# ENVIRONMENTAL ASSESSMENT REPORT

For the review of Temephos in the product COOPERS ASSASSIN SHEEP DIP

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# **GLOSSARY** (Definitions of Terms)

AF = Assessment Factor

DEH = Department of Environment, Heritage, Water and the Arts, previously

Department of Environment and Heritage

EC = Emulsifiable Concentrate

 $EC_{50}$  = The concentration of a test substance which results in 50% of the test

animals being adversely affected, i.e. both mortality and sub-lethal

effects.

EEC = Estimated Environmental Concentration

EQS = Environmental Quality Standards

 $LC_{50}$  = The concentration of a test substance which results in a 50% mortality

of the test species.

MAC = Maximum Allowable Concentration

NOEC = No-observed effect concentration, i.e. the test concentration at which

no adverse effect occurs.

OP = Organophosphate

PNEC = Predicted No Effect Concentration

Q = Quotient (of EEC/PNEC)

WWP = Wool Withholding Period, equivalent to the Wool Harvesting Interval

# COOPERS ASSSASSIN SHEEP DIP (CONTAINING) TEMEPHOS

#### 1. INTRODUCTION

Coopers Assassin Sheep Dip is a currently registered veterinary product that has not been marketed for some years. It contains temephos, an organophosphate (OP) insecticide, which in other registered products is currently used in the control of mosquitoes and midges, as a pour-on insecticide for the control of lice on cattle and for dipping/jetting of sheep.

At the time the review commenced, *Coopers Assassin Sheep Dip* was the only registered product containing temephos for use on sheep. The product is used for the control of body lice (including synthetic pyrethroid resistant strains) on wet or dry short wool sheep by plunge or shower dipping and for the treatment of body lice on long wool sheep by hand jetting.

In February 2000, a range of occupational health and safety and environmental concerns were identified by the APVMA in relation to the use of organophosphate chemicals in sheep dip products. The registrant obtained approval for a late renewal of the product in 2001. Given the concerns relating to the environment and to occupational health and safety, the APVMA decided to place the product under reconsideration and temephos was subsequently placed under review in November 2001.

This report is based on the data submitted for the original registration, and additional data, dated December 2001, submitted for this assessment, which cross references all data provided for the Sheep Ectoparasiticide Review in March 2000. A Wool Withholding Period (WWP) of 3 months is currently stated on the product label based on the assessment of the original data.

The purpose of this assessment report is to ascertain whether continued use of the product would not represent an undue risk to the environment based on the additional information now available. The review will examine whether the Department of Environment and Heritage (DEH, currently the Department of Environment, Water, Heritage and the Arts) can support the continued registration of the product under the current or revised conditions.

#### 2. CHEMICAL IDENTITY

Name CAS: Phosphorothioic acid, *O,O'*-(thiodi-4,1-phenylene)-

O,O,O',O'-tetramethyl ether

Common name: Temephos

Trade name: Coopers Assassin Sheep Dip

CAS number: 3383-96-8

Molecular formula:  $C_{16}H_{20}O_6P_2S_3$ 

Molecular weight: 466.4

Structural formula:

$$(H_3CO)_2PO$$
  $S$   $OP(OCH_3)_2$ 

Purity: Not less than 93%

#### 3. PHYSICO-CHEMICAL PROPERTIES

Appearance: Amber liquid with mercaptan-like odour (active

constituent)

Melting Point: 30.0-30.5°C (pure active); 10-15°C (active constituent)

Relative Density: 1.33 g/mL at 20°C

Vapour Pressure: 7.17 X 10<sup>-8</sup> mm Hg at 25<sup>o</sup>C

Water Solubility:  $0.03 \pm 0.007$  mg/L at 25°C

Partition Coefficient: Log  $P_{OW} = 4.9$  (measured and estimated values between

3.9 and 6.2 have been reported in the scientific literature).

Dissociation Constant: Not applicable since temephos does not dissociate.

Stability: Temephos appears to be thermally and hydrolytically

stable for extended periods at normal temperatures.

#### 4. FORMULATION OF END-USE PRODUCT

*Coopers Assassin Sheep Dip* is an emulsifiable concentrate containing 350 g/L temephos dissolved in liquid hydrocarbons.

# 5. ENVIRONMENTAL EXPOSURE

#### **5.1 Environmental Release**

#### **5.1.1** *Volume*

Most recent estimates by the registrant indicate that, should the product return to the market without any amendments to existing instructions for use, between 0.5-2.5

tonnes of temephos per annum could be used for the purpose of treating sheep, with the majority likely to be used off shears<sup>1</sup>.

# 5.2 Application and Use Pattern

#### 5.2.1 Short wool

Sheep are treated using plunge or shower dips, up to 6 weeks off shears. There is also a restraint statement indicating that sheep should not be treated within 2 weeks of shearing. The label directs users to initially charge plunge and shower dips at 100 mL/100 L of water (35 g ai/100 L), and to top up (replenish the dip) at 100 mL/100 L.

The label instructs users to yard sheep overnight and preferably dip early in the morning to allow sheep to dry before nightfall. The dip should be topped up before its volume drops by more than 25%, and dipped out when excessively fouled (generally when one sheep has been dipped for every 2 L of original sump volume) or at the end of each day for shower dips. The label advises against leaving fouled plunge dips for more than a day in mild or warm weather, recommending that a disinfectant be added when dipping has finished for the day should retention for a longer period be unavoidable. Sheep must be thoroughly wetted. Inspection of the first few sheep to emerge from shower dips is recommended to ensure this. The label instructs users to ensure each sheep swims for at least 30 seconds in plunge dips and has its head submerged twice.

# 5.2.2 Long wool

The product is registered for use on sheep with up to 9 months wool (i.e. up to 3 months before shearing). It is diluted at a rate of 100 mL to every 100 L of water and applied by hand jetting from the poll to the rump of the sheep in a band 15-25 cm in width with some fluid sprayed into the shoulder wool. The label instructs to apply fluid to wet backline fleece to skin level, and to use approximately 0.5 L of fluid (concentration of  $100/100,000 \times 350 \text{ g}/\text{L} = 0.35 \text{ g}$  ai/L) for each month of wool growth, with a minimum of 2.5 L per sheep, and a maximum of 4.5 L for sheep with 9 months wool growth. This equates to a range of 0.875 to 1.575 g of temephos applied per sheep.

# 5.3 Formulation, Handling and Disposal

Any spills during formulation will be contained and transferred to sealed containers for disposal by incineration or to landfill as special waste. Any formulation wastes will be similarly disposed of.

When used on short wool the current label statement instructs, under **Disposal of Unwanted Dip Wash Liquid**, that "Unwanted dip wash liquid should be transferred to a pit on level ground in a situation where overflow or seepage into waterways is unlikely. The degradation of *Assassin* may be accelerated by addition of 5 litres of a solution of 100 g/L sodium hydroxide (caustic soda) in water per 10,000 litres of dip

<sup>1</sup> Note that this assumption is no longer applicable as label instructions have been amended.

wash." Elsewhere (under **Protection of Wildlife, Fish, Crustacea and Environment**) the label instructs "Dispose of used dip in a clay-lined pit specifically designed for this purpose. Do not discharge waste liquid into streams."

The above are similar to the statements that appeared on the original label, which at the time were accepted without comment or assessment. However, since then a national policy on the disposal of spent dip solution is being developed through the Registration Liaison Committee (RLC)/Australian Pesticide and Veterinary Medicines Authority (APVMA). While disposal to a pit remains an acceptable option, at least for the interim, there are concerns about the practicality of the use of pits, in particular properly lined pits rather than "soakaways" which may simply consist of a hole in the ground dug by a back hoe. Based on experimental data on other organophosphate (OP) dips, disposal over a larger area of bunded, grassed land is preferred, which should enhance both evaporation of water and degradation of temephos. While data indicate that temephos is non-persistent to slightly persistent in soils and aquatic systems (see below), degradation may be significantly slowed when concentrated in a pit.

Therefore the registrant was asked to comment whether a statement similar to that recently proposed for diazinon would be preferable, ie "Dispose of used dip solution and sludge over an area of dedicated and bunded flat land, away from watercourses and any drainage areas etc that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months". This is considered more practical and appropriate and would assist in the development of a more generic disposal statement for spent OP sheep dips, noting that shower dips should be dipped out at the end of each day.

The registrant has responded that while there are no objections to the revised statement *per-se*, the company felt that it may be impractical and that it will take a large educational effort to make farmers aware that they should be disposing of used dip solution in this manner. DEH notes this would also be the case for disposal to properly lined pits.

DEH also has concerns about the instruction to add a small amount of caustic soda. This does not appear to be based on sound science since temephos appears to be hydrolytically stable. Further, it appears that there is no practical way to add sufficient caustic soda to raise the pH high enough to effect hydrolysis of temephos, with anecdotal reports indicating that addition of 0.5% slaked lime (calcium hydroxide, usually preferred due to its lower cost) will not raise the pH to >10 as opposed to the >12 sought. Lastly such strongly alkaline solutions represent a hazardous material and disposal of them onto flat land is reported to be extremely phytotoxic. Therefore DEH considers that the instruction is unworkable and recommends that it be deleted from the label.

When applied to long wool sheep the jetting solution is not to be recycled so the product draining from sheep will fall onto the soil at the site of jetting, presumably a race within the sheep yards. In trials conducted to test the use, the treated sheep retained only approximately one third of the applied jetting fluid so the majority of the applied fluid drains off the sheep. Due to the suggested non-stripping nature of the product, less temephos may be retained on the sheep and more will reach the soil in comparison to other OPs, which because of their stripping nature, will tend to be adsorbed to fleece to a

greater degree (note the non-stripping claim should be treated with caution as the only support for it appears to be indirectly from the trial of Burman et al, 1997).

DEH is concerned that dripping in this manner could lead to soil that is contaminated to relatively high levels which could persist if biodegradation is retarded by higher concentrations of temephos.

At the time of the original assessment (February 1998) it was noted that the issue may require further consideration if usage increases. This has now been done, (refer Section 8.1 of this component report).

# **5.4 Sources of Environmental Exposure**

In the original application for *Assassin*, spills of the product and discharge of dipbaths after use were identified as sources of environmental exposure. These sources would involve the terrestrial compartment.

Discharge of wool scouring effluent also represents a potentially significant source of environmental exposure to temephos. Residues in scouring effluent are a major current concern (Pattinson, 1995) for the wool industry. The original report by DEH estimated that temephos residues from short wool treatment would not be of concern. However, residues from long wool treatment will be higher and the overall effect of residues from both off shears and long wool treatments is dealt with in the environmental hazard section.

# 6. ENVIRONMENTAL CHEMISTRY AND FATE

#### **6.1** Environmental fate

A detailed assessment of the environmental fate of temephos, with particular reference to coastal environments, is contained in DEH's publicly available environmental assessment report of July 1994 (can be provided on request from DEH). In the original submission the registrant provided some general literature references to the environmental characteristics of temephos, and recommended reference to that report for more detail. A brief summary of DEH's conclusions follows.

# 6.1.1 Abiotic degradation (hydrolysis, photolysis)

Temephos is hydrolytically stable but susceptible to photochemical oxidation about the thioether linkage. Product information indicates that hydrolysis may be expected after prolonged periods at high pH, suggesting possible hydrolytic degradation during wool scouring.

#### 6.1.2 Metabolism in soils

The main degradative pathway operating in the environment is likely to be microbial metabolism, which proceeds by way of oxidation of the thioether and thiophosphate functionalities and phosphate hydrolysis to a range of products that break down further to carbon dioxide.

# 6.1.3 Aerobic aquatic metabolism

An aerobic study with lakewater and a sandy sediment indicated that around 30% of the applied radiolabel was in the water and 50% in the sediment by the end of the 30-day study. Temephos degraded with an estimated half-life of 17.2 days to give at least 5 products of which three were identified as the sulphoxide, the bis(phenol) derivative and its sulphone. The degradation is largely an oxidative one, impacting on the thiophosphate and thioether functionalities.

# 6.1.4 Anaerobic aquatic metabolism

Aside from a total absence of evolved carbon dioxide, the degradation pathway did not differ under anaerobic conditions carried out similarly to the above but under a  $N_2$  atmosphere. The rate of degradation appeared faster initially but slowed thereafter. As in the aerobic study, temephos partitioned initially to sediment. However, by the end of the 1 year study, >90% of applied radioactivity was present in water. Of the remainder <4% of the applied radioactivity was unextractable from the sediment at any stage.

#### 6.1.5 Persistence

Temephos is non-persistent to slightly persistent in soils and aquatic systems, with half-lives of a few days or weeks being typical in the field. Biphasic dissipation, consisting of rapid sorption to organic matter followed by more gradual metabolism, occurs in water.

# 6.1.6 Sorption

Temephos sorbs strongly to soils and can be considered a non-leacher. However, its phenolic metabolites are more hydrophilic and mobile. In aquatic systems, temephos sorbs rapidly to sediment, where it is immobile.

# 6.1.6 Volatilisation

Model calculations indicate that volatilisation may also be a significant pathway for dissipation of temephos from water. A study by Prasad and Jain (1988) tends to support these predictions in that dissipation of Emulsifiable Concentrate (EC) formulations, which would leave significant amounts of temephos as a surface film, was more rapid than for granular formulations. This study also suggested a significant contribution from volatilisation during the first 24 hours after application to soil.

#### 6.1.7 Bioaccumulation

A bioaccumulation factor of 2,300 and a depuration half-life of 8 days were obtained for bluegill sunfish exposed to  $^{14}C\text{-temephos}$  under flow through conditions at an average level of 0.65  $\mu g/L$  for 28 days in the laboratory. Residues in whole fish reached 1500  $\mu g/kg$  during the uptake phase and appeared to be still increasing, but had declined to 380  $\mu g/kg$  after 14 days depuration. The metabolite profile was not investigated. This is indicative of a moderate level of bioaccumulation and slow depuration, which has been confirmed in the field.

#### 6.1.8 US EPA Assessment

Note that since DEH's 1994 assessment the US EPA has published a Re-registration Eligibility Document (RED, US EPA, 1999a), and a Revised Environment Fate and

Effects Document (EFED, US EPA, 1999b). Apart from field studies more relevant to the mosquito application, this does not contain any additional relevant fate data.

# 6.2 Degradation in fleece

#### 6.2.1 Short wool

The significance of the scouring source will depend on the residues in the fleece before scouring and their fate in the scouring process. Information on fleece residues from use on short wool is summarised in a study designed to determine the likely exposure of shearers to temephos (Martin 1994).

The study involved shower dipping of ten sheep three weeks after shearing, followed by fleece sampling (5 X 5 cm) of backline and flank at 1, 6, 12 and 26 weeks. Backline and flank were assumed to contribute 30 and 70% to the total fleece weight, respectively. Results are tabulated as mg/kg greasy wool as shown in Table 1. The reduction of fleece residues with time represents a combination of growth dilution and degradation. No initial levels were determined, and the half-life for degradation cannot be determined accurately from these data. However, it is evident that use on short wool should not leave residues in excess of 1 mg/kg at shearing (see further discussion Section 8.2.4 below).

Table 1: Temephos residue levels in wool at different sites of the sheep

Site	Weeks post-treatment				
	1	6	12	26	
	868	10.2	4.2	ND	
Backline (mg/kg)					
Flank (mg/kg)	906	6.5	2.5	0.9	
Combined (mg/kg)	895	7.6	3.0	0.6	

#### 6.2.2 Long wool

Information on temephos residues resulting from application to sheep with long wool is available from a study by Burman *et al* (1997). Five groups of 10 medium wool Merino sheep were selected. At nine months from shearing one group was treated with temephos at 350 mg/L and another was treated with diazinon at 200 mg/L. At ten months from shearing one of the remaining three groups was treated with temephos and another was treated with diazinon. The final group remained untreated and was used to monitor wool growth rates. Wool samples were taken from a 5 cm circumferential strip around each of five sheep in each group. Sampling began before treatment and at 1 week, 1, 2 and 3 months or 1 week, 1 and 2 months after treatment. The final sampling occurred when the sheep had 12 months wool growth and was equivalent to the next shearing. The mean values for temephos residues (mg/kg) are listed in Table 2 below.

Table 2: Mean wool residue levels in sheep with 9 or 10 months wool growth sampled on days 7, 30, 60 and 90 after treatment

9 months wool growth			10 months wool growth			
Days post treatment	Fleece weight (kg)*	Temephos concentration mg/kg (range of values)	Temephos in fleece (mg)	Fleece weight (kg)*	Temephos concentration mg.kg <sup>-1</sup> (range of values)	Temephos in fleece (mg)
0	3.70	123**	455	4.4	159**	700
7	3.80	52 (40-65)	197	4.50	106 (75-125)	477
30	4.12	46 (40-70)	190	4.82	70 (55-85)	337
60	4.54	19 (15-30)	86	5.24	45 (30-70)	236
90	4.96	18 (10-30)	89	NA	NA	NA

<sup>\*</sup> Based on wool growth rate of 14 g per day (Burman et al, 1997)

Since no initial samples were taken, the researchers used wool growth measurements to calculate theoretical fleece concentrations at treatment based on the volume of jetting fluid retained by the sheep. The values calculated were 123 and 159 mg/kg for 9 and 10 months of wool growth, respectively. These estimated values are much higher than those actually recorded 7 days after treatment. The researchers suggested that temephos may not be retained on fleece after treatment to the same extent as other organophosphate products used for sheep jetting. The evidence, while only circumstantial, is consistent with the relatively poor hexane solubility of temephos compared with other organophosphate ectoparasiticides, resulting in less temephos being retained on the fleece.

# 6.2.3 Half-life

DEH has used the wool growth rates and temephos concentrations measured by Burman *et al* (1997) to estimate the values in the above table for the amount of temephos contained in each fleece. As the temephos concentration immediately after treatment was not recorded, it was not possible to accurately calculate a half-life value from these data. However, the loss of temephos from day 7 to day 90 after treatment, from the sheep with 9 months wool, would suggest a half-life in the order of two to three months. Later, the registrant provided in an appendix to the submission the half-lives of degradation for each sheep, by manipulating the fleece residue results in individual sheep, and has clarified that the equation used was as follows:

$$T_{1/2} = -7XLn2/\beta XLn10$$

Where -7 converts to days, Ln2 = 0.693,  $\beta$  is the slope of the regression line for the plotted degradation data, and Ln10 = 2.303.

The results are shown in Table 3.

<sup>\*\*</sup> Theoretical value calculated by Burman et al (1997)

Table 3: Half-lives of depletion of temephos on sheep treated at 9 or 10 months wool growth

Treatment	Sheep No.	Half-life (days)
Sheep treated at 9 months wool growth and wool	0131	30
sampled on days 7, 30, 60 and 90 after treatment	0140	40
	0148	62
	0155	62
	0162	46
	Mean	48
Sheep treated at 10 months wool growth and wool	0121	34
sampled on days 7, 30 and 60 after treatment	0143	26
	0149	128
	0151	39
	0173	36
	Mean	53

It appears that the degradation half-lives of temephos on wool are not significantly different between the treatments at 9 or 10 months wool growth. However, the limited sampling points (days 7, 30 and 60) used for the half-life calculation for the latter treatment may incur significant error. It is noted that for sheep No. 0149, the half-life of 128 days is significantly different (greater) from those of other animals treated at 10 months wool growth, which the registrant notes may be related to the method of application or sampling method. However, despite the lack of an initial value, the data for the 9 months wool growth give a clear indication of the wool residue degradation with time.

# 6.2.4 Core Sampling of Wool from Efficacy Trials

The registrant also provided temephos residue data from two efficacy trials conducted for the registration process (Nunn and Russell, 1998). In the first trial at Tambar Springs 1280 merino wethers with nine months wool were treated with *Assassin* at 350 mg/L by hand jetting three months before shearing. After shearing the 32 bale clip produced from these sheep was machine sampled, one sample per bale taken with an 18 mm tip, and the samples were analysed for temephos residues by the CSIRO Division of Wool Technology. It appears that the samples from the 32 bales were blended and then sub-sampled and two analyses were conducted.

The temephos residues measured were 6.7 and 5.9 mg/kg. These values are lower than the mean value of 18 mg/kg (range 10-30) measured by Burman *et al.* (1997) where sheep with nine months wool were also treated three months before shearing. The lower values measured by core sampling of bales support the hypothesis presented by the registrant that band sampling, the method of sampling used by Burman *et al.* (1997), tends to overestimate residue values with backline applications as it does not sample untreated areas of the fleece such as the neck.

In the second efficacy trial reported 1087 merino wethers were again treated with *Assassin* at 350 mg/L by hand jetting at 88 days before shearing. No information is available on the number of bales produced at shearing but five bales were manually sampled using an 18 mm core tip taking four samples from the base and cap of each

bale. Samples from each bale were blended and sub-sampled to provide samples for analysis. Two samples were analysed from four of the bales and five samples were analysed from the fifth bale giving a total of thirteen samples for analysis.

The concentrations of temephos measured ranged from 0.9 to 9.6 mg/kg with a mean value of  $3.9 (\pm 2.49)$  mg/kg. Again the mean value is lower than the value recorded by Burman *et al.* (1997) for the equivalent time of treatment before shearing. As stated above, these data also support the hypothesis that band sampling tends to overestimate residue levels. Given that the bale samples are more appropriate than the band samples as input concentration for the hazard calculation, in the absence of wool clip residue data the maximum temephos concentration of 9.6 mg/kg will be used by DEH for the hazard calculations.

However, the wool residue data from these efficacy trials should be regarded with some caution as a full range of measurements was not made. For example, no attempt was made to record the volume of jetting fluid applied to each sheep or the volume retained on the fleece by measuring a sample of the treated sheep. This would have provided data that may have given a more accurate picture of actual decline of residue levels in commercial practice.

Lipophilic pesticides such as temephos should follow the wool grease during scouring. The implications for environmental exposure will be discussed below, under environmental hazard.

# **6.2.5** *Summary*

The registrant has provided data on the half-lives of degradation of temephos on sheep treated at 9 or 10 months wool growth. The results indicate that, with a half-life of around 50 days, the degradation of temephos on wool is relatively fast. The results for the efficacy trials based on the core sampling of wool clearly indicate that under the registered use pattern the fleece residues analysed from core sampling are significantly lower than those for band sampling. While there are no data on the amount applied per sheep etc, the registrant has pointed out the core samples were taken according to Australian Standard and AWTA procedures and should therefore be an accurate reflection of likely temephos levels following long wool treatment under commercial conditions.

#### 7. ENVIRONMENTAL TOXICOLOGY

# 7.1 Existing data

Temephos has low mammalian toxicity but is moderately to highly toxic to birds and fish, and very highly toxic to invertebrates, particularly aquatic invertebrates. Aquatic toxicity is summarised in the figure overleaf which is taken from the publicly available environmental assessment report of July 1994 produced by the then Environment Protection Agency. Note that since the 1994 assessment the US EPA has published a Re-registration Eligibility Document (RED) dated 29 September and an Environment Fate and Effects Document (EFED) dated 4 October 1999 (US EPA 1999a,b). Apart from field studies more relevant to the mosquito application, this does not contain any relevant additional toxicity data.

Crustaceans are particularly sensitive to temephos. As noted in our public environmental assessment report, the following end-points for local marine species are available from published sources.

The results ( $LC_{50} = 2.3-3.1 \,\mu\text{g/L}$ , where the  $LC_{50}$  is the concentration that kills 50% of the test animals) of toxicity testing on mud crab larvae (*Scylla serrata*) indicate very high toxicity to juvenile crustacea (Mortimer, 1990). This contrasts with end-points for adult crabs, which fall in the low mg/L range, some three orders of magnitude higher than concentrations, which kill juveniles.

More recently (Chapman, 1993) recorded end-points of  $0.2 \,\mu\text{g/L}$  in 48 hour static tests on yabby larvae (*Trypaea australiensis*). Even adults were sensitive, with a 96 hour LC<sub>50</sub> below  $1 \,\mu\text{g/L}$ .

As reported in the DEH's publicly available environmental assessment report of July 1994, overseas results are available for mangrove tree crab larvae, indicating that the stress of moulting may exacerbate the toxic effects of temephos exposure. Measured concentrations (initially ranging between 2 and 70  $\mu$ g/L) were observed to decline by at least 50%, and generally considerably more, during 48 hours of static laboratory testing. The critical concentration below which exposed larvae did not experience statistically significant reductions in survival through 72 hours was 7  $\mu$ g/L. In the field, significant reductions in survival (typically 50-70% compared with 80-90% survival in controls) were observed by 12 days after application in larvae exposed to spray applications of temephos that left residues of 4  $\mu$ g/L one hour after application (Pierce *et al*, 1993).

Summaries of some further studies, which provide additional data on the toxicity of temephos, are consistent with previous results. In laboratory studies temephos had a median LC<sub>50</sub> of 10  $\mu$ g/L for the shrimp *Leander tenuicornis*, which is a native of south eastern Queensland (Brown *et al*, 1996). In other laboratory studies with larvae of the mosquito species *Mansonia uniformis*, the LC<sub>50</sub> of temephos was 7.69  $\mu$ g/L (Yap *et al*, 1996). Static toxicity testing of temephos on the mouth brooder cichlid fish (*Tilapia melanopleura*) and dragonfly larvae (*Neurocordulia virginiensis*) found 96 hour LC<sub>50</sub> values of 30.2 mg/L and 2.0 mg/L for the fish and dragonfly larvae respectively (Anadu *et al*, 1996).

Table 4: Comparative LC<sub>50</sub> results

Fish		su	ss-	SS	S-S
Cladocerans					
l s	-ss	-S-SS	S-S		
Decapods (including crabs)					
uu				S-S	
Amphipods (including shrim	p) s-s-s	ss	s-s	-S-S	
Copepods		S-S-S		S	
Ostracods		S		S	
Mosquitoes s					
Plecopterans (stoneflies)	S			s acute t	oxicity
Ephemeropterans (mayflies)	s-ss			u sub-acı	ute toxicity
Odonatans (dragonflies)		S		1 no effe	ct level
Coleoptera (beetles)		S			
Hemiptera (true bugs)		S			
Trichopterans (caddisflies)			S	-S	
Algae and phytoplankton		ss			
Molluses		u		S	S
Amphibians (including toads	s)	u	S		
	1.0	10	100 1	000 10	10000 7
0.001 0.01 0.1	1.0	10			0000 100000 μg/L
			(1	mg/L)	

# 7.1.1 Conclusions based on existing data

Temephos is categorised as being very highly toxic to aquatic invertebrates on an acute basis. On the basis of the ecotoxicological data available, the freshwater organism most sensitive to acute toxicity of temephos is *Daphnia magna*, with a 48 hours LC<sub>50</sub> of 11 ng/L. This is from the static test using the Abate 4E formulation by Forbis and Frazier (1986). Importantly, the US EPA RED (1999) notes that this was considered a Core study, meeting all regulatory requirements. The RED quotes a No Observable Effect Concentration (NOEC) of 30 ng/L for *Daphnia magna*, but this would seem to be a typographical error for 3 ng/L. Note that it appears that results for the sensitive marine organism, the mysid shrimp, were not available to the US EPA, and that no acceptable studies on chronic toxicity were available, as the US EPA guidelines were not fulfilled.

#### 7.2 New Data

The registrant has provided data on the acute toxicity testing of temephos to *Daphnia magna* (Rhodes, 1999) performed in accordance with the US EPA FIFRA Guideline 72-2 and OECD Guideline 202.

First-instar *Daphnia magna* neonates (<24 hours old) were obtained from an in-house culture. A total of ten range-finding exposures were conducted. Five of these tests consisted of static exposures and five consisted of flow-through exposures. Three of the flow-through tests were conducted using DMF as an organic solvent and two were conducted without the organic solvent.

The data indicate that the range-finding tests conducted without an organic solvent resulted in variable mortality patterns, suggesting temephos was not always totally available in solution. Three attempts, conducted for definitive testing without using an organic solvent and under flow-through conditions, resulted in a similar pattern. The definitive tests were initiated with the addition of five neonate *Daphnia magna* to each test chamber, a total of 20 organisms per treatment. Analysis of the test solutions for temephos was performed using HPLC based on a validated method prior to the initiation of the study.

On the basis of the definitive testing, a nominal concentration range of 0.0 (control), 0.0 (0.10 mL/L DMF control), 0.0025, 0.0050, 0.010, 0.020, and 0.040  $\mu$ g/L was selected. After 48 hours of exposure, immobility/mortality and sublethal effects were observed at concentrations of 0.0050  $\mu$ g/L and above. All test solutions appeared clear with no visible precipitate or surface film. Water quality measurements were within acceptable limits throughout the exposure. Although analysis of temephos in solution was unsuccessful, confirmation of the diluter stock solutions indicated appropriate dosing was carried out.

Based on the nominal test concentrations, the 48 hours EC $_{50}$  for *Daphnia magna* exposed to temephos was estimated to be 0.007 µg/L with 95% confidence limits of 0.006 and 0.009 µg/L, based on nominal concentrations. This is slightly more toxic than the 48 hours EC $_{50}$  of 0.011 µg/L derived from the Forbis and Frazier (1986) study in DEH's original report. The NOEC was 0.0025 µg/L based on the lack of immobilisation/mortality and sublethal effects.

# 7.3 Relevant environmental endpoint for Australian calculations

The most sensitive end-point is the above EC<sub>50</sub> of 0.007  $\mu$ g/L for *Daphnia magna*. Note this is based on a recent reliable test for which a full report has been provided by the registrant. While this was under flow-through conditions it is close to the static test result of 0.011  $\mu$ g/L considered by the US EPA to be a Core result.

However, we note that the ANZECC Water Quality Guidelines (ANZECC and ARMCANZ, 2000) contain a marine **moderate reliability** trigger value for temephos of 0.05  $\mu$ g/L for 95% protection calculated using the statistical distribution method, with the 99% protection level being much lower at 0.0004  $\mu$ g/L. The database for this calculation included eight fish species, nine species of marine crustaceans (with five species of shrimps and prawns being most sensitive at 1-45  $\mu$ g/L, not clear if this included a mysid shrimp result), one marine insect, two molluscs and one annelid. Further, only a freshwater **low reliability** trigger value of 0.05  $\mu$ g/L, based on adoption from the marine value, could be derived. The guidelines rejected the alternative estimate obtained by applying an assessment factor of 100 to results for twenty-one species of fish (with the most sensitive value of 4.1  $\mu$ g/L not accepted) but only one species of freshwater crustacean (*Gammarus* at 80-140  $\mu$ g/L - note results for eight species of freshwater insects were discarded as they included mosquitoes, the target species for temephos).

It is not clear why the ANZECC guidelines did not consider the published results of  $0.2 \mu g/L$  and  $2.3-3.1 \mu g/L$  respectively for the freshwater yabby larvae (Chapman,

1993) and the mud crab larvae (Mortimer, 1990). The latter is close to the most sensitive marine organism result.

The environmental end-point for temephos related to the release of the scouring effluent in Australia is based on the assessment factor (AF) approach. The volume of acute toxicity data available for temephos is considered to be adequate to enable an AF of 10, even though DEH has not necessarily fully assessed all the individual test reports. On this basis a predicted no effect concentration (PNEC) value of 0.7 ng/L has been set, which is significantly more sensitive than those previously used and much tighter than the ANZECC Water Quality Guideline value of 50 ng/L, derived using the statistical distribution approach.

However, as noted above the derived ANZECC Water Quality Guideline values do not include all the data available to EA, importantly lacking some of the most sensitive data, and are of medium and low reliability for the marine and freshwater aquatic environments respectively. Crustaceae are clearly the most sensitive group, and in the absence of a mysid shrimp result (in DEH's experience usually even more sensitive than daphnids), a PNEC of 0.7 ng/L is used in our hazard assessment, considering the worst case will be discharge from a coastal outfall.

# 8. ENVIRONMENTAL HAZARD FROM AUSTRALIAN SCOURNG

#### **8.1 Soil**

The use of temephos for the control of body lice in short wool involves plunge or shower dipping. As treatment is normally carried out in concreted yards specially set up for the purpose, the environmental exposure during treatment is expected to be minimal. After treatment, animals are turned out into holding paddocks/yards where any drippings will contaminate the soil, although it is recognised that some yards are concreted and channel run-off away from soil. As temephos is claimed to be non-stripping, it is estimated that up to two-thirds of the applied amount will run-off from the sheep and one-third will retain on the fleece.

Assuming approximately two-thirds of the applied active ingredient runs off, 1.050 g ai/sheep will contaminate the soil of the fenced yard. At a temporary holding density of about 3 sheep/m² while treatment solution drips, this equates to an Effective Environmental Concentration (EEC) of 7.7 mg ai/kg soil in the top ten centimetres of soil with a density of 1.35 g/cm³.

No ecotoxicity data are available for temephos on earthworms. By comparison with other organophosphates assessed by DEH in the Chemical Review process, an EEC of 7.7 mg/kg is significantly below the  $LC_{50}$  range of 65-231 mg/kg for fenitrothion, diazinon, chlorpyrifos and parathion-methyl for toxicity to earthworms. While there are likely to be effects on soil invertebrates (note no data available for temephos) in the holding yard, these will be localised to this area and are not considered as significant. Soil degradation would then reduce the residues where studies have shown that photodegradation on soil surfaces would allow temephos to disappear rapidly in all cases with <5% remaining on soil after 28 days, allowing immigration from uncontaminated areas.

However, there could be a period when runoff could cause broader environmental concern. Assuming that the runoff from a holding yard for 2000 sheep runs into a pond one hectare in size and fifteen centimetres deep and that temephos runoffs in the runoff water at 5% of applied, then:

Wt of temephos in pond water = 1.05 g ai/sheep X 5% X 2000

= 105 g

Volume of water =  $10000 \text{ m}^2 \text{ X} .15 \text{ m X } 1000 \text{ L/m}^3$ 

= 1.5 ML

Concentration in pond =  $105 \text{ g} \div 1.5 \text{ ML}$ 

 $=70 \mu g/L$ 

The above calculation is very rough and can readily be further refined. For chlorfenvinphos, another organophosphate insecticide, a US review reported runoff after rainfall was only 0.3-0.6% of applied (ATSDR, 1997). Temephos binds strongly to soil and using a figure of 0.5%, the EEC in water from runoff is 7  $\mu$ g/L and for *Daphnia magna* with an EC<sub>50</sub> of 0.007  $\mu$ g/L, the Q = 7/0.007 = 1000 (where the Q value is the EEC/PNEC), still indicating a very significant hazard to aquatic invertebrates. Even assuming only 200 sheep are treated, the Q remains unacceptably high at 100. While this calculation does not allow for degradation in the soil or water column, due to the extremely high aquatic invertebrate toxicity, runoff from dipping areas should not be allowed to contaminate natural waterways, and label statements to that effect should be incorporated.

DEH recommends the following label statement be included as a new third sentence to the current label statement under **Protection of Wildlife**, **Fish**, **Crustacea and Environment**:

"Drippings of product onto soil from treated sheep should not be allowed to runoff or seep into any river, stream or ground water".

#### 8.2 Water

As noted above, the risk that temephos would impact adversely on aquatic environments when scouring effluent is disposed of to land is low because of the low mobility of temephos in soils to which effluent would be applied. The main concerns arise in relation to discharge to sewer. Knowledge of sewage volumes, scouring rates and wool residues can be used to estimate concentrations leaving the outfall, which can then be compared with toxicity data to determine the environmental hazard.

# 8.2.1 Residue levels in the Australian wool clip

No monitoring data are available for temephos since products containing this active have not been supplied to the market for some years. However, during the 2001-02 Australian Wool Innovations (AWI) wool residue survey, a mean fleece residue level of 1.4 mg/kg (Scott Williams AWI, personal communication) was found for total organophosphates (OPs). As diazinon is the main contributor to the total OP levels, it is likely that the current temephos contribution in the mean wool clip has historically been considerably less. No specific temephos results appear in the previous wool clip

data available to DEH, either it hasn't been tested for, or more likely levels are very low, ie well below 0.1 mg/kg.

#### 8.2.2 Australian Model

As a result DEH has initially used a maximum residue level of 9.6 mg/kg from the bale samples at 88 days after treatment (see Section 6.3.4) as the worst case scenario for the hazard calculation. The results of the calculation performed by DEH take into consideration the following parameters as shown in Table 5.

Table 5: Determination of initial Q values by DEH

Parameters	Worst case	30% long
	bale sampling	wool
	results	treatment**
Concentration of temephos in wool at harvest	9.6	5.0
(mg/kg)		
Mass of wool scoured in one day (tonnes)	50	50
Predicted market share of Cooper Assassin Sheep	1*	0.3***
<i>Dip</i> (%)		
Mass of temephos entering scouring plant on wool	4.8	0.75
(g)		
Percentage remaining on scoured wool (%)	4	4
Percentage removed with grease during scouring	30	30
(%)		
Percentage removed during sewage treatment (%)	50	50
Mass of temephos discharged (g)	1.6	0.25
Flow rate of sewage treatment plant (ML/d)	50	50
Predicted concentration in sewage outflow (ng/L)	32	5
Dilution in plume#	0.02	0.02
Effective Environmental Concentration (EEC)	0.64	0.10
(ng/L)		
Predicted No Effect Concentration (PNEC) (ng/L)	0.7	0.7
Quotient (EEC/PNEC)	0.91	0.14

<sup>\*</sup> Based on the registrant's estimate of 1 million sheep treated in a flock size of 100 million – assumes all long wool treatment.

# A plume dilution factor of 0.02 was derived from the study by Grundy et al. (2000)

While the worst case hazard calculations for Australian scouring conditions indicate an acceptable EEC/PNEC (Q) value of <1, the safety margin is very narrow, and it also relies on a low market share. However, it must be emphasised that this a very worst case estimate as it assumes that all treatments are on long wool sheep at nine months, i.e. applied at the last legally available time when treatment can occur, and that the highest residues found in any tested bale will always occur. Clearly this is highly unlikely.

For a more realistic calculation if we assume that only 30% is used for long wool treatment (as estimated by the registrant), and use a residue value of 5 mg/kg for long wool treatment<sup>2</sup>, then the Q is lowered to below 0.2 (see Table 4). Alternatively this

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<sup>\*\*</sup> Assumes only 30% of treatment is on long wool, with much treatment before 9 months growth, and that the contribution from short wool treatment is minor, ie less than 1 mg/kg.

<sup>\*\*\*</sup> Of long wool treatment (assumes).

 $<sup>^2</sup>$  The worst case 9.6 mg/kg from five bales was employed, whereas the mean for these was 3.9 mg/kg and the range 0.9 to 9.6 mg/kg. In a separate trial, two other bales had residues of 6.7 and 5.9 mg/kg respectively (see Section 6.3.4).

calculation assumes a mean residue level of about 4 mg/kg from the five long wool treatment bales and that many sheep will be treated prior to nine months wool growth. It also assumes only a limited contribution in the fleece from off shears treatment, as noted above residues may be expected to be below 1 mg/kg in this case (see also below).

Under the latter scenario, should use on long wool actually be 70% as in the registrant's previous estimates, then the Q rises to 0.34, indicative of how sensitive the potential hazard is to relatively small changes in market share and to the short/long wool split<sup>3</sup>.

# 8.2.3 Discussion of potential Australian hazard and calculation of further scenarios

There is a great deal of uncertainty in the above hazard estimations, due to the lack of hard data. There is no certainty in the registrant's prediction of market share, or for the estimated 70:30 short/long wool split. Importantly there are no mechanisms available to regulate changes in market share.

The lack of any data on levels in the Australian wool clip, as determined by the AWI, is a further drawback, as it means that residue levels from experimental bales of treated long wool have to be used, either the worst case 9.6 mg/kg or the mean from seven bales of about 5 mg/kg (and assuming a minor contribution for wool treated off shears).

The level of use of OP sheep ectoparasiticides has been declining in past years. Savage (1998) estimated 76% of the national flock was treated with OPs in 1997–98, which at the time resulted in a mean wool clip residue of 5.8 mg/kg. Since that time OP levels have fallen significantly, with the mean OP levels on Australian fleece wools being 1.4 mg/kg in 2001–02 (see above). Despite this, 54% of the samples tested had residues, which suggests that at least 50% of the flock is still being treated with an OP.

The percentage of the OP market that temephos may gain is very difficult to forecast. This market is currently dominated by diazinon, which made up about 90% of detected residues in 2001–02, while chlorfenvinphos and propetamphos made up about 7.7 and 2.6% respectively. This suggests that while they are disappearing off the market, these two OPs were still being used to treat about 4.4 and 1.5 % of the national flock.

To cover this uncertainty several other scenarios are modelled in Table 6. These include a 5% market share based on 30 or 70% long wool use. Alternatively a mean clip level of 0.1 mg/kg is assumed, similar to that of the other OPs (chlorfenvinphos and propetamphos) currently available, apart from diazinon.

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<sup>&</sup>lt;sup>3</sup> Note that this concern is not longer applicable as label instructions have been amended to remove use on sheep with more than six weeks wool growth.

Table 6: Determination of further Q values covering various scenarios by DEH

Parameters	5% market	5% market	0.1 mg/kg
	share- 30%	share- 70%	residues in
	long wool	long wool	total clip
	treatment*	treatment**	
Concentration of temephos in long wool	5.0	5.0	0.1
at harvest (mg/kg)			
Mass of wool scoured in one day	50	50	50
(tonnes)			
Predicted market share of Cooper	1.5***	3.5***	NA
Assassin Sheep Dip (%)			
Mass of temephos entering scouring	3.75	8.75	5
plant on wool (g)			
Percentage remaining on scoured wool	4	4	4
(%)			
Percentage removed with grease during	30	30	30
scouring (%)			
Percentage removed during sewage	50	50	50
treatment (%)			
Mass of temephos discharged (g)	1.26	2.94	1.68
Flow rate of sewage treatment plant	50	50	50
(ML/d)			
Predicted concentration in sewage	25.2	58.8	33.6
outflow (ng/L)			
Dilution in plume#	0.02	0.02	0.02
Effective Environmental Concentration	0.504	1.176	0.672
(EEC) (ng/L)			
Predicted No Effect Concentration	0.7	0.7	0.7
(PNEC) (ng/L)			
Quotient (EEC/PNEC)	0.72	1.68	0.96

<sup>\*</sup> Assumes only 30% of treatment is on long wool, with much treatment before 9 months growth.

NA = Not applicable

The above calculations show either a hazard exists or at best there is only a very small safety margin. Clearly if the market share reaches 5% of the national flock, with more than about 40% (or 2% of the national flock) used on long wool, a potential hazard to aquatic invertebrates inhabiting waters close to the ocean outfall could arise. There could be a similar hazard if temephos residues in the national clip rise above 0.1 mg/kg. This very low acceptable level in the clip compared with other OPs (see above) reflects the much higher aquatic toxicity of temephos to daphnia.

The latter calculation assumes complete mixing of wool after shearing and before scouring takes place. Clearly if this does not occur, and a "hot spot" arises, for example with 10% of a single daily scour lot containing temephos residues close to the maximum level of 9.6 mg/kg (i.e. all treated with nine months wool), resulting in a residue of 0.96 mg/kg when combined with clean wool, a hazard clearly exists (Q  $\sim$ 10). This would still be the case if the "hot spot" is in the order of the mean value of around 5 mg/kg (Q  $\sim$  5).

<sup>\*\*</sup> Assumes 70% of treatment is on long wool, with much treatment before 9 months growth.

<sup>\*\*\*</sup> Of long wool treatment (assumes that the contribution from short wool treatment is minor, ie less than 1 mg/kg).

<sup>#</sup> A plume dilution factor of 0.02 was derived from the study by Grundy et al. (2000)

# 8.2.4 Conclusions regarding retention of long and short wool uses

Table 5 indicates a local hazard will exist if the scour lot contains more than 1% of wool contaminated with the maximum expected temephos residues. DEH has no information on the likelihood/probability of such a scenario occurring. However, from the total calculations it is clear that if much above 1% of the sheep flock is to receive late long wool treatment with temephos, or more than 2% of sheep receive long wool treatment at any time, scouring of wool could pose an unacceptable hazard to aquatic invertebrates inhabiting waters close to the ocean outfall.

Given that there are no mechanisms available to regulate changes in market share, including the short/long wool split, DEH concludes that continued use of the product on long wool sheep according to current label directions at the current three month WWP may have an unintended effect that is harmful to animals, plants or things or to the environment, i.e. to aquatic invertebrates inhabiting waters close to the ocean outfall. This is the direct outcome of the much higher aquatic toxicity of temephos to daphnia, which has been demonstrated since our original assessment of long wool use.

DEH has considered whether a longer WWP might acceptably reduce the likelihood of this harm. Based on a 5% market share and assuming a 50 day half-life (Table 4) for a 4.5 months WWP residues of around 2.5 mg/kg could result and the Qs from the scenarios in the first two columns in Table 6 would be approximately half (0.35 and 0.83 respectively) and still raise concerns, particularly for a high percentage of long wool treatment. On the other hand with a six month WWP, with residues of approximately 1.25 mg/kg the Qs would be more acceptable at about 0.18 and 0.42 respectively.

However, these are calculations based on extrapolations from very limited data. To determine an acceptable WWP, actual residue data would be required, noting that there is some evidence for a slowing in degradation over time in the figures in Table 2. Thus DEH is unable to recommend a varied WWP instruction that would realise use on long wool sheep that would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

It follows then, that the only variation to the approved label that DEH can recommend is the removal of all instructions pertaining to the treatment of long wool sheep. This variation would realise use that would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The limited data (see Table 1) for residues on short wool indicate that when treated three weeks off shears residues 26 weeks later averaged 0.6 mg/kg. Importantly these were obtained using band sampling, which is accepted as being a conservative method and usually results in levels double the more accurate bale sampling. Taking this into consideration and given up to a further 23 weeks of wool growth and temephos degradation on the fleece, the actual value at shearing may be more realistically estimated as <0.1 mg/kg. Given that the scenario in the third column of Table 6 indicates that close to 100% of the flock could be treated with temephos off shears before a hazard would arise, DEH concludes that use on short wool use would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

# 8.2.5 DEH's Conceptual Model under Australian Conditions

The maximum mean concentration in raw wool can be estimated from the target concentration at the ocean outfall. The Victorian Environmental Protection Agency (EPA) requirement is that effluent be non-toxic at the point of discharge, thus a PNEC of 0.7 ng/L to *Daphnia magna* is used in this model. The result of this calculation is shown in Table 7.

Table 7: Calculated concentration of temephos (ng/L) in raw greasy wool based on the target concentration of 0.7 ng/L at the Black Rock ocean outfall for temephos

Parameters	DEH's estimates
Target concentration (ng/L)	0.7
Load entering the ocean which takes into account the plume dilution factor of 50 (ENV) (g)	50 ML X 0.7 ng/L X 50 = 1.75
Load entering sewage treatment plant (STP) (g)	$100/50 \times 1.75 = 3.5$
Load entering wax recovery (WAX) (g)	$100/70 \times 3.5 = 5.0$
Load entering scour (SCR) (g)	$100/96 \times 5.0 = 5.2$
Concentration of residues on wool (mg/kg)	5.2/50 = 0.10

The above calculation confirms that the maximum acceptable mean residue in the wool clip is 0.1 mg/kg and confirms that the maximum market share for long wool treatment before a potential hazard arises to aquatic invertebrates inhabiting waters close to the ocean outfall is not much above 1%. This is also the case if a "hot spot" were to arise. However, continued use on short wool can be expected to result in wool residue levels that conform with this target.

# 9. TRADE

Pesticide residues in greasy wool can have implications for trade. There is increasing pressure from international sources to reduce both the biological oxygen demand and pesticide residue levels in scours.

# 9.1 UK/EU EQS/MAC Requirements

In the UK, Environmental Quality Standards (EQS) and Maximum Allowable Concentration (MAC) are in place for the textile industry to meet environmental standards. The EQS and MAC values for organophosphates of 10 and 100 ng/L respectively used by Savage (1998) were UK 'draft operational standards' and subject to review. Subsequently an EQS of 30 ng/L and a MAC of 100 ng/L have been established for total organophosphates in UK<sup>4</sup>. However, there are no specific values for temephos.

The calculated wool residue levels on the basis of the EU/UK total OP requirements are shown in Table 7.

<sup>&</sup>lt;sup>4</sup> The former website (<a href="http://www.basicweb.fsnet.co.uk/index.htm">http://www.basicweb.fsnet.co.uk/index.htm</a>) included a toxicity database holding EQS values for fresh and marine waters. There are no EQS values for temephos. Hence, values of 30 ng/L and 100 ng/L for AA and MA, respectively, for total OPs are assumed for temephos.

Table 7: Predicted concentration of temephos (ng/L) in river based on the EU/UK model by DEH

Parameters	Bale data	
	EQS	MAC
	(chronic)	(acute)
Concentration of temephos in wool at harvest	9.6	9.6
(mg/kg)		
Mass of wool scoured in one day (tonnes)	27.6	27.6
Predicted market share for Assassin (%)	1	1
Mass of temephos entering scouring plant on	2.65	2.65
wool (g)		
Percentage remaining on wool (%)	4	4
Percentage removal as recovered wool grease and	80	80
by associated on-site effluent treatment processes		
(%)		
Percentage removed during sewage treatment (%)	50	50
Mass of temephos discharged (g)	0.25	0.25
Flow rate of river (ML/d)	149	71
Predicted Environmental concentration in river	1.7	3.5
(ng/L)		
UK/EU expected requirement (ng/L)	30	100

On the basis of wool residue level from the bale samples and the estimated 1% market share, the predicted environmental concentrations for both EQS and MAC would readily meet the expected UK/EU requirements. Calculations suggest a market share of close to 20% could be achieved before a hazard arises. It should also be remembered that this is a very worst case estimate as it assumes that all treatments are on long wool sheep at nine months, i.e. on the last legally available time when treatment can occur, and that the highest residues found in any bale will always occur. Clearly this is highly unlikely.

Due to the much less sensitive end point used there is also a much lower hazard if a "hot spot" were to occur, as this would have to constitute about 20% of the scour lot and contain the maximum residue levels of about 10 mg/kg. Therefore, the registered use of *Assassin* as labelled on both long and short wool is unlikely to adversely prejudice Australia's export trade.

# 9.2 DEH's Conceptual Model for EU/UK requirements

Using the conceptual model, the maximum mean concentration in raw wool can be estimated from the target concentration at the river outfall as shown in Table 9.

Table 9: Calculated concentration of temephos (ng/L) in raw greasy wool based on the proposed EU/UK model with the target concentrations of 30 (EQS) and 100 (MAC) ng/L for temephos.

DEH calculations based on UK/EU proposed EQS/MAC Requirements				
Parameters	EQS (Chronic)	MAC (Acute)		
Target concentration (ng/L)*	30	100		
Load entering the river (ENV) (g)	(149  ML X  30  ng/L = 4.47)	71  ML X  100  ng/L = 7.1		
Load entering sewage treatment plant	100/50  X  4.47 = 8.94	100/50  X  7.1 = 14.2		
(STP) (g)				
Load entering on-site treatment plant	$100/20 \times 8.94 = 44.7$	100/20  X  14.2 = 71		
(OST) (g)				
Load entering scour (SCR) (g)	$100/96 \times 44.7 = 46.6$	$100/96 \times 71 = 74$		
Concentration of residues on wool	46.6/27.6 = 1.69	74/27.6 = 2.68		
(mg/kg)				

<sup>\*</sup> UK is the 'worst case scenario' for the EU and has established an EQS and MAC of 30 and 100 (ng/L) for both individual and total organophosphates (Refer to footnote 2), which do not include temephos. Hence these EQS and MAC values are assumed for temephos.

On the basis of the maximum residue level of 9.6 mg/kg from bale samples and the predicted market share of 1%, it is estimated that the residue concentration in the wool clip would be 1% X 9.6 mg/kg = 0.096 mg/kg which is well below the EQS and MAC of 1.69 and 2.68 mg/kg (see above table), respectively. Thus there is a low likelihood undue prejudice to Australia's export trade under the current WHI of three months for temephos as long as its market share stays below 20% (this is based on a more likely level of 5 mg/kg, which takes into account that not all sheep would be treated with nine months wool growth).

#### 10. CONCLUSIONS

The registrant obtained approval for a late renewal of the product COOPERS ASSASSIN SHEEP DIP in 2001. However, given the concerns relating to the environment and to occupational health and safety, the APVMA decided to place the product under review.

The registrant has provided additional data on the toxicity testing of temephos to *Daphnia magna*. The results indicate that the very sensitive result for *Daphnia magna* should be used as the environmental end-point for aquatic organisms arising from wool scouring under Australian conditions.

The registrant has also provided the calculated half-lives for the depletion of temephos in wool in sheep treated at nine or ten months wool growth indicating no significant difference between the two treatments and mean half-lives of 48 and 53 days for the nine or ten months wool treatment, respectively. In particular, the data for the nine months wool growth give a clear indication of the wool residue degradation with time.

Our calculations indicate that, with the current wool withholding period (WWP) of 3 months, if much above 1% of the sheep flock is to receive late long wool treatment with temephos, or more than 2% of sheep receive long wool treatment at any time, scouring of wool could pose an unacceptable hazard to aquatic invertebrates inhabiting waters close to the ocean outfall. DEH has no information on the

likelihood/probability of such a scenario occurring. Given that there are no mechanisms available to regulate changes in market share, including the short/long wool split, DEH is not satisfied that continued use of the product on long wool sheep according to current label directions at the current 3 month WWP would not be likely to be harmful to aquatic invertebrates inhabiting waters close to the ocean outfall. This is the direct outcome of the much higher aquatic toxicity of temephos to daphnia, which has been demonstrated since our original assessment of long wool use.

Preliminary calculations indicate a longer WWP of around 6 months may enable the to conclude that the use would not be likely to have an unintended harmful effect on the environment. However, these are calculations based on extrapolations from very limited data. To determine an acceptable WWP, actual residue data would be required, noting that there is some evidence for a slowing in degradation over time. Thus DEH is unable to recommend a varied WWP instruction that would realise use on long wool sheep that would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. It follows then, that the only variation to the approved label that DEH can recommend is the removal of all instructions pertaining to long wool sheep. This variation would realise use that would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

On the other hand DEH can be satisfied that continued use on short wool will not be likely to have an unintended harmful effect on aquatic invertebrates inhabiting waters close to the ocean outfall.

Regarding export trade, on the basis of wool residue level from the bale samples and the estimated 1% market share, the predicted environmental concentrations for both EQS and MAC would readily meet the expected UK/EU requirements. Calculations suggest a market share of close to 20% could be achieved before a hazard arises. It should also be remembered that this is a very worst case estimate as it assumes that all treatments are on long wool sheep at nine months, ie on the last legally available time when treatment can occur, and that the highest residues found in any bale will always occur. Clearly this is highly unlikely. Calculations also show an acceptable hazard if a "hot spot" were to occur, as this would have to constitute about 20% of the scour lot and contain the maximum residue levels of about 10 mg/kg. Therefore, the registered use of temephos on both long and short wool is unlikely to unduly prejudice Australia's export trade.

The issue of soil contamination as a result of dripping of temephos from treated sheep has also been considered. Run-off from treatment areas should not be allowed to contaminate waterways. DEH recommends the following label statement be included as a new third sentence to the current label statement under **Protection of Wildlife**, **Fish**, **Crustacea and Environment**:

"Drippings of product onto soil from treated sheep should not be allowed to runoff or seep into any river, stream or ground water".

In addition DEH recommends a label statement for disposal of spent dip similar to that proposed for diazinon, ie "Dispose of used dip solution and sludge over an

area of dedicated and bunded flat land, away from watercourses and any drainage areas etc that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months".

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