitted for review indicate that there is very little, if any, impact on birds. In fact the mitigation of this calculation includes that the dissipation in water of the active substance is rapid, the depuration of the active substance present in fish tissues is also fast and nearly complete, therefore chronic exposure is not likely to

occur limiting the potential for secondary poisoning or effects to fish eating birds as well as mammals. (US-EPA).

1.2.5. Toxicity to bees - hazard quotients

Table 07: Toxicity data of temephos to bees

Test substance	Temephos
Test object	Honeybee
LD_{50} µg a.s./bee Contact toxicity, 48 h	1.55
Reference	MSDS Temephos technical Gharda Chemicals Ltd Pesticide Manual, Agritox

According the European directive 96/12/EC, the risk towards bees may be assessed with the calculation of hazard quotients (HQ), based on the ratio of the maximum applied dose (in g a.s./ha) to the LD_{50} (in µg a.s./bee).
Because the product is applied directly on water, we consider that the risk for bees is due to the contamination on the adjacent zone of the treated area by the drift of spraying.

The maximum drift to adjacent zones corresponds to an aeroplane application. According to the Guidance document FOCUS (2001) the drift is 33.2% (data extracted from AgDrift). The maximum dose susceptible to contaminate the adjacent zones is 41.5 g a.s./ha.

The contact hazard quotient (QH_C) is calculated based on the maximum drift rate (41.5 g a.s./ha) and the corresponding LD_{50} values from the toxicity tests (in µg a.s./bee).

Table 08: Hazard quotients for honeybees exposed to temephos

Application rate (g a.s./ha)	Acute toxicity (µg a.s./bee)	Hazard quotient[1]	Annex VI trigger value
41.5	Contact LC_{50} = 1.55	26.7	< 50

[1] Application rate divided by the LD/C_{50}.

The contact hazard quotient is lower than the trigger value of the Directive 97/57 (50) indicating no potential risk for bee populations after application of TEMEPHOS at the recommended application rate.

1.2.6. Impact on soil non-target micro-organisms

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US-EPA Reregistration Eligibility Decision (RED) Document. Reregistration Eligibility Decision (RED)

LIST OF ABBREVIATIONS

BCF: Bioconcentration factor
CG: Encapsulated granule (A granule with a protective or granule release-controlling coating)
EC: Emulsifiable Concentrate (A liquid, homogenous formulation to be applied as an emulsion after dilution in water
ETE: Estimated Theoretical Exposure
HQ: Hazard quotient
LC_{50}: Lethal concentration, 50%
LD_{50}: Lethal dose, median
NOEL: No Observed Effect Level
PIP : Pesticide Information Profiles

TEMEPHOS

Toxicology

DATE

mars 2006

1. INTRODUCTION

Temephos is an organophosphate insecticide which is widely used for larval control.

Several formulations are currently used in Europe for this purpose:

Commercial name	Active substance content	Formulation type	Authorised dose
Abate 500 E moustiques	500 g/L	EC	125 g/ha
Larviphos 500 EC	500 g/L	EC	125 g/ha
Abate 1% granule moustiques	500 g/L	EC	125 g/ha

As individual reports were not available to the reviewer, this evaluation is based on reviews previously conducted by different official bodies (references indicated in part I of the reference section). The references of individual studies, when found, are indicated in part II.

2. METABOLISM

2.1. ADME STUDIES

When [3H-phenylene]temephos,was administered to rats by mouth, radioactivity reached a peak in the blood between 5 and 8 hr and then dissipated with a half-time of about 10 hr. Appreciable radioactivity was found only in the gastrointestinal tract and fat. Both in the faeces and in the fat, most of the activity came from unchanged insecticide, but small amounts of the sulfoxide were present also. Traces of temephos were found in the urine, but the principal urinary metabolites were sulfate ester conjugates of 4,4'-thiodiphenol, 4,4'-sulfinyldiphenol, and 4,4'-sulfonyldiphenol. At least 10 other components could be extracted but were not identified. In the guinea pig, absorption apparently was less than in the rat, and biliary excretion of metabolites was demonstrated (Blinn, 1969).

2.2. DERMAL PENETRATION STUDIES

In a non-guideline dermal penetration study, 14C-ring labeled temephos (98% a.i.) was applied to the intact clipped mid lumbar area of Sprague-Dawley male rats, New Zealand White male rabbits and male beagle dogs (number of animals/species/group not specified). The area of application (8.25 cm^2) was covered with a non-occlusive patch for 7 days (HSPA Letter, 1976).
The quantitative dose was diluted in methanol and applied at 4 µg/cm^2 or 33 µg/each species (rat, rabbit and dog). Another group of dogs received a higher dose of 40 µg/cm^2 or 330 µg/dog. Urine and fecal excretions of 14C were quantitated daily by counting radioactivity in liquid scintillation counter. Immediately following the final urine collection, all animals were sacrificed and sections of organs and tissues (lungs, liver, kidneys, spleen, testes, skin, muscle, fat and bone) were analyzed for retained radioactivity. A second group of animals were given labeled temephos intravenously to determine renal efficiency and to assess the systemic elimination for each species. The femoral vein of the rat, the marginal ear vein of the rabbit, and the cephalic vein of the dog was injected with methanol solutions of 14C-temephos. Urine and fecal excretion was collected from rats, rabbits and dogs daily for 7

days. Excretion rates for each day's collection were calculated as percent of the initial or applied dose. Blood was drawn from dogs only, prior to injection, immediately after and at timed intervals to determine the disappearance rates from the circulation. At termination, representative specimens were taken from various organs and tissues (lungs, liver, kidneys, spleen, testes, skin, muscle, fat and bone) of each animal to determine retained labelled compound.

Mean total urinary recovery of 14C- temephos following intravenous administration ranged from 46.9% in rabbits, 17.7% in rats and 11.8% and 9.6% in dogs. Fecal elimination accounted for 23% and 10.5% of recovered activity in dogs given 33 and 330 µg/dog, respectively but only 6.9 % in rats and 7.8% in rabbits . In all three species, the greatest percentage (69-79%) of 14C-labeled temephos was excreted within the first 24 hours. Urinary excretion of dermally applied 14C-temephos was greatest in the rabbit (24.6%), less in the rat (6.7%) and least in the dog (<1%).
Fecal elimination following dermal application accounted for a larger percentage of the total activity recovered from the rat (11%) compared to the dog (0.9%) or the rabbit (9%). The greatest percentage excreted in the urine occurred within 2 days following administration. Negligible amounts of activity were found in the organs and tissues of any animal or species following dermal administration. This suggests that most of the administered dose was metabolized and eliminated quickly and did not accumulate in any tissue or organ. The low overall recovery in excreta following dermal and intravenous dosing indicates that 14C-temephos is stored in some tissues or eliminated by a route not accounted for in this study
One possible explanation for the dermal study is that most of the activity remained at the application site which was not monitored by the study. Support for this explanation was seen in the 330 µg/dog study where approximately 88% of the applied dose was recovered from 14C-labeled "protective patch". The patches were not analyzed for radioactivity in the 33 µg/animal in the dog, rat or rabbit study. Percent dermal absorption for each species was calculated by dividing percent of the dose excreted in the urine following dermal route to the percent of the dose excreted in the urine by the i.v. route and multiplying by 100:

Percent Dermal Absorption = $\frac{\text{\% Dose Recovered in Urine via Dermal X 100}}{\text{\% Dose Recovered in Urine via Intravenous}}$

Rat Percent Dermal Absorption = $\frac{6.7\ \%}{17.7\%} \times 100 =$ **38%**

The percent dermal absorption was 38% in rats, 52% in rabbits and ~ 5.2% in dogs. The rat is the required species because the Test Guideline (870.7600) has been designed and validated for the rat. The rat was not intended as a model of dermal absorption through the human skin but rather as a test system for dermal absorption because the rat has been extensively used for metabolic and toxicological studies.

According to US EPA (Environmental Protection Agency), for risk assessment purposes, the dermal absorption percentage for rats (38%) should be used.
Overall estimation of EPA for the quality of this study is as follows:

- "This study is classified as Acceptable - Non-Guideline and does not meet the guideline (870.3100; 82-1) requirement for Dermal Penetration Study because only a summary report was submitted which contained many guideline deficiencies, number of animals/groups/species was not indicated; only one dose used in rats and rabbits; dermal site of application was less than 10% of the body surface area; dermal site was not washed; urine/faeces was not collected at early time periods (0.5, 1, 2, 4 and 10 hrs); the solvent used for labelled chemical dilutions was methanol (volatile solvent causing rapid evaporation); saturation dose is unknown. In spite of these study deficiencies, this study provides a reasonable estimate of dermal absorption of temephos in the species studied (EPA Memorandum from January 27, 1999)."

3. ACUTE TOXICITY

Temephos is of low acute toxicity with oral and dermal LD50 which are all more than 4000 mg/kg bw with the exception of one rabbit dermal toxicity study in which the LD50 is 1300 mg/kg bw and one oral rat female toxicity study in which the LD50 is 1300 mg/kg bw (see Appendix 1).

Temephos LC50 is > 1.3 mg/L.

Temephos is slightly irritating to eyes but not irritating to skin of rabbits. The compound is not a dermal sensitiser.

Information on batches used for these acute toxicity studies was not available.

4. SUBCHRONIC TOXICITY

Groups of 7 rats received doses of temephos of 0, 1, 10, or 100 mg/kg bw/day by gavage for 44 days (dosing regimen not indicated). After 11 days, administration of the test compound to 'some' of the animals of the high-dose group was stopped. No mortality was reported in any of the groups. Rats given the highest dose developed typical symptoms of organic phosphorus intoxication (not specified) after 3 doses when their red blood cell AChE activity was inhibited by 64%. Gradual recovery from symptoms occurred while dosing progressed, even though the red blood cell AChE activity continued to fall to 87% inhibition after 11 days of dosing. In the animals that were allowed to recover after 11 days, red blood cell AChE activity was inhibited by 27% at the end of the experiment (44 days). The rats receiving 10 mg/kg bw showed no symptoms of intoxication, but red blood cell AChE was inhibited by 31% and 47% after 14 and 44 days, respectively. The NOAEL for inhibition of red blood cell AChE was 1 mg/kg bw/day (Gaines et al., 1967).

In a subchronic toxicity study, groups of rats (45 rats/dose/sex) were fed Temephos (purity 96.4%) in their diet at levels of 2, 6, or 18 ppm (equivalent to 0.1, 0.3 or 0.9 mg/kg/day) for 92 days to determine the highest dietary level which would not inhibit plasma, RBC or brain cholinesterase activity.
Another group of 45 rats/sex/group was fed with a diet containing Temephos at 350 ppm (17.5 mg/kg/day) dose level to determine a maximum tolerated dose and to induce histopathological effects. There were 65 rats/sex in the control group. Seven controls of each sex and 4 rats/sex/dose group were sacrificed at 1, 3, 5, 9 and 13 weeks of the study period for RBC, plasma and brain cholinesterase activity evaluation. ChE activity was also evaluated on four rats of each sex at week 12 of the study dosed at 350 ppm. At week 13 all survivors were given control diet and recovery of the ChE activity was determined 2 and 4 weeks later. One control male and one female each of the 6 and 18 ppm dose groups died during the study. At 350 ppm the female body weight gain was significantly depressed as compared to the controls. No treatment related changes were observed in clinical sign observations, ophthalmology evaluations and food consumption, clinical chemistry and hematology evaluations at all dose levels. No gross and microscopic treatment-related changes were noted in any dose group during the study. The liver/body weight ratio of the 2 and 350 ppm males and the 18 ppm females were significantly decreased as compared to the controls. Since dose-related trends in the liver/body weight ratio were not evident, these decreases are not considered to be treatment-related. Because the greatest decrease in the liver/body weight ratio occurred in the 350 ppm males (-23% of control), this is judged to be treatment-related. Decreased RBC cholinesterase activity was noted in the 6 ppm males at

weeks 9 and 13 (75% and 84% of control, respectively) and in 18 ppm males and females throughout the treatment period (64-85% and 65-89% of control, respectively). Significantly decreased RBC cholinesterase activity was noted in the 350 ppm males and females (8% and 11% of control, respectively) at week 12 (only measured time period). The RBC ChE activity decrease in the 18 and 350 ppm males and females were judged to be dose-related. At 6 ppm, the RBC ChE activity was decreased only in males (84% and 83% of controls, on weeks 9 and 13, respectively); this decrease was considered to be a borderline occurrence. Only the plasma cholinesterase activity was significantly depressed at 350 ppm in males and females at week 13 (52% and 39% of control, respectively) and this is judged to be treatment-related. Significant decrease in the brain cholinesterase activities was noted in males and females dosed at 350 ppm at week 13 (23% and 22% of females, respectively). Inhibition of the brain ChE activity in the 18 ppm males and females in the first five weeks of the study was also noted (81-85% and 81-91% of controls, respectively); these effects disappeared after the five weeks. Therefore this inhibition was considered borderline occurrence.

Since RBC ChE activity inhibition in the 6 ppm males and brain ChE activity inhibition in the 18 ppm males and females in the first five weeks of the study were considered to be equivocal, the study was repeated at dietary levels of 0, 6, 18 and 54 ppm to ascertain if borderline ChE activity inhibitions seen in this study were a definite and reproducible effect. In the repeated study, statistically significantly decreases in RBC cholinesterase activity was seen in both sexes at 18 and 54 ppm.

Based on the results of the first experiments, the systemic LOAEL is 350 ppm (17.5 mg/kg/day) based on decreased body weight (15%) and liver/body weight ratio (23%). The systemic NOAEL is 18 ppm (0.9 mg/kg/day). The ChE LOAEL for this subchronic study is 18 ppm (0.9 mg/kg/day), based on inhibition of RBC cholinesterase activity observed in both sexes in both repeated experiments. The ChE NOAEL is 6 ppm (0.3 mg/kg/day) (Levinskas GJ and Shaffer CB, 1970; EPA Memorandum from May 12, 1998).

According to US EPA, dose and endpoint for Risk Assessment: NOAEL = 0.3 mg/kg/day based on inhibition of RBC cholinesterase activity observed in both sexes at 0.9 mg/kg/day (LOAEL) as early as one week This is considered as supported by the findings of a chronic study in dogs (Gaines et al., 1967) with a NOAEL of 0.46 mg/kg/day based on RBC, plasma, and brain ChE activity inhibition at 12.5 mg/kg/day (LOAEL) where RBC and plasma ChE activity inhibition occurred from week 1 onward.

5. MUTAGENICITY

The effect of temephos on several strains of bacteria has been tested (EXTOXNET 2002). Although one strain showed weak mutagenicity, the overall conclusion in this document was that temephos is not mutagenic. Tests on rabbits (test not specified) also have shown no signs of mutagenicity.

6. CHRONIC AND ONCOGENICITY STUDIES

6.1. COMBINED CHRONIC TOXICITY/CARCINOGENICITY STUDY IN RATS

Groups of 60 rats/sex/group were fed a diets containing Temephos (purity 93.5%) at 0, 10, 100, and 300 ppm (0, 0.5, 5.0, and 15 mg/kg/day) for two years. Rats used for the treated

groups were derived from the offspring of 140 pregnant CD Sprague-Dawley rats that were treated with 100 ppm Temephos in the diet. The controls were from a separate shipment of the same strain of rats and age, derived from untreated female rats. No treatment-related effects were observed in survival, clinical signs, body weight/body weight gain, food consumption as well as in hematology, clinical chemistry and urinalysis parameters evaluated at 6 weeks, 3 months, 12 months and at termination of the study. There was a slight increase in absolute liver weight and liver/body weight ratio of both sexes of rats at 300 ppm (absolute weight: 8% in males and 14% in females, and relative liver weight, 18% in males and 6% in females). However, since dose-related trends were not evident in either sex, these increases were not judged to be related to treatment. The most frequently noted gross pathology finding was mammary masses in the females. Histopathologically, these masses were identified as adenocarcinoma. These tumor incidences are evenly distributed among all groups (18, 21, 19 and 18 in the control, 10, 100, and 300 ppm females, respectively). Pituitary adenomas were also frequently noted in all groups, and no differences were noted as compared to their respective controls. Since no treatment related trends were evident, these mammary adenocarcinoma and pituitary adenoma findings were not considered to be treatment-related. For chronic toxicity, the NOAEL was 300 ppm; a LOAEL was not established.

Discussion of Tumor Data: There is no evidence of carcinogenicity
US EPA considers that, for chronic toxicity, the NOAEL was 300 ppm (EPA Memorandum from May 12, 1998).

6.2. CARCINOGENICITY STUDY IN MICE: NOT AVAILABLE.

There was no sufficient data available for an adequate assessment of the compound carcinogenicity, as only one study on one species (rats) was available. In this study, no evidence of carcinogenicity was found.

7. REPRODUCTION AND DEVELOPMENT

7.1. REPRODUCTION TOXICITY

One-generation and a three-generation reproduction studies were conducted with temephos. The original study report for this one generation study was not available to confirm the reported symptoms of organophosphate induced poisoning in adult rats.

In a one-generation reproduction study (Gaines et al., 1967), a group of male and female rats (number of individuals unknown) was fed in the diet at 500 ppm (approximately 25 mg/kg/day) Temephos (90%) at the time they were placed together for breeding. Dosing was maintained through mating, gestation, parturition and lactation. Based on the results of the study, no significant differences in the fertility (pregnancy/matings), gestation (litters born alive/pregnancies), viability (pups surviving/pups born alive) and lactation indices for the Temephos-fed animals were observed compared with the controls. Numbers of litters and pups born alive and mean pup weight at weaning were comparable among the dose groups; numbers of litters (15 from 15 matings) were produced and the litter size averaged 10.5. Some 500 ppm Temephos-treated rats (number of individuals not indicated) showed signs of ChE poisoning. Based on the data as presented in the study report, administration of temephos at 500 ppm (25 mg/kg/day) in the diet, had no adverse effects on the reproduction and lactation performance of rats. The toxicity endpoint was not verified because the original report was not found. The reproductive NOAEL is > 500 ppm (25 mg/kg/day) (highest dose tested). The systemic ChE NOAEL is < 500 ppm (25 mg/kg/day).

In a 3-generation reproduction toxicity study (Levinskas GJ and Shaffer CB, 1970; EPA Memorandum from May 12, 1998), Temephos (87.1% a.i.) was fed in the diet to rats at dose levels of 0, 25, and 125 ppm (0, 1.25, and 6.25 mg/kg/day). For the P generation, 24 rats/dose were mated once. For the F1 generation, 16 rats/dose were mated once, and for the F2 generations, 16 rats/dose were mated twice. In each generation, rats were mated when they were 3-4 months old. The pups were weaned directly onto the respective dose levels of their parents. The size of the litters was reduced to 10 pups on the fifth day after birth. This study was conducted as per standard procedures for a 3-generation reproduction study. Body weights of adult rats were comparable among the dose groups in all generations; slight decreases (<10%) in body weights were noted in the 125 ppm F1 and F2 males and females, but since the difference was small and dose-related trends were not evident, these decreases were not judged to be treatment-related. The gestation, viability and lactation indices for the P generation were comparable among the groups; slight decreases of the 25 and 125 ppm fertility indices and the 125 ppm pup weights as compared to the controls were noted, but they are not judged to be treatment-related. The fertility, gestation, viability and lactation indices for the F1 generation were comparable among the groups; a slight decrease in the 25 and 125 ppm pup weights as compared to the controls is not judged to be treatment-related. No adults died during the reproduction and lactation periods.

The fertility, gestation and lactation indices for the first mating of the F2 generation were comparable among the groups. Since a decrease in the 125 ppm pup viability index was noted as compared to the controls (82% versus 94%), a second mating was conducted for the F2 rats. No F2 adults died during the reproduction and lactation periods in the first mating. In the second mating of the F2 generation, one 25 ppm female died after delivering 6 dead pups. Two controls and four 25 ppm females failed to conceive. The fertility, viability, and lactation indices of the 125 ppm dose group exceeded the controls. Since the viability index of the 125 ppm dose group was higher than the controls (99% versus 83%), the low viability index of 82% noted in the F2 first mating is judged to be coincidental and hence not related to treatment. Overall the differences noted in the reproduction data in the F2 are not judged to be related to treatment. Gross observations without necropsy were conducted on all P and F1 pups. Gross and microscopic evaluations were conducted for all F2 pups of the control and 125 ppm groups. No consistent gross and microscopic effects were noted. However, a number of spleen hematopoiesis in pups were noted (20% in the control and 17% in the 125 ppm dose group); spleen hematopoiesis is a common occurrence in pups up to weaning.
Based on the results of the study, the fertility (pregnancy/matings), gestation (litters born alive/pregnancies), viability (pups surviving 5 days/pups born alive) and lactation (pup weaned/remaining pups after litter reduced at 5 days) indices for the temephos-fed animals were comparable with the controls. The combined (of all matings) mean pup weight at weaning was slightly higher in the 25 ppm dose group and slightly lower in the 125 ppm dose group as compared to the controls. There was a slight reduction in mean pup weights at weaning for both males and females in the 25 and 125 ppm P and in the 125 ppm F1 generations. Based on the data as presented in the study report, administration of temephos at 25 and 125 ppm in the diet, had no systemic toxicity and adverse effects on the reproduction and lactation performance of the rats were not noted.

For parental systemic toxicity, the NOAEL was > 125 ppm (6.25 mg/kg/day, highest dose tested.). For offspring toxicity, the NOAEL was also > 125 ppm (6.25 mg/kg/day, highest dose tested).

Only two instead of three treated groups were used. The lack of any signs of parental toxicity in the study even at 125 ppm (6.25 mg/kg/day) dose level suggests that this level was too

low. Also, pups of the P and F1 generations were not subjected to gross necropsy. The test substance purity was low.

Based on these studies, the HIARC concluded that an adequate evaluation of the reproductive toxicity of temephos can not be made at the present time.

7.2. DEVELOPMENTAL TOXICITY

In a prenatal oral developmental toxicity study, pregnant New Zealand rabbits received oral administration of temephos (90.4%) in Tween 80 (1%) and deionized water at 0, 3, 10, or 30 mg/kg/day during days 6 through 18 of gestation. No maternal or developmental toxicity was seen at the highest dose tested (30 mg/kg/day). This study was classified as unacceptable since the highest dose tested was inadequate to elicit maternal toxicity and thus evaluate the developmental toxicity potential of temephos (EPA Memorandum from May 12, 1998).

In a prenatal dermal developmental toxicity study, pregnant New Zealand rabbits received repeated dermal applications of formulations containing temephos at 0, 12.5, 25 or 50 mg/kg/day during days 6 through 18 of gestation. For maternal toxicity, the NOAEL was 25 mg/kg/day and the LOAEL was 50 mg/kg/day based on decrease in body weights. For maternal cholinesterase inhibition, the LOAEL was 12.5 mg/kg/day based on plasma cholinesterase inhibition (brain ChE activity was not evaluated); a NOAEL was not established. For developmental toxicity, the NOAEL was 50 mg/kg bw/day (highest dose tested) (EPA Memorandum from May 12, 1998).

8. NEUROTOXICITY STUDIES

No evidence of organophosphate induced delayed neurotoxicity or neuropathology was observed in three acute delayed neurotoxicity studies in hens; however, these studies were judged to be inadequate for various technical deficiencies (Gaines et al. 1967).

9. HEALTH EFFECTS IN HUMAN

Few health-effect studies in humans have been conducted on temephos, and no effects have been reported (HSDB 2003). Nevertheless, it acts as an organophosphate cholinesterase inhibitor, for which much literature is available. Health effects from a typical cholinesterase inhibitor are as follows:

- Common early signs or mild symptoms of acute cholinergic poisoning include miosis (pinpoint pupils), headache, nausea/vomiting, dizziness, muscle weakness, drowsiness, lethargy, agitation, and anxiety.
- Moderate or severe poisoning can result in chest tightness, difficulty breathing, bradycardia, tachycardia, hypertension, pallor, abdominal pain, incontinence, diarrhoea, anorexia, tremor/ataxia, fasciculation, lacrimation, heavy salivation, profuse sweating, blurred vision, poor concentration, confusion, and memory loss.
- Life-threatening or very severe signs and symptoms, such as coma, seizures, respiratory arrest, pulmonary oedema, loss of reflexes, and flaccid paralysis, can occur at high doses, such as in the cases of attempted suicide.

Effects of temephos on humans have not been reported in the literature, presumably because of its low acute toxicity (ATSDR, 2005).

Human exposure through drinking water

A 19-month study was conducted with temephos added to all cisterns and other potable water containers in a community of approximately 2,000 people (Laws et al., 1968). The treatment occurred once a month and consisted of 1% temephos adsorbed to sand, in sufficient quantity to achieve a calculated concentration of 1 ppm (19 g of sand per 50 gallon/188 liter drum). Only one water sample ever had a Temephos concentration >0.5 ppm, attributable to the combined effects of adsorption, solubility, and dilution over time. No significant change was measured in either plasma or erythrocyte cholinesterase of the villagers at any time during the 19-month study. Urinary excretion of temephos reached steady state after 4 months. No illness attributable to the insecticides occurred, and all of eight babies born were normal.

Human volunteer study

Humans who ingested 256 mg/day for 5 days or 64 mg/day for 4 weeks had no symptoms or any detectable effects on plasma or erythrocyte cholinesterase activity (Laws et al. 1967). At 70 kg for an adult, the doses are equivalent to 3.7 mg/kg/day for 5 days or 0.9 mg/kg/day for 4 weeks. When the standard water ingestion rate of 2 liters/day and the solubility of temephos (<1 ppm) are considered together, adult humans would be expected to receive <2 mg/day (0.028 mg/kg) from drinking water treated with Temephos. This scenario is extreme because daily water treatments are unlikely, so concentrations of temephos would decrease between treatments. The concentrations may be considerably below saturation (~1 ppm) even at their peak (the time of treatment). Given the no-observed-adverse-effect level (NOAEL) of 64 mg/day for 4 weeks, temephos is not expected to present a health hazard when used for larvicide water treatment.

Dermal exposure

A 2% formulation of temephos in pyrax powder was applied to participants and their bedding from a shaker (57 g, equivalent to 1.1 g of temephos) or to clothed subjects from a powder duster (31 g, equivalent to 0.62 g) for an unknown duration (Steinberg et al. 1972). The treatment was considered safe although no specific criteria are indicated.

Occupational exposure

Cholinesterase Monitoring: The Lee County Mosquito Control District in the US has submitted limited monitoring data from their cholinesterase testing program to EPA.
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 A.

Table A. 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 A 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 or carbamates 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 A 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 A 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 history of subjects is not known. 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 self-reporting questionnaires and more quantifiable measures (e.g., blood pressure, heart rate).
- A non-exposed group (control) of individuals was not sampled. While it is important to establish the pattern of individual baseline (pre-treatment) blood levels, a separate control group needs to be established to compare values as well as to provide statistical comparisons.

10. OVERALL EVALUATION AND DERIVATION OF RELEVANT DERMAL PENETRATION, RELEVANT NOAEL AND REFERENCE MOS (REFMOS)

10.1. SELECTION OF THE MOST RELEVANT DERMAL PENETRATION FACTORS FOR OPERATOR RISK ASSESSMENT:

A 38% dermal absorption has been determined in rat. However, no information is available on the tested formulation which is likely to be a solid formulation.
Considering the high level of penetration, the non-GLP character of the study and the fact that only a summary is available, a dermal penetration factor of 50%, based on an expert judgement, is proposed for the operator exposure evaluation.

10.2. SELECTION OF THE MOST RELEVANT NOAEL FOR OPERATOR RISK ASSESSMENT:

Operators are likely to be exposed several days per week during several weeks, if not months in case of important outbreak of vector born disease.
The most sensitive adverse effect appears to be RBC ChE inhibition.
One of the most relevant studies is the 28-day human study by oral route (Laws et al.
1967). In this study, no clinical symptoms or RBC ChE inhibition have been reported at a daily dose of 0.9 mg/kg bw/day.
This study is consistent with the 44-day rat study in which the NOAEL is 1 mg/kg bw/day (Gaines et al., 1967) which tends to demonstrate that rat and human are similarly sensitive to ChE inhibition effects of temephos. However, exposure duration may be short compared to expected duration and in the 90-day repeated oral rat study, 0.9 mg/kg bw/day appears to be a LOAEL. In the repeated study (cf p 5), 0.3 mg/kg bw/day is the NOAEL.

10.3. SELECTION OF THE MOST RELEVANT ASSESSMENT FACTORS (AF) FOR OPERATOR RISK ASSESSMENT

Assessment factors applied for the calculation of refMOS for subchronic toxicity

Assessment factors	Value
Interspecies	1 Several studies are available in Human. They all indicate that, as for most organophosphate insecticides, rat and human have similar sensitivity)
Intraspecies	5 (workers are considered as a more homogeneous population than the general population. Although there is no indication that some parts of the population are more sensitive to this type of insecticide, a factor of 10 can be used for bystander)
Exposure duration	2 (NOAEL clearly tends to decrease with the duration of the study and exposure of the operators may last more than 90 days)
Route-to-route extrapolation	1 (taken into account by dermal penetration)
Quality of the database	3 (non GLP studies and only summaries available)
refMOS	30

11. REFERENCE LISTS

Part I: list of review documents issued by official bodies and used for the constitution of this document:

- EPA Memorandum from September 23, 1999: 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; Reregistration Branch II; Health Effects Division (7509C)
- EPA Memorandum from January 27, 1999: Dermal Penetration of Radio-labeled Temephos from Nicole Paquette, PH.D. Reregistration Branch II; Health Effects Division (7509C)
- EPA Memorandum from September 29, 1999: TEMEPHOS: Revised HED Chapter for the Reregistration Eligibility Decision (RED) Document. PC Code: 059001. From Jonathan Becker, Ph.D. Reregistration Branch 2; Health Effects Division (7509C)
- EPA Memorandum from May 12, 1998: *TEMEPHOS* - Report of the Hazard Identification Assessment Review Committee. From David S. Liem, Ph.D. Reregistration Branch II Health Effects Division (7509C)
- EPA Memorandum from 21 May 1998: Occupational and residential exposure assessment and recommendations for the reregistration eligibility decision document for Temephos. From: Jonathan Becker, Ph.D., Environmental Health Scientist. Reregistration Branch II. Health Effects Division (7509C)
- EPA Memorandum from July 6, 1998: TEMEPHOS: HED Chapter for the Reregistration Eligibility Decision (RED) Document. Chemical No. 059001 Case No. 0006 Barcode D243362. From Nicole C. Paquette, Ph.D. Risk Assessor. Reregistration Branch 2. Health Effects Division (7509C)
- EXTOXNET (2002). Pesticide information profile for Temephos. Available at http://pmep.cce.cornell.edu/profiles/extoxnet/pyrethrins-ziram/temephos-ext.html. Accessed December 2, 2002; PIP “published” September 1993 and “last modified” December 19, 2001.
- HSDB (2003). Hazardous Substances Databank: Temephos. National Library of Medicine, National Toxicology Program. Available at http://www.toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB. Accessed February 19, 2003.
- Toxicologic Information About Insecticides Used for Eradicating Mosquitoes (West Nile Virus Control) April 2005. Prepared by: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Agency for Toxic Substances and Disease Registry. Division of Toxicology Atlanta, Georgia

Part II: list of the primary references of the studies discussed in this document :

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- Gaines TB, Kimbrough R, Laws ER Jr (1967). Toxicology of Abate in laboratory animals. Arch Environ Health 1967; 14: 283-8.
- Hayes, Wayland J, Jr (1982) Pesticides Studied in Man. Baltimore/London: Williams and Wilkins, 1982., p. 376

- HSPA Letter (1976), HSPA-H, US Army Health Services Command, Investigational. New Drug Application for Abate Pediculicide, US Army Environmental Hygiene. Agency (USAEHA), Aberdeen Proving Ground, MD, Study # 75-51-1302-80, October 20, 1976. Unpublished Study.
- Laws ER Jr, Morales FR, Hayes WJ Jr, et al. (1967). Toxicology of Abate in volunteers. Arch Environ Health 1967; 14: 289-91.
- Laws ER Jr, Sedlak VA, Miles JW, Romney-Joseph C, Lacomba JR, Diaz-Rivera A. (1968). Field study of the safety of Abate for treating potable water and observations on the effectiveness of a control programme involving both Abate and Malathion. Bull. World Health Org. 38:439–45.
- Levinskas GJ, Shaffer CB (1970). Toxicity of Abate, a mosquito larvicide, and its sulfoxide. Toxicol Appl Pharmacol 1970; 17: 301-2.
- Steinberg M, Cole MM, Miller TA, Godke RA (1972). Toxicological and entomological field evaluation of Mobam and Abate powders use as body louse toxicants (Anoplura: pediculidae). J Med Entomol 9:73–7.

Appendix 1. NOAEL and LOAEL – Human and animal studies with Temephos

Route	Duration	Species	NOAEL	LOAEL	Organ/Effect	Comments	Reference
Acute Duration Toxicity							
dermal	unique	human	1.1 g/person		Signs of toxicity	Applied with a device used for topical treatment against lice. The conclusion is that this treatment does not present risks and is efficient	Steinberg et al. 1972
dermal	unique	rat (m)		>4,000 mg/kg	LD_{50}	LD_{50}	INCHEM 2002
dermal	unique	rat (f)		>4,000 mg/kg	LD_{50}	LD_{50}	INCHEM 2002
dermal	unique	dog		>5,000 mg/kg	LD_{50}	LD_{50}	EXTOXNET 2002
dermal	unique	cat		>5,000 mg/kg	LD_{50}	LD_{50}	EXTOXNET 2002
dermal	unique	rabbit		1,300 mg/kg	LD_{50}	LD_{50}	INCHEM 2002
dermal	5 days	rabbit		0.4 ml/kg/day (178 mg a.i./kg/day)	Cholinesterase inhibition; diarrhoea	Cholinesterase inhibition and diarrhoea	INCHEM 2002
oral	5 days	human	256 mg/day (~3.7 mg/kg/day)		Cholinesterase inhibition	No cholinesterase inhibition and no symptoms observed.	Laws et al. 1967
oral	unique	rat (m)		8,600 mg/kg	LD_{50}	LD_{50}	INCHEM 2002
oral	unique	rat (f)		1,300 mg/kg	LD_{50}	LD_{50}	INCHEM 2002
oral	unique	mouse		4,700 mg/kg	LD_{50}	LD_{50}	EXTOXNET 2002
oral	5 days	lapin		100 mg/kg/day	Liver	Focal and diffuse hepatic necrosis noted.	HSDB 2003
oral	5 days	guinea pig	100 mg/kg/day		OP poisoning	No pathological findings	INCHEM 2002

Route	Duration	Species	NOAEL	LOAEL	Organ/Effect	Comments	Reference
			Intermediate Duration Toxicity				
dermal	3 weeks, 5days/wk	rat	12 mg/kg/day	60 mg/kg/day	Lesions; tissue changes; body weight	When applied dermally as aqueous emulsion, half of rats had abraded skin. Decreased weight gain noted in 60 mg/kg/day group (intact and abraded skin), but no other effects seen.	INCHEM 2002
oral	28 days	human	64 mg/day (~0.9 mg/kg/day)		Cholinesterase inhibition; clinical symptoms	No inhibition or symptoms observed.	Laws et al. 1967
oral	30 days	rabbit		10 mg/kg/day	Liver	Mild hepatic pathologic changes.	HSDB 2003
oral	44 day	rat	1 mg/kg/day	10 mg/kg/day	Erythrocyte cholinesterase inhibition	10 mg/kg/day resulted in 31% inhibition at 14 days and 47% at 44 days. No signs of organophosphate poisoning seen. Rats receiving 100 mg/kg/day showed signs of poisoning after 3 days (at 64% inhibition); gradual recovery from symptoms ensued, although inhibition progressed to 87% after 11 days.	Gaines et al. 1967
oral	35 days	rabbit	1 mg/kg/day	10 mg/kg/day	Cholinesterase inhibition; liver effects	No effects or significant inhibition were noted at 0.1 mg/kg/day or 1 mg/kg/day. The 10 mg/kg/day group developed 26% inhibition by day 7 and 47% inhibition by day 35. No animals showed signs of poisoning; no higher doses were used.	INCHEM 2002; HSDB 2003
oral	90 days	rat	6 ppm (0.3 mg/kg/day)	350 ppm (17.5 mg/kg/day)	Cholinesterase inhibition; clinical signs	Cholinesterase inhibition was the only effect noted.	INCHEM 2002; HSDB 2003
oral	35 days	rat	1 mg/kg/day		Cholinesterase inhibition	No cholinesterase inhibition was seen.	HSDB 2003
oral	186 days	sheep	5 mg/kg/day			No effects were noted.	HSDB 2003

Route	Duration	Species	NOAEL	LOAEL	Organ/Effect	Comments	Reference
oral	99 days	rat		2,000 ppm (~100 mg/kg/day)	Death, clinical signs, and erythrocyte cholinesterase inhibition	8 animals of 10 died within 10 days; 100% erythrocyte cholinesterase inhibition; signs of poisoning.	Hayes and Wayland, 1982
Chronic Duration Toxicity							
oral (in drinking water)	19 months	human	0.5 ppm		Cholinesterase inhibition; clinical symptoms	No inhibition or symptoms observed in village of 2,000 when water containers were treated once a month with temephos; 0.5 ppm estimated maximum dose.	Laws et al. 1968
oral	2 years	rat	300 ppm		Not specified	No effects were noted.	HSDB 2003
oral	422 days	sheep	2.5 mg/kg/day		Not specified	No effects were noted.	HSDB 2003
oral	1 year	cow		1 mg/kg/day	Not specified	“Signs of poisoning” were noted.	HSDB 2003
oral	2 years	rat	1 ppm	10 ppm	Liver effects	Minor pathologic changes noted in liver.	EXTOXNET 2002
Developmental/Reproductive Toxicit y							
oral (in drinking water)	19 months	human	0.5 ppm		Cholinesterase inhibition; clinical symptoms; reproduction	No symptoms observed in village of 2,000 when water containers were treated once a month with temephos; 0.5 ppm estimated max. dose. Eight normal births were observed.	Laws et al. 1968
oral (diet)	3 generations	rat	125 ppm		Fertility, gestation, reproduction, lactation, congenital defects	No effects were noted. Dietary exposure continued from weaning through reproductive age.	HSDB 2003
oral	unspecified	rat		500 ppm (25 mg/kg/day)	Number of littersand size, viability, congenital defects, cholinesterase; signs of toxicity	No developmental or reproductive effects were noted, but some cholinesterase inhibition and toxicity were seen.	EXTOXNET 2002; HSDB 2003
oral	1 year	cow		1 mg/kg/d	Fertility.	Evidence indicated that it may affect the fertility in heifers	HSDB 2003

TEMEPHOS

exposure evaluation and risk assessment

DATE

mars 2006

INTRODUCTION:

Temephos will be applied for larval control of mosquitoes. The application equipment used for these applications is close to the one used for pesticide application. For this reason, models derived from agricultural technology will be used.

The following models will be used:

UK POEM:
This model is derived from studies conducted in UK in the early 80th. These were mainly non-GLP studies and the raw data are no more available. This model is considered as very conservative. However, as it is a recognised model in the EU, these results will be presented when it is relevant for one of the uses.

BBA Model:
This model is derived from studies conducted in Germany in the 80th. These were mainly non-GLP studies and the raw data are available. This model is considered as moderately conservative. However, as it is a recognised model in the EU, these results will be presented when it is relevant for one of the uses.

EUROPOEM II:
This model has been built by a team of academics, regulators and industry under an EU contract. The model comprises the results of 78 studies which were available to the group. The results, as presented at the end of the contract, have been considered by the Commission as too variable to be easily usable by regulators. However, these data are available at the following address: http://europoem.csl.gov.uk/ and it is useful when results have to be refined or when it is the only source of exposure data for an use.

PHED V 1.1 February 1995.
This model has been built by North American regulatory agencies and industry. The model comprises about 1800 replicates for very different types of uses. This model is currently used in North American and some of the uses modelled are relevant for use in other countries.

For each use, all relevant models will be presented. As some are clearly more conservative than others, all the results will be discussed before concluding.

1. SCENARIO 1: 1% GRANULES APPLIED WITH A SPOON

These are 1% granules applied at the dose of 125 g a.i./ha equivalent to 12.5 kg product/hectare.

There is no model available for this type of application.

Considering the reference NOAEL of 0.3 mg/kg bw/day, an acceptable MOS of 30X and a dermal penetration of 50%, this represents, for a 70 kg worker an acceptable skin contamination of 1.4 mg a.i. on the skin equivalent to 140 mg of formulation.

Although extremely variable it can be estimated that the maximum adherence of soil to skin in an adult is 0.4 mg/cm[22]. An amount of 140 mg would then represent the maximum amount retained on 350 cm^2 of skin, i.e. two third of the area of the hand applying the product.

This looks highly improbable and this use is expected to be safe.

2 Exposure Factors Sourcebook for European Populations, with Focus on UK Data. NICOLE Exposure Factors Project: Sponsored by ExxonMobil, ICI, and Shell

2. SCENARIO 2: PRE-PRESSURED HAND HELD EQUIPMENT (5 L)

There is no available model for 5 L pre-pressure hand held sprayer. The knapsack model will then be used.

Application parameters are as follows:
Application rate: 125 g a.i. /ha
Application volume: 15 L/ha (which corresponds to spot treatment)
Estimated size of the tank: 5 L
Speed: 2-3 km/hour
Area treated /day: 3 hectares
a.i. handled/day: 0.75 kg

Evaluation will be performed with UK POEM and BBA models.

UK POEM (details in Annex I)

Total dose absorbed	**No protection**	**Gloves ML**	**Gloves & Coverall ML and Applic.**	
Dermal Exposure				
Mixing/loading	22.50000	2.25000	2.25000	*mg/day*
Application	425.00000	425.00000	40.00000	*mg/day*
Total dose	447.50000	427.25000	42.25000	*mg/day*
Inhalation	1.00000	1.00000	1.00000	*mg/day*
Total dose absorbed	**448.50000**	**428.25000**	**43.25000**	*mg/day*
Total absorbed dose in mg/kg for 70 kg	**6.41**	**6.12**	**0.62**	mg/kg bw./day
MOS	**0.0468**	**0.0490**	**0.4855**	

BBA model (details in Annex II)

Total absorbed dose	**No protection**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading	39.21	0.39	0.39	0.39	mg/pers./day
Application	7.73	7.73	5.72	1.18	mg/pers./day
Total dose	46.93	8.12	6.11	1.57	mg/pers./day
Inhalation					
Mixing/loading	0.02	0.02	0.02	0.02	mg/pers./day
Application	0.11	0.11	0.11	0.11	mg/pers./day
Total dose	0.13	0.13	0.13	0.13	mg/pers./day
Total absorbed dose	**47.07**	**8.25**	**6.25**	**1.70**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.67**	**0.12**	**0.09**	**0.02**	mg/kg bw./day
MOS	**0.45**	**2.54**	**3.36**	**12.33**	

2.1. CONCLUSIONS FOR SCENARIO 2:

There is presently no publicly available model for 5 L tanks pre-pressure hand equipment. Knapsack is probably the closest model although contamination occurring on the back with knapsack is unlikely to occur with 5 L tanks pre-pressure hand equipment.

Exposure evaluation using POEM or BBA models, even with coverall and gloves is unacceptable with MOS of less than 1 with UK POEM and reaching one third of the RefMOS with BBA Model.

Adding Respiratory Protection Equipment (RPE) or an additional layer on the body will not change significantly the results.

There is not enough data in PHED to refine the assessment.

3. SCÉNARIO 3: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB

There is no publicly available model for these uses. The orchard model will be used.
As the equipment used to generate the model is significantly larger than in the intended use, the model may not be enough conservative.

Application parameters are as follows:
Application rate: 125 g a.i. /ha
Application volume: 2.5 à 3.5 L/ha
Estimated size of the tank: 50 L
Speed: 6-8 km/hour
Area treated /day: 20 hectares
a.i. handled/day: 2.5 kg

Evaluation will be performed with UK POEM, BBA and PHED models.

POEM (details in Annex III)

Total dose absorbed	**No protection**	**Gloves ML**	**Gloves & Coverall ML and Applic.**	
Dermal Exposure				
Mixing/loading	12.50	1.25	1.25	*mg/day*
Application	1010.00	1010.00	28.19	*mg/day*
Total dose	1022.50	1011.25	29.44	*mg/day*
Inhalation	6.00	6.00	6.00	*mg/day*
Total dose absorbed	**1028.50**	**1017.25**	**35.44**	*mg/day*
Total absorbed dose in mg/kg for 70 kg	**14.69**	**14.53**	**0.51**	mg/kg bw./day
MOS	**0.0204**	**0.0206**	**0.5926**	

BBA model (details in Annex IV)

Total absorbed dose	**No protection**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading	3.00000	0.03000	0.03000	0.03000	mg/pers./day
Application	14.37500	14.37500	13.50875	2.10875	mg/pers./day
Total dose	17.37500	14.40500	13.53875	2.13875	mg/pers./day
Inhalation					
Mixing/loading	0.00150	0.00150	0.00150	0.00150	mg/pers./day
Application	0.04500	0.04500	0.04500	0.04500	mg/pers./day
Total dose	0.04650	0.04650	0.04650	0.04650	mg/pers./day
Total absorbed dose	**17.42150**	**14.45150**	**13.58525**	**2.18525**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.25**	**0.21**	**0.19**	**0.03**	mg/kg bw./day
MOS	**1.21**	**1.45**	**1.55**	**9.61**	

PHED (details in Annex V)

Per Kg a.i.

Total absorbed dose	No gloves	Gloves M/L	Gloves M/L & Applic.	Gloves M/L & Applic.&Cover.	
Dermal exposure					
Mixing/loading	9.52500	0.05760	0.05760	0.05760	mg/pers./day
Application	0.89400	0.89400	0.66300	0.64300	mg/pers./day
Total dose	10.41900	0.95160	0.72060	0.70060	mg/pers./day
Inhalation					
Mixing/loading	0.00040	0.00040	0.00040	0.00040	mg/pers./day
Application	0.00670	0.00670	0.00670	0.00670	mg/pers./day
Total dose	0.00710	0.00710	0.00710	0.00710	mg/pers./day
Total absorbed dose/kg a.i.	**5.21660**	**0.48290**	**0.36740**	**0.35740**	mg/pers./day
Total absorbed dose/day	**3.91245**	**0.36218**	**0.27555**	**0.26805**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.06**	**0.01**	**0.00**	**0.00**	mg/kg bw./day
MOS	**5.37**	**57.98**	**76.21**	**78.34**	

CONCLUSION FOR AIRBLAST APPLICATION:

There is presently no publicly available model for small airblast equipment without cab.

Airblast orchard is probably the closest model as in both cases application is made using air assisted spray. However there are difference between usual orchard treatment equipment and the one proposed for Temephos application:

- the equipment for Temephos is much smaller than the one used in the model which should underestimate exposure
- the equipment used for Temephos is much more directed than the one used normally for orchard which should overestimate exposure.

None of the scenarios is acceptable using POEM or BBA models.

Using PHED, results (at geometric mean) are acceptable with gloves during preparation and application.

Results should be interpreted with caution with regards to the limited relevance of the model.

4. SCENARIO 4: NON AIR ASSISTED SPRAY MOUNTED ON A 4WD PICK-UP. HIGH OR LOW PRESSURE.

There is no publicly available model for these uses.
A model based on lance and pistol spray will be used from EUROPOEM II
Low and high pressure hand wand will be selected from PHED.
With models, low and high pressure applications are combined as exposure in the two datasets appears similar in the PHED database and cannot be easily separated in EUROPOEM II.

All these data have been generated with people applying from the ground where there were more likely to be in contact with the treated plants. For this reason, the model is expected to be conservative. On the other hand, droplet size is expected to be in the same range.

Application parameters are as follows:
Application rate: 125 g a.i. /ha
Application volume: 100 L/ha
Estimated size of the tank: 200 L
Speed: 5-15 km/hour
Area treated /day: 5 hectares
a.i. handled/day: 0.625 kg

Evaluation will be performed with PHED and EUROPOEM II models.

PHED (details in Annex VI)

Per Kg a.i.

Total absorbed dose	**No gloves**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading					mg/pers./day
Application					mg/pers./day
Total dose	225.00000		1.14000	0.72000	mg/pers./day
Inhalation					
Mixing/loading					mg/pers./day
Application					mg/pers./day
Total dose	0.04600		0.04600	0.04600	mg/pers./day
Total absorbed dose/kg a.i.	**112.54600**		**0.61600**	**0.40600**	mg/pers./day
Total absorbed dose/day	**281.36500**		**1.54000**	**1.01500**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**4.02**		**0.02**	**0.01**	mg/kg bw./day
MOS	**0.07**		**13.64**	**20.69**	

EUROPOEM II (details in Annex VII)

Total absorbed dose	**No gloves**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading	10.02	0.04	0.04	0.04	mg/pers./day
Application	30.72	30.72	17.93	17.93	mg/pers./day
Total dose	41	31	18	18	mg/pers./day
Inhalation					
Mixing/loading	0.00	0.00	0.00	0.00	mg/pers./day
Application	0.07	0.07	0.07	0.07	mg/pers./day
Total dose	0	0	0	0	mg/pers./day
Total absorbed dose/kg a.i.	**20**	**15**	**9**	**9**	mg/pers./day
Total absorbed dose/day	**51**	**39**	**23**	**23**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.73**	**0.55**	**0.32**	**0.32**	mg/kg bw./day
MOS	**0.41**	**0.54**	**0.93**	**0.93**	

4.1. CONCLUSION:

There is presently no publicly available model for non air assisted spray mounted on a vehicle..

Application using hand wand equipment is probably the closest model as in both cases application is made using either a spray gun or a lance on a hose connected to a spray tank. . However there are differences between these two methods of application:

- In the case of Temephos there may be general contamination of the area of the van where operator stays which should underestimate exposure
- On the other hand the operator won't be in contact with the directly treated plants which should overestimate exposure.

This scenario far to be acceptable with EUROPOEM II and is close to be acceptable with PHED and PPE during M/L and application.

Results should be interpreted with caution with regards to the limited relevance of the model.

5. SCENARIO 5: AERIAL APPLICATION

The only available model for this uses is in PHED.

Application parameters are as follows:
Application rate: 125 g a.i. /ha
Application volume: 1.5 to 2.5 L/ha
Estimated size of the tank: 800 to 1500 L
Speed: 160 km/hour
Area treated /day: 400 hectares
a.i. handled/day: 50 kg

As Mixer/loader and applicator (pilot) are unlikely to be the same person, they will be evaluated separately.

Evaluation will be performed with PHED models the pilot.
No suitable model exists for mixing loading of planes unless there is a premix tank. In this case, POEM or BBA model could be considered suitable but:

- this situation is very unlikely as it supposes fixed setting
- this will lead to extremely high calculated exposure.

PHED: (details in Annex VIII)

Per Kg a.i.

Total absorbed dose	**No gloves**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading					mg/pers./day
Application	0.00730			0.64300	mg/pers./day
Total dose	0.00730			0.00760	mg/pers./day
Inhalation					
Mixing/loading					mg/pers./day
Application	0.00008			0.00008	mg/pers./day
Total dose	0.00008			0.00008	mg/pers./day
Total absorbed dose/kg a.i.	**0.00373**			**0.00388**	mg/pers./day
Total absorbed dose/day	**0.18635**			**0.19385**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.00**			**0.00**	mg/kg bw./day
MOS	**112.69**			**108.33**	

5.1. CONCLUSION FOR AERIAL APPLICATION

Exposure of the mixer/loader cannot be assessed properly
Exposure to the pilot is acceptable even without protection.

6. SCENARIO 6: BYSTANDER EXPOSURE

6.1. GRANULES APPLIED WITH A SPOON

No bystander exposure is expected during granule application.

6.2. PRE-PRESSURED HAND HELD EQUIPMENT (5 L)

The size of the droplets delivered by a pre-pressure hand held sprayer is too high to be inhaled and droplets fall on the ground very close from the emission point. A few seconds after application, no droplets remain in the air. Therefore, even when application is performed close to inhabited areas, the risk for bystander is negligible.

6.3. AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB

The drift occurring during application with such equipment may be similar to this measured during vineyard treatment. For the worst case data (Rautmann, 2001[3]) on the drift from application with groundboom show that at 10 m (at distance to represent a bystander outside the boundary of a treated area) the levels of drift deposits are 0.3% or less of the applied dose (90th percentile). For application on vineyard (Rautmann, 2001), the level of drift deposit at 10 m corresponds to 1.23% of the applied dose. According to this extrapolation, it is considered that contamination during application on vineyard is 4.1 folds higher than during application with tractor mounted boom with hydraulic nozzles. If the exposure of a bystander compared to an operator is proportional to the duration of exposure and to the amount of airborne material it is unlikely that exposure of bystanders outside the treatment area will exceed the AOEL.
Further support to this conclusion come from direct measurements of bystander exposure made in the UK for boom spray applications (Lloyd and Bell, 1983): in a typical case following a single pass of the sprayer mean potential dermal exposure (PDE) was measured as 0.1 mL of spray on a bystander positioned at 8 m from the edge of the treatment area. Typical mean potential inhalation exposure was measured as 0.02 mL spray/m^3. Maximum values were about five times these mean values. When extrapolating these values of dermal and inhalation contamination to vineyard and considering the 4.1 higher exposure assessed in the study of Rautmann (2001), it can be considered that for vineyard, PDE will be 0.41 ml spray. The contamination by inhalation will be 0.082 ml spray/m^3.

For temephos, it is assumed that:
1) NOEL = 0.3 mg/kg/day;
2) a maximal spray concentration of 50 mg temephos/ml;
3) an actual dermal exposure (ADE) equal to 50 % (oral AOEL) of the potential dermal exposure (PDE);
4) a 100 % absorption and retention of potential inhalation exposure;

[3] Rautmann, D., Streloke, M., Winkler, R. (2001) New basic drift values in the authorization procedure for plant protection products. In: Forster, R.; Streloke, M. (eds): Workshop on risk assessment and risk mitigation measures in the context of authorization of plant protection (WORMM): 27. -29. September 1999. Organised by Federal Biological Research Centre for Agriculture and Forestry, Biology Division, Braunschweig, Germany. Berlin: Parey. Mitt. Biol. Bundesanst. Land- Forstwirtsch. 383, 133 - 141. Published

5) a respiratory rate of 20 L/min (1.2 m^3/hour),
6) an exposure duration of 5 minutes,
7) a body weight of 70 kg.

The following exposures can be predicted :

* Dermal exposure:
0.41 mL/day x 50 mg/mL = 20.5 mg/day
equivalent to 0.293 mg/kg/day
* Inhalation exposure:
1.2 m^3 x 5 min / 60 min x 0.082 mL/m^3/day x 50 mg/mL = 0.41 mg/day
equivalent to 0.0059 mg/kg/day

With internal AOEL, dermal absorbed = dermal contamination x 50 %

	Dermal absorbed	Inhalation	Total dose absorbed
Dose (mg/kg bw/day)	0.1465	0.0059	0.152
MOS (internal NOEL)			**2**

This figure is probably extremely pessimistic as the number have been derived from application methods using around 400L/hectare, i.e. a spray volume close to 100 times higher while in both cases, the droplet size is expected to be in the same range. The real exposure is then expected to be significantly lower but the available data are not sufficient to indicate by which factor the exposure should be decreased.

6.4. NON AIR ASSISTED SPRAY SPRAY MOUNTED ON A 4WD PICK-UP – HIGH OR LOW PRESSURE

The drift occurring during application with such equipment may be similar to this measured during cereals field treatment (see point 1.3 above).

With a maximal spray concentration of 1.25 g/L, the following exposures can be predicted :

* Dermal exposure:
0.1 mL/day x 1.25 mg/mL = 0.0125 mg/day
equivalent to 0.001785 mg/kg/day
* Inhalation exposure:
3.6 m^3 x 5 min / 60 min x 0.02 mL/m^3/day x 1.25 mg/mL = 0.00075 mg/day
equivalent to 0.000107 mg/kg/day

With internal AOEL, dermal absorbed = dermal contamination x 50 %

	Dermal absorbed	Inhalation	Total dose absorbed
Dose (mg/kg bw/day)	0.000892	0.0000107	0.000999
MOS (internal NOEL)			**300**

6.5. AERIAL APPLICATION

Using the worse case where the person is directly exposed under the plane.

For inhalation exposure, a worse case calculation can be done with the hypothesis that the plane flies at 10 m above the ground and that the concentration is stable and evenly distributed in this volume during the time the person is exposed, In this case, an application rate of 125 g/ha gives a concentration in the air respired by the person of 12.5 mg/10 m^3 and

a dermal exposure of 12.5 mg/day. With a flow rate of 20 L/min for a bystander of 70 kg and an exposure duration of 5 minutes, 12.5 µg of temephos may be inhaled (worst case with the hypothesis that all the droplets are small enough to be inhaled).
If this person is sprayed on one face (about 1 m^3) at the target rat, the skin exposure will be 12.5 mg equivalent to an internal dose of 0.044 mg/kg bw/day for a bystander weighing 70 kg when considering 50% protection by clothes and 50% dermal penetration.

Total internal exposure is: (0.044) + 0.0125 = 0.0565 mg/kg bw/day

Therefore, the **MOS is 5.1**.

These hypotheses are very conservative as:

- Target droplet size in 200 µm which is not inhalable due to a very rapid fall (>1 m/s) and concentration will also decrease very rapidly. Inhalation can then occur only from the lowest droplet size tail which should only represent a very small fraction.
- A m^2 of skin exposure implies that the person is lying of the ground or exposure due a significant wind.

The real exposure is then probably acceptable but no data are available to precisely refine exposure.

7. OVERALL CONCLUSION

The following conclusions can be drawn for operator using the maximum precautions (MOS>30 are considered acceptable):

MOS according to the scenario and the model used with the maximum precautions:

Scenario	**POEM**	**BBA**	**EURO POEM II**	**PHED**
Granules applied with a Spoon	No model	No model	No model	No model
Pre-Pressure Hand Held	0.62	12.3	No model	No model
Air Assisted Spray	0.6	9.6	No model	78.34
Non Air assisted Spray	No model	No model	0.93	20.7
Aerial Application	No model	No model	No model	108.3

The use of risk mitigation measures for occupational handlers (i.e., maximum PPE and engineering controls) results in **MOS greater than the RefMOS of 30 with at least one model** for the following scenarios:

- Air Assisted Spray on quad bike or caterpillar without cab.
- Aerial application

The use of risk mitigation measures form occupational handlers (i.e., maximum PPE and engineering controls) results in **MOS less than the RefMOS of 30 whatever the model used** for the following scenarios:

- Pre-pressure hand held equipment with 5L tank.
- Non air assisted Spray monted on a 4WD pick-up.

The use of risk mitigation measures form occupational handlers (i.e., maximum PPE and engineering controls) could not be evaluated for the following scenario:

- Granules with a spoon.

For re-entry exposure, there is probably no exposure with granule and when the product is applied using pre-pressure hand held equipment with 5L tank.
Exposure when using non air assisted Spray mounted on a 4WD pick-up is considered as acceptable.
When using air Assisted Spray on quad bike or caterpillar, the models gives unacceptable exposure but this is mainly due to the use of a very conservative model.
Exposure by direct spray during aerial application is expected to be borderline, then exposure due to simple drift should be acceptable.

ANNEX I: PRE-PRESSURED HAND HELD EQUIPMENT: POEM

Data relative to Product					
Name	Temephos				
Active Substance	Temephos				
a.s. Concentration s.a. in formulation	500.000				mg/ml
Formulation Type	EC				
Solvent concentration					
Spray concentration	8.333				g/l
Dose a.s./ha	125.000				g/ha
Spray volume applied/ha	15.000				l/ha
Dermal exposure during Mixing/loading					
Container size	1				l
Hand Contamination /operation	0.010				ml/op
Formulation application rate	0.255				l/ha
Area treated/day	3.0				ha/day
Number of operations/day	9	9			op./day
Hand contamination /day	0.090	0.090			ml/day
Protection	None	Gloves			
Transmission to skin	100	10			%
Dermal exposure	0.090	0.009			ml/day
Active substance concentration	500.000	500.000			mg/ml
Dermal exposure to active substance	45.000	4.500			mg/day
Skin penetration	50.00	50.00			%
Dermal absorbed dose	22.5000	2.2500			mg/day
Dermal exposure during application					
Application Technic					
Spray Volume	15.000				l/ha
Contamination Volume	50.000				ml/h
	Hands	Hands	Trunk	Legs	
Distribution	25	25	25	50	%
Protection	None	Gloves	prot clothes	prot clothes	
Transmission to skin	100	10	1	0.9	%
Dermal exposure	10.000	1.250	0.125	0.225	ml/h
Exposure Duration	6				h
Protective Measures	None	Gloves & prot clothes			
Total dermal exposure during application	102.000	9.600			ml/day
Active Substance Concentration	8.333	8.333			mg/ml
Dermal exposure to active substance	850.000	80.000			mg/day
Skin penetration	50.00	50.0			%
Absorbed Dose by Dermal Exposure	425.000	40.000			mg/day
Exposure by inhalation during application					
Exposure to formulation (inhalation)	0.020				ml/h
Exposure Duration	6				h
Concentration to Active Substance	8.333				mg/ml
Exposure to Active Substance (inhalation)	1.000				mg/day
Absorption (%)	100				%
Absorbed Dose (inhalation)	1.000				mg/day

Total dose absorbed	No protection	Gloves ML	Gloves & Coverall ML and Applic.		
Dermal Exposure					
Mixing/loading	22.50000	2.25000	2.25000		mg/day
Application	425.00000	425.00000	40.00000		mg/day
Total dose	447.50000	427.25000	42.25000		mg/day
Inhalation	1.00000	1.00000	1.00000		mg/day
Total dose absorbed	448.50000	428.25000	43.25000		mg/day
Total absorbed dose in mg/kg for 70 kg	6.41	6.12	0.62		mg/kg bw./day
MOS	0.0468	0.0490	0.4855		

ANNEX II: PRE-PRESSURED HAND HELD EQUIPMENT: BBA MODEL

Product	**Temephos**			
Active Substance active (a.s.)	**Temephos**			
Formulation	EC			
Concentration a.s. in formulation	500.000	g/l		
Application rate	0.255	l/ha		
Area treated	3	ha/day		
A.s. handled	0.383	kg/day		
Mixing/loading (M/L)	**No protection**	**Gloves**		
Inhalation exposure				
Generic Exposure	0.05	0.05	mg/kg s.a./day	
Exposure to a.s. handled	0.01913	0.01913	mg/pers./day	
Absorption	100	100	%	
Absorbed dose	0.01913	0.01913	mg/pers./day	
Dermal exposure (hands)				
Generic Exposure	205.00	205.00	mg/kg s.a./day	
Transfer to skin	100	1	%	
Exposure to a.s. handled	78.41250	0.78413	mg/pers./day	
Skin penetration	50.00	50.00	%	
Absorbed dose	39.20625	0.39206	mg/pers./day	
Total absorbed dose	**39.22538**	**0.41119**	mg/pers./day	
Application (Applic.)	**No protection**	**Gloves**	**Gloves&Cover**	
Inhalation exposure				
Generic Exposure	0.300	0.300	0.300	mg/kg s.a./day
Exposure to a.s. handled	0.11475	0.11475	0.11475	mg/pers./day
Absorption	100	100	100	%
Absorbed dose	0.11475	0.11475	0.11475	mg/pers./day
Dermal exposure (head)				
Generic Exposure	4.80	4.80	4.80	mg/kg s.a./day
Transfer to skin	100	100	100	%
Exposure to a.s. handled	1.83600	1.83600	1.83600	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	0.91800	0.91800	0.91800	mg/pers./day
Dermal exposure (hands)				
Generic Exposure	10.60	10.60	10.60	mg/kg s.a./day
Transfer to skin	100	1	1	%
Exposure to a.s. handled	4.05450	0.04055	0.04055	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	2.02725	0.02027	0.02027	mg/pers./day
Dermal exposure (body)				
Generic Exposure	25.00	25.00	25.00	mg/kg a.s./day
Transfer to skin	100	100	5	%
Exposure to a.s. handled	9.56250	9.56250	0.47813	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	4.78125	4.78125	0.23906	mg/pers./day
Total absorbed dose	**7.84125**	**5.83427**	**1.29209**	mg/pers./day

Total absorbed dose	**No protection**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading	39.21	0.39	0.39	0.39	mg/pers./day
Application	7.73	7.73	5.72	1.18	mg/pers./day
Total dose	46.93	8.12	6.11	1.57	mg/pers./day
Inhalation					
Mixing/loading	0.02	0.02	0.02	0.02	mg/pers./day
Application	0.11	0.11	0.11	0.11	mg/pers./day
Total dose	0.13	0.13	0.13	0.13	mg/pers./day
Total absorbed dose	**47.07**	**8.25**	**6.25**	**1.70**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.67**	**0.12**	**0.09**	**0.02**	mg/kg bw./day
MOS	**0.45**	**2.54**	**3.36**	**12.33**	

ANNEX III: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB (POEM)

Data relative to Product			**Europe**		
Name	**Temephos**		Pome fruit		
Active Substance	**Temephos**				
a.s. Concentration s.a. in formulation	500.000				*mg/ml*
Formulation Type	EC				
Main solvent					
Solvent concentration					
Spray concentration	50.000				*g/l*
Dose a.s./ha	*125.000*				*g/ha*
Spray volume applied/ha	*2.500*				*l/ha*
Dermal exposure during Mixing/loading					
Container size	**1**				*l*
Hand Contamination /operation	0.010				*g/op.*
Formulation application rate	0.250				*l/ha*
Area treated/day	20				*ha/day*
Number of operations/day	5	5			*op./day*
Hand contamination /day	0.050	0.050			*g/day*
Protection	**None**	**Gloves**			
Transmission to skin	100	10			*%*
Dermal exposure	0.050	0.005			*g/day*
Active substance concentration	500.000	500.000			*mg/ml*
Dermal exposure to active substance	25.000	2.500			*mg/day*
Skin penetration	50.00	50.00			*%*
Dermal absorbed dose	**12.5000**	**1.2500**			*mg/day*
Dermal exposure during application					
Application Technic					
Spray Volume	2.500				*l/ha*
Contamination Volume	50				*ml/h*
	Hands	Hands	Trunk	Legs	
Distribution	10	10	65	25	*%*
Protection	None	Gloves	prot clothes	prot clothes	
Transmission to skin	100	**10**	0.1	0.25	*%*
Dermal exposure	5.000	0.500	0.033	0.031	*ml/h*
Exposure Duration	2				*h*
Protective Measures	**None**	**Gloves & prot clothes**			
Total dermal exposure during application	40.400	1.128			*ml/day*
Active Substance Concentration	50.000	50.000			*mg/ml*
Dermal exposure to active substance	2020.000	56.375			*mg/day*
Skin penetration	50.00	50.0			*%*
Absorbed Dose by Dermal Exposure	**1010.000**	**28.188**			*mg/day*
Exposure by inhalation during application					
Exposure to formulation (inhalation)	0.020				*ml/h*
Exposure Duration	6				*h*
Concentration to Active Substance	50.000				*mg/ml*
Exposure to Active Substance (inhalation)	6.000				*mg/day*
Absorption (%)	100				*%*
Absorbed Dose (inhalation)	**6.000**				*mg/day*

Total dose absorbed	**No protection**	**Gloves ML**	**Gloves & Coverall ML and Applic.**		
Dermal Exposure					
Mixing/loading	12.50	1.25	1.25		*mg/day*
Application	1010.00	1010.00	28.19		*mg/day*
Total dose	1022.50	1011.25	29.44		*mg/day*
Inhalation	6.00	6.00	6.00		*mg/day*
Total dose absorbed	**1028.50**	**1017.25**	**35.44**		*mg/day*
Total absorbed dose in mg/kg for 70 kg	**14.69**	**14.53**	**0.51**		mg/kg bw./day
MOS	**0.0204**	**0.0206**	**0.5926**		

ANNEX IV: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB (BBA)

Product	**Temephos**			
Active Substance active (a.s.)	**Temephos**			
Formulation	EC			
Concentration a.s. in formulation	500.000	*g/l*		
Application rate	0.250	*l/ha*		
Area treated	20	ha/day		
A.s. handled	2.500	kg/day		
Mixing/loading (M/L)	**No protection**	**Gloves**		
Inhalation exposure				
Generic Exposure	0.0006	0.0006	mg/kg s.a./day	
Exposure to a.s. handled	0.00150	0.00150	mg/pers./day	
Absorption	100	100	%	
Absorbed dose	0.00150	0.00150	mg/pers./day	
Dermal exposure (hands)				
Generic Exposure	2.40	2.40	mg/kg s.a./day	
Transfer to skin	100	1	%	
Exposure to a.s. handled	6.00000	0.06000	mg/pers./day	
Skin penetration	50.00	50.00	%	
Absorbed dose	3.00000	0.03000	mg/pers./day	
Total absorbed dose	**3.00150**	**0.03150**	mg/pers./day	
Application (Applic.)	**No protection**	**Gloves**	**Gloves&Cover**	
Inhalation exposure				
Generic Exposure	0.018	0.018	0.018	mg/kg s.a./day
Exposure to a.s. handled	0.04500	0.04500	0.04500	mg/pers./day
Absorption	100	100	100	%
Absorbed dose	0.04500	0.04500	0.04500	mg/pers./day
Dermal exposure (head)				
Generic Exposure	1.20	1.20	1.20	mg/kg s.a./day
Transfer to skin	100	100	100	%
Exposure to a.s. handled	3.00000	3.00000	3.00000	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	1.50000	1.50000	1.50000	mg/pers./day
Dermal exposure (hands)				
Generic Exposure	0.70	0.70	0.70	mg/kg s.a./day
Transfer to skin	100	1	1	%
Exposure to a.s. handled	1.75000	0.01750	0.01750	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	0.87500	0.00875	0.00875	mg/pers./day
Dermal exposure (body)				
Generic Exposure	9.60	9.60	9.60	mg/kg a.s./day
Transfer to skin	100	100	5	%
Exposure to a.s. handled	24.00000	24.00000	1.20000	mg/pers./day
Skin penetration	50.00	50.00	50.00	%
Absorbed dose	12.00000	12.00000	0.60000	mg/pers./day
Total absorbed dose	**14.42000**	**13.55375**	**2.15375**	mg/pers./day

Total absorbed dose	**No protection**	**Gloves M/L**	**Gloves M/L & Applic.**	**Gloves M/L & Applic.&Cover.**	
Dermal exposure					
Mixing/loading	3.00000	0.03000	0.03000	0.03000	mg/pers./day
Application	14.37500	14.37500	13.50875	2.10875	mg/pers./day
Total dose	17.37500	14.40500	13.53875	2.13875	mg/pers./day
Inhalation					
Mixing/loading	0.00150	0.00150	0.00150	0.00150	mg/pers./day
Application	0.04500	0.04500	0.04500	0.04500	mg/pers./day
Total dose	0.04650	0.04650	0.04650	0.04650	mg/pers./day
Total absorbed dose	**17.42150**	**14.45150**	**13.58525**	**2.18525**	mg/pers./day
Total absorbed dose in mg/kg for 70 kg	**0.25**	**0.21**	**0.19**	**0.03**	mg/kg bw./day
MOS	**1.21**	**1.45**	**1.55**	**9.61**	

ANNEX V: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB (PHED).

Subset Specifications for TEMP.NAME.MLOD
With Solid Type Not Equal to 1 and Not Equal to 2 and Not Equal to 3 and Not Equ
Subset originated from TEMP.NAME.MLOD
With Liquid Type Not Equal to 5 and Not Equal to 4 and
With Tank/Hoppers Capacity Less than or Equal to 150 and Greater than or Equal t
Subset originated from MLOD.FILE

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	.574	23.3188	556.9495	1.1759	35
NECK.FRONT	Other	.0993	1.2863	278.2736	.2501	32
NECK.BACK	Other	.0486	.2671	271.9008	.0947	32
UPPER ARMS	Lognormal	2.5695	7461.2914	199.9426	22.4305	4
CHEST	Other	1.5673	3.0278	116.6521	2.2143	22
BACK	Lognormal	1.5673	2.547	56.3703	2.2494	8
FOREARMS	Lognormal	2.9382	16.7982	247.9486	2.9439	9
THIGHS	Lognormal	1.2649	1.2649	47.1379	1.1925	2
LOWER LEGS	Lognormal	4.7285	34.8256	226.8116	7.4408	7
FEET	Lognormal	1.1567	2.1208	119.3921	1.4265	6
HANDS	Lognormal	10.3656	143.2865	266.1745	16.0442	28
TOTAL DERM:	56.017	26.8799	7690.0344		57.4629	
INHALATION:	Lognormal	1.1038	1.7157	214.5008	.3991	33
COMBINED:	56.4161	27.9837	7691.7501		57.862	

95% C.I. on Mean: Dermal: [-303496.5827, 318876.6516]
95% C.I. on Geo. Mean: Inhalation: [.0078, 20.4416]
Inhalation Rate : 25 Liters/Minute Number of Records: 36
Data File: MIXER/LOADER Subset Name: TEMP.NAME.MLOD

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	.574	23.3188	556.9495	1.1759	35
NECK.FRONT	Other	.0993	1.2863	278.2736	.2501	32
NECK.BACK	Other	.0486	.2671	271.9008	.0947	32
UPPER ARMS	Lognormal	2.5695	7461.2914	199.9426	22.4305	4
CHEST	Other	1.5673	3.0278	116.6521	2.2143	22
BACK	Lognormal	1.5673	2.547	56.3703	2.2494	8
FOREARMS	Lognormal	2.9382	16.7982	247.9486	2.9439	9
THIGHS	Lognormal	1.2649	1.2649	47.1379	1.1925	2
LOWER LEGS	Lognormal	4.7285	34.8256	226.8116	7.4408	7
FEET	Lognormal	1.1567	2.1208	119.3921	1.4265	6
HANDS	Lognormal	8672.343	14461.2669	91.5957	9525.3086	9
TOTAL DERM:	9565.2814	8688.8574	22008.0148		9566.7274	
INHALATION:	Lognormal	1.1038	1.7157	214.5008	.3991	33
COMBINED:	9565.6805	8689.9611	22009.7305		9567.1265	

95% C.I. on Mean: Dermal: [-339591.1342, 383607.1638]
95% C.I. on Geo. Mean: Inhalation: [.0078, 20.4416]
Inhalation Rate : 25 Liters/Minute Number of Records: 36
Data File: MIXER/LOADER Subset Name: TEMP.NAME.MLOD

ANNEX V: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB. (CNTN…)

Application :

Subset Specifications for TEMP.NAME.APPL
With Application Method Equal to 1 and
With Cab Type Equal to 1 and
With Total lb ai Applied Less than or Equal to 40
Subset originated from APPL.FILE

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	858.3444	1942.0731	140.4455	481.9623	53
NECK.FRONT	Lognormal	31.606	76.417	150.7969	23.0475	44
NECK.BACK	Lognormal	23.2263	62.4422	149.5685	20.2247	48
UPPER ARMS	Other	15.4172	142.0216	192.6326	31.7695	47
CHEST	Lognormal	19.5916	115.8594	181.527	27.7726	51
BACK	Other	15.6733	108.0534	193.7485	22.9751	51
FOREARMS	Other	6.9448	40.43	178.4355	11.5404	47
THIGHS	Lognormal	31.2009	84.9631	225.3248	26.0442	53
LOWER LEGS	Lognormal	15.7616	33.6492	130.8428	14.5545	43
FEET						0
HANDS	Lognormal	193.9141	1208.9278	252.8146	235.0258	28
TOTAL DERM:		866.6669	1211.6801	3814.8369	894.9166	
INHALATION:	Other	6.9391	16.0475	210.5482	6.7095	67
COMBINED:		873.606	1218.6192	3830.8843	901.626	

95% C.I. on Mean: Dermal: [-25045.8992, 32675.573]
95% C.I. on Geo. Mean: Inhalation: [.3927, 114.6403]
Inhalation Rate : 25 Liters/Minute Number of Records: 71
Data File: APPLICATOR Subset Name: TEMP.NAME.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	858.3444	1942.0731	140.4455	481.9623	53
NECK.FRONT	Lognormal	31.606	76.417	150.7969	23.0475	44
NECK.BACK	Lognormal	23.2263	62.4422	149.5685	20.2247	48
UPPER ARMS	Other	15.4172	142.0216	192.6326	31.7695	47
CHEST	Lognormal	19.5916	115.8594	181.527	27.7726	51
BACK	Other	15.6733	108.0534	193.7485	22.9751	51
FOREARMS	Other	6.9448	40.43	178.4355	11.5404	47
THIGHS	Lognormal	31.2009	84.9631	225.3248	26.0442	53
LOWER LEGS	Lognormal	15.7616	33.6492	130.8428	14.5545	43
FEET						0
HANDS	Lognormal	3.1461	13.2879	105.2181	3.4687	33
TOTAL DERM:		635.1098	1020.9121	2619.1969	663.3594	
INHALATION:	Other	6.9391	16.0475	210.5482	6.7095	67
COMBINED:		642.0489	1027.8512	2635.2444	670.0689	

95% C.I. on Mean: Dermal: [-13267.2392, 18505.633]
95% C.I. on Geo. Mean: Inhalation: [.3927, 114.6403]
Inhalation Rate : 25 Liters/Minute Number of Records: 71
Data File: APPLICATOR Subset Name: TEMP.NAME.APPL

ANNEX V: AIR ASSISTED SPRAY ON QUAD-BIKE OR CATERPILLAR WITHOUT CAB. (CNTN…)

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Protective overall over long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	858.3444	1942.0731	140.4455	481.9623	53
NECK.FRONT	Lognormal	31.606	76.417	150.7969	23.0475	44
NECK.BACK	Lognormal	23.2263	62.4422	149.5685	20.2247	48
UPPER ARMS						0
CHEST	Lognormal	29.3874	35.1342	36.1151	33.362	6
BACK	Lognormal	29.3874	35.1342	36.1151	33.362	6
FOREARMS	Lognormal	12.6876	12.8658	31.2223	12.3296	6
THIGHS	Lognormal	31.6225	37.8064	36.1152	35.8993	6
LOWER LEGS						0
FEET						0
HANDS	Lognormal	3.1461	13.2879	105.2181	3.4687	33
TOTAL DERM:	643.6561	1019.4077	2215.1607		643.6561	
INHALATION:	Other	6.9391	16.0475	210.5482	6.7095	67
COMBINED:	650.5952	1026.3468	2231.2082		650.3656	

95% C.I. on Mean: Dermal: [-13446.1908, 17876.5122]
95% C.I. on Geo. Mean: Inhalation: [.3927, 114.6403]
Inhalation Rate : 25 Liters/Minute Number of Records: 71
Data File: APPLICATOR Subset Name: TEMP.NAME.APPL

ANNEX VI: NON AIR ASSISTED SPRAY MOUNTED ON A 4WD PICK-UP. HIGH OR LOW PRESSURE

PHED DATA
Subset Specifications for TEMP.NAME.MLAP
With Application Method Equal to 7 (low pressure hand wand) and
With Solid Type Not Equal to 1 and Not Equal to 2 and Not Equal to 3 and Not Equal to 4
Subset originated from MLAP.FILE

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER AVERAGE KG AI Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	586.7219	1453.7221	136.7049	641.2841	80
NECK.FRONT	Lognormal	45.7285	304.4649	369.6483	41.7819	80
NECK.BACK	Lognormal	37.3466	190.5682	429.9868	32.7481	79
UPPER ARMS	Lognormal	33.404	246.8682	232.934	72.0113	10
CHEST	Other	40.7506	519.1777	185.929	108.1139	10
BACK	Other	40.7506	361.5828	202.4421	91.7711	10
FOREARMS	Other	13.8896	90.4161	267.6492	20.777	10
THIGHS	Other	43.8499	83.8583	115.1859	61.0898	9
LOWER LEGS	Lognormal	27.3201	147.7503	164.3135	66.2784	9
FEET						0
HANDS	Lognormal	212777.289	296912.7662	83.7697	224347.8781	70
TOTAL DERM:		225286.6604	213647.0506	300311.1748	225483.7338	
INHALATION:	Other	57.4872	89.4956	105.042	46.843	80
COMBINED:		225344.1476	213704.5377	300400.6704	225530.5768	

95% C.I. on Mean: Dermal: [-940019.7125, 1540642.0622]
95% C.I. on Geo. Mean: Inhalation: [2.9013, 756.2973]
Inhalation Rate : 25 Liters/Minute Number of Records: 80
Data File: MIXER/LOADER/APPLICATOR Subset Name: TEMP.NAME.MLAP

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER AVERAGE KG AI Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	586.7219	1453.7221	136.7049	641.2841	80
NECK.FRONT	Lognormal	45.7285	304.4649	369.6483	41.7819	80
NECK.BACK	Lognormal	37.3466	190.5682	429.9868	32.7481	79
UPPER ARMS	Lognormal	33.404	246.8682	232.934	72.0113	10
CHEST	Other	40.7506	519.1777	185.929	108.1139	10
BACK	Other	40.7506	361.5828	202.4421	91.7711	10
FOREARMS	Other	13.8896	90.4161	267.6492	20.777	10
THIGHS	Other	43.8499	83.8583	115.1859	61.0898	9
LOWER LEGS	Lognormal	27.3201	147.7503	164.3135	66.2784	9
FEET						0
HANDS	Other	4.5989	22.9029	252.7287	6.664	10
TOTAL DERM:		943.3812	874.3605	3421.3115	1142.5196	
INHALATION:	Other	57.4872	89.4956	105.042	46.843	80
COMBINED:		1000.8684	931.8477	3510.8071	1189.3627	

95% C.I. on Mean: Dermal: [-18146.6494, 24989.2723]
95% C.I. on Geo. Mean: Inhalation: [2.9013, 756.2973]
Inhalation Rate : 25 Liters/Minute Number of Records: 80
Data File: MIXER/LOADER/APPLICATOR Subset Name: TEMP.NAME.MLAP

ANNEX VI: NON AIR ASSISTED SPRAY MOUNTED ON A 4WD PICK-UP. HIGH OR LOW PRESSURE (CNTN …)

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Protective overall over long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER AVERAGE KG AI Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	586.7219	1453.7221	136.7049	641.2841	80
NECK.FRONT	Lognormal	45.7285	304.4649	369.6483	41.7819	80
NECK.BACK	Lognormal	37.3466	190.5682	429.9868	32.7481	79
UPPER ARMS						0
CHEST						0
BACK						0
FOREARMS						0
THIGHS						0
LOWER LEGS						0
FEET						0
HANDS	Other	4.5989	22.9029	252.7287	6.664	10
TOTAL DERM:		665.8508	674.3958	1971.6581	722.4781	
INHALATION:	Other	57.4872	89.4956	105.042	46.843	80
COMBINED:		723.338	731.883	2061.1536	769.3212	

95% C.I. on Mean: Dermal: [-9379.0502, 13322.3664]
95% C.I. on Geo. Mean: Inhalation: [2.9013, 756.2973]
Inhalation Rate : 25 Liters/Minute Number of Records: 80
Data File: MIXER/LOADER/APPLICATOR Subset Name: TEMP.NAME.MLAP

ANNEX VII: NON AIR ASSISTED SPRAY MOUNTED ON A 4WD PICK-UP. HIGH OR LOW PRESSURE: EUROPOEM

M/L	PDE excl hands in µg/kg a.s.	ADE excl hands in µg/kg a.s.	Protected hands in µg/kg a.s.	Unprotected hands in µg/kg a.s.	Protective gloves in µg/kg a.s.	Potential hands in µg/kg a.s.	Potential dermal in µg/kg a.s.	Actual dermal in µg/kg a.s.	Inhalation in µg/kg a.s.
Number of values	35	12	20	40	15	55	31	8	21
% of BLQ									
A.M.	5 853	21	170	78 730	24 582	63 995	55 635	53	1
ASD	15 561	25	283	234 137	22 676	200 788	133 572	59	1
GM	721	10	33	10 012	13 964	10 983	14 635	25	1
GSD	7	4	8	7	4	6	5	4	3
Max value	83 173	85	1 018	1 340 246	78 571	1 340 246	601 900	154	3
90th percentile	14 824	41	545	87 231	53 762	59 960	56 071	135	2
75th percentile	1 875	36	147	27 774	33 869	30 214	40 635	84	1.4
50th percentile	582	9	28	9 329	21 071	10 733	16 614	24	1
25th percentile	208	4	9	2 435	7 798	3 522	5 184	10	0
Min Value	12	1	0	175	453	175	780	3	0

Appl	PDE excl hands in µg/kg a.s.	ADE excl hands in µg/kg a.s.	Protected hands in µg/kg a.s.	Unprotected hands in µg/kg a.s.	Protective gloves in µg/kg a.s.	Potential hands in µg/kg a.s.	Potential dermal in µg/kg a.s.	Actual dermal in µg/kg a.s.	Inhalation in µg/kg a.s.
Number of values	103	12	11	47	62	109	85	6	89
% of BLQ									
A.M.	245 137	42 619	15 357	31 519	51 544	44 413	271 920	54 093	329
ASD	333 152	44 864	26 414	34 006	106 703	84 591	357 273	49 343	541
GM	111 743	14 797	3 128	15 927	16 926	14 797	139 440	23 271	73
GSD	4	6	7	4	5	6	3	6	7
Max value	2 008 450	126 119	71 512	145 721	644 343	644 343	2 012 155	127 004	2 639
90th percentile	646 736	97 742	64 594	81 265	79 573	99 379	676 023	108 599	1 098
75th percentile	272 585	73 624	10 658	37 124	59 791	45 857	309 605	83 160	356
50th percentile	131 801	26 983	2 223	23 364	14 714	17 568	142 601	51 006	82
25th percentile	48 591	3 664	673	8 124	6 636	7 288	74 900	12 930	11
Min Value	719	1 014	303	551	538	538	2 856	1 425	2

ANNEX VIII AERIAL APPLICATION

Subset Specifications for TEMP.NAME.APPL

With Solid Type Not Equal to 4
Subset originated from TEMP.NAME.APPL
With Application Method Equal to 5
Subset originated from APPL.FILE

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	.13	1.3035	208.6229	.3801	74
NECK.FRONT	Other	.03	.1256	218.7102	.0415	70
NECK.BACK	Other	.011	.0843	247.6868	.0251	62
UPPER ARMS	Other	.291	2.7882	207.3668	.9003	43
CHEST	Other	.355	2.6786	237.0081	.8459	55
BACK	Other	.355	3.4209	232.4359	.9279	55
FOREARMS	Other	.242	1.3557	195.6701	.4239	44
THIGHS	Other	.382	4.2118	229.9349	1.2216	39
LOWER LEGS	Other	.238	2.3523	245.9975	.6721	43
FEET	Lognormal	.393	.4803	88.8195	.3311	12
HANDS	Lognormal	1.9125	7.4962	229.5403	1.562	58
TOTAL DERM:		3.9271	4.3395	26.2974	7.3315	
INHALATION:	Lognormal	.0739	.2827	250.1238	.0726	65
COMBINED:		3.9997	4.4134	26.5801	7.4041	

95% C.I. on Mean: Dermal: [-181.1279, 233.7227]
95% C.I. on Geo. Mean: Inhalation: [.0025, 2.1307]
Inhalation Rate : 25 Liters/Minute Number of Records: 81
Data File: APPLICATOR Subset Name: TEMP.NAME.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES
SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	.13	1.3035	208.6229	.3801	74
NECK.FRONT	Other	.03	.1256	218.7102	.0415	70
NECK.BACK	Other	.011	.0843	247.6868	.0251	62
UPPER ARMS	Other	.291	2.7882	207.3668	.9003	43
CHEST	Other	.355	2.6786	237.0081	.8459	55
BACK	Other	.355	3.4209	232.4359	.9279	55
FOREARMS	Other	.242	1.3557	195.6701	.4239	44
THIGHS	Other	.382	4.2118	229.9349	1.2216	39
LOWER LEGS	Other	.238	2.3523	245.9975	.6721	43
FEET	Lognormal	.393	.4803	88.8195	.3311	12
HANDS	Lognormal	2.8942	5.5983	116.814	1.8411	16
TOTAL DERM:		4.2062	5.3212	24.3995	7.6106	
INHALATION:	Lognormal	.0739	.2827	250.1238	.0726	65
COMBINED:		4.2788	5.3951	24.6822	7.6832	

95% C.I. on Mean: Dermal: [-159.1306, 207.9296]
95% C.I. on Geo. Mean: Inhalation: [.0025, 2.1307]
Inhalation Rate : 25 Liters/Minute Number of Records: 81
Data File: APPLICATOR