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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: April 7, 1999

MEMORANDUM

SUBJECT: **EPTC (S-Ethyl dipropylthiocarbamate)**: HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Chemical No. 041401. Case No. 0064. Barcode D244982.

FROM: Paula A. Deschamp, Risk Assessor
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Attached is HED's risk assessment of the thiocarbamate herbicide, EPTC for purposes of issuing a Reregistration Eligibility Decision (RED) Document for this active ingredient. Cumulative risk assessment considering risks from other pesticides or chemical compounds having a common mechanism of toxicity is not addressed in this document. The disciplinary science chapters and other supporting documents for the EPTC RED are also included as attachments as follows:

Report of the Hazard Identification Assessment Review Committee. Fricke/Rowland (10/23/98)
Report of the FQPA Safety Factor Committee. Brenda Tarplee (11/18/98)
Product Chemistry Chapter. Ken W. Dockter (05/05/98; D245001)
Residue Chemistry Chapter. Stephen C. DeVito (09/25/98; D245000)
EPTC Anticipated Residues. Stephen C. DeVito (03/11/98; D254210)
Toxicology Chapter. Robert F. Fricke (01/21/99; D244999)
Occupational and Residential Exposure Assessment. Renee Sandvig (01/06/99; D244998)
Dietary Exposure and Risk Estimates for Reregistration. Carol Christensen (02/18/99)
Addendum: Chronic Dietary Exposure Analysis for EPTC. Carol Christensen (03/23/99; D254454)
Incident Report. Jerome Blondell and Monica Spann (06/23/98; D247064)
Environmental Fate and Effects Chapter. James K. Wolf (Draft 03/04/99)

HED's Hazard Identification Assessment Review Committee (HIARC) reviewed the toxicological database for EPTC and selected toxicological endpoints for acute and chronic dietary and for occupational (dermal and inhalation) exposure risk assessment on September 17, 1998 (memorandum dated October 23, 1998). HED's FQPA Safety Factor Committee reviewed the hazard and exposure data for EPTC on November 2, 1998 and recommended that the FQPA Safety Factor (as required by Food Quality Act of August 3, 1996) be retained in assessing the risk posed by this chemical (memorandum dated November 18, 1998).

RDI: BRSrSci:ANielsen

1.0 EXECUTIVE SUMMARY

The Health Effects Division (HED) has conducted a human health assessment for the active ingredient EPTC (S-ethyl dipropylthiocarbamate) for the purposes of making a reregistration eligibility decision.

EPTC is a thiocarbamate herbicide used to control the growth of germinating annual weeds, especially grasses. It is used in the agricultural production of a wide variety of food crops and is available to the residential home gardener for use in vegetable and ornamental gardens. As with other thiocarbamate herbicides, EPTC exerts its herbicidal action through inhibition of cuticle formation at the early stages of seedling growth. Formulated products include emulsifiable concentrate (EC) liquids containing up to 87.8% EPTC active ingredient and granular (G) formulations containing up to 25% EPTC active ingredient. EPTC is typically applied as a single annual, pre-emergence or early post-emergence application and is usually incorporated into the soil immediately after application to prevent volatilization.

HED evaluated the toxicological, residue chemistry, and exposure data bases for EPTC and determined that the data are adequate to support a reregistration eligibility decision. In assessing aggregate risk, HED considered potential dietary exposure of the general population to EPTC residues from food and drinking water, and potential dermal and inhalation exposure from use in residential settings. The aggregate assessment for the general population and specific subgroups addressed food, water, and residential exposures. HED also considered dermal and inhalation exposure to occupational pesticide handlers, mixers, loaders, applicators and postapplication workers during harvesting activities.

The toxicological database indicates that EPTC is moderately toxic via the dermal and oral routes and is highly toxic via the inhalation route. The treatment-related effects of toxicological concern are cardiomyopathy and neuronal cell necrosis. These effects were observed in studies of varying length of treatment and in different species. EPTC did not produce any significant reproductive or developmental toxicity, and was negative in two oncogenicity studies. The neurotoxic effects exhibited by EPTC are consistent with toxic effects on the central and peripheral nervous system seen with other thiocarbamates. With EPTC, there was an increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems of both rats and dogs. Because of the neurotoxic effects (neuronal necrosis/degeneration) and the potential for residential exposure to infants and children from use of EPTC, HED's FQPA Safety Factor Committee recommended that the **10x FQPA safety factor be retained for all populations which includes infants and children.** The uncertainty regarding the effects on the developing fetal nervous system after such exposure is being addressed by the requirement of a developmental neurotoxicity study in rats.

HED conducted acute and chronic dietary (food) exposure analyses using the Dietary Exposure Evaluation Model (DEEM). In both assessments, exposure (consumption) was compared to a population adjusted dose (PAD) reflecting retention of the FQPA 10x factor. The PAD is equal to the acute or chronic RfD divided by the FQPA Safety Factor. HED considers dietary residue contributions greater than 100% of the PAD of concern. **Acute dietary** exposure at the 95th percentile comprised 40.5% of the aPAD for the general population and 87.5% of the aPAD for the most highly exposed subgroup, children (1-6 years). **Chronic dietary** exposure comprised 11.1% of the cPAD for the general population and 20.6% of the cPAD for the most highly exposed subgroup, children (1-6 years). The acute analysis at the 95th percentile is a conservative, deterministic upper-bound estimate which utilized tolerance-level input residues and assumed 100% crop treated. The chronic analysis (Tier 3) is a refined estimate which used average field trial residues and percent of crop treated data.

The available environmental fate data suggest that EPTC is volatile and mobile in soil and does not appear to be persistent under most conditions. Although limited, there are data available indicating that metabolites of EPTC are less persistent than the parent compound. The Environmental Fate and Effects Division (EFED; draft memo by James K. Wolf dated March 4, 1999) has provided a screening-level assessment using simulation models and an analysis of available monitoring data to estimate the potential concentration of EPTC in ground and surface water.

EFED performed screening-level model estimates of EPTC concentrations in ground water using SCI-GROW and in surface water using Tier II PRZM/EXAMS. Inputs to the models included high exposure agricultural scenarios for major crops (alfalfa, citrus, corn, and potatoes) at the maximum application rates. The estimated drinking water environmental concentration (DWEC) of EPTC in ground water using the SCI-GROW screening model, which does not consider EPTC losses due to volatilization, was **1.84 µg/L**. Estimated average and peak DWECs for EPTC in surface water using the PRZM/EXAMS screening model were **3.44 µg/L and 57.35 µg/L**, respectively. The calculated drinking water levels of comparison (DWLOCs) as a contribution of chronic and acute aggregate exposures are 20 and 84 µg/L, respectively, for the most highly exposed population subgroup. Therefore, when considered along with exposure from food uses, residues of EPTC in drinking water are not expected to result in unacceptable levels of aggregate acute or chronic dietary risk.

EFED also conducted an analysis of monitoring data available in USGS NAWQA databases, in EFED's Pesticides in Ground Water Data Base (PGWDB), and in EPA's STORET database. The majority of EPTC levels in ground water were reported to be "0" or less than the detection limit (generally $\leq$0.05 µg/L). The maximum reported EPTC concentration in surface water, which was not outside the range of method calibration, was 10 µg/L. The monitoring data indicate that EPTC concentrations in surface water are generally very low (generally less than 0.05 µg/L, but rarely greater than 1 µg/L) **Based on model estimates and monitoring data, EFED has provided HED with estimates of EPTC concentrations in drinking water of 10 µg/L for acute and 1.0 µg/L for chronic risk assessments.**

Occupational and residential exposure to EPTC residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities; however, the potential for postapplication occupational exposure is minimal. Residential postapplication exposure is expected to be greater than occupational postapplication exposure. Individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules.

Based on toxicological criteria and potential for exposure, HED has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and residential postapplication dermal and inadvertent oral ingestion exposure to adults and/or children. Because different endpoint effects were selected for the assessment of dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. The duration of exposure is expected to be short- and intermediate-term for the occupational handler and short-term for the residential handler. The Pesticide Handler's Exposure Database (PHED) and the Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December, 1997) were used as data sources and methods of estimating occupational and residential exposures.

Occupational risk estimates exceed HED's level of concern. Several of the occupational handler scenarios reflecting baseline protective clothing exceed HED's level of concern defined by target MOEs of 300 for short-term dermal risk, 100 for intermediate-term dermal risk, and 100 for short- and intermediate-term inhalation risk. MOEs for **short-term dermal** risk at baseline ranged from 60 to 190 for scenarios involving "upper-bound" dermal exposure activities such as mixing and loading for chemigation at maximum rates and mixing/loading/applying with hand held equipment. Short-term dermal risks for these scenarios are mitigated with PPE (personal protective equipment) and/or engineering controls such that MOEs are $\geq$12,000 and substantially below HED's level of concern. MOEs for **intermediate-term dermal** risk at baseline ranging from 3 to 84 are mitigated with additional PPE such that MOEs are $\geq$150. However, an MOE of 60 for mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) exceeds HED's level of concern. MOEs for **short- and intermediate-term inhalation** risk ranged from 40 to 90 for scenarios involving "upper-bound" inhalation exposure activities such as mixing and loading for chemigation, loading granular products for aerial application, and applying EPTC-impregnated dry bulk fertilizer. Inhalation risks for these scenarios are mitigated with PPE and/or engineering controls; however, MOEs of 75 and 83 somewhat exceed HED's level of concern for two scenarios (mixing for impregnation of dry bulk fertilizer and applying granular product with aerial equipment). Further mitigation

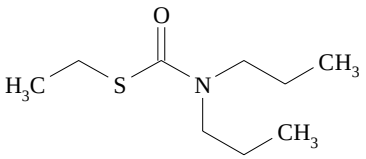
might be achieved by reduction in the amount handled. It should be noted that the estimated MOEs for mixing/loading EC formulation for impregnation on dry fertilizer are based on unit exposure values in PHED which do not reflect the actual use of the pesticide.

Residential risk estimates exceed HED's level of concern. The majority of residential handler exposure scenarios exceed HED's level of concern defined by target MOEs of 3000 for short-term dermal risk and 1000 for short-term inhalation risk. MOEs exceeding HED's level of concern for the residential handler ranged from 190 to 2,500 for short-term **dermal** risk and from 94 to 1,800 for short-term **inhalation** risk. HED's level of concern is greatest where maximum application rates are prescribed for control of certain perennial weeds in ornamental gardens and where granular formulations are applied using a hand-held spoon. It should be noted that the estimated MOEs for applying granular formulations with a spoon are based on unit exposure values in PHED for applying granular formulations by hand. Incidental ingestion of granules in EPTC-treated areas by a toddler is the only residential postapplication exposure scenario that exceeds HED's level of concern. Residential postapplication risk estimates do not exceed HED's level of concern for dermal exposure of adults or children in EPTC-treated gardens.

In conclusion, HED finds that aggregate chronic and acute dietary (food + water) risk estimates associated with the consumption of EPTC and its toxicological residues do not exceed HED's level of concern. However, an aggregate short-term risk estimate was not conducted because residential dermal, inhalation, and inadvertent oral exposures alone exceed HED's level of concern. Any additional exposure through food and water would further contribute to the existing risk concern for residential exposure. HED recommends that the Agency explore possible mitigation measures to reduce the potential for dermal, inhalation, and inadvertent oral ingestion exposure to EPTC in residential settings.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

EPTC [S-ethyl dipropylthiocarbamate] is a selective preemergence herbicide registered for use on a variety of field, vegetable, orchard, and ornamental sites for the control of certain annual grasses and broadleaf weeds.



Empirical Formula:	$C_9H_{19}NOS$	
	Molecular Weight:	189.3
	CAS Registry No.:	759-94-4
	PC Code:	041401

EPTC is an amber or pale yellow to almost colorless liquid with a boiling point of 137-138 C at 30 mm Hg [232 C at 760 mm Hg]; a vapor pressure of 4.7 mbar at 25 C; a density of 0.9546 at 30 C; and an octanol/water partition coefficient of 1600 (log P=3.21). EPTC is stable under normal storage conditions but is hydrolyzed in the presence of warm strong acids. The solubility of EPTC in water is 370 ppm at 20 C. It is miscible in most common organic solvents (acetone, ethyl alcohol, kerosene, methyl isobutyl ketone, and xylene). Underlined data are from published sources.

3.0 HAZARD CHARACTERIZATION

3.1 Hazard Profile

The database for EPTC is adequate to assess the toxicology hazard profile. Review of the database revealed treatment-related effects of toxicological concern. Cardiomyopathy and neuronal cell necrosis were observed in studies of varying length of treatment and in different species. EPTC did not produce any significant reproductive and developmental toxicity, and was negative in two oncogenicity studies.

EPTC is a reversible inhibitor of cholinesterase (ChE). Toxicology studies with EPTC did not show any consistent pattern of ChE inhibition among different species, lengths of treatment, or the type of ChE enzyme measured. Inhibition of plasma with dose related increases in RBC and brain ChE inhibition are the typically expected results. In some studies brain ChE activity was inhibited without any effect on either plasma or erythrocyte ChE activities. In other studies, erythrocyte ChE was inhibited with no inhibition of either plasma or brain ChE. Two studies which yielded commonly expected results were a chronic dog oral dosing (capsule) study where plasma, but not other ChE was inhibited, and a rabbit developmental study in which plasma and erythrocyte ChE were inhibited. As a class of compounds, thiocarbamates do not produce consistent ChE inhibition profiles. A study with rats measured the inhibition of ChE by cycloate, butylate, pebulate or vernolate at doses at or near the acute median lethal doses. While vernolate, pebulate and cycloate inhibited plasma, erythrocyte and brain ChE to varying degrees, butylate inhibited plasma ChE only, and EPTC inhibited only erythrocyte and brain ChE but not plasma ChE.

Cardiotoxicity was observed in subchronic and long-term studies, and, in general, the severity and incidence of the lesion increased with increasing dose of EPTC. In 90-day feeding and inhalation studies and in two chronic feeding/oncogenicity studies, all in the rat, histopathological evaluation revealed myocardial degeneration. Additional studies in the rat, revealed myocardial degeneration in adult animals in two separate two-generation reproduction studies. In two chronic oral dosing studies in the dog,

degenerative changes in the cardiac muscle were observed when EPTC was administered in a capsule, but not when administered (at comparable doses) in the diet. In both of the dog studies, electrocardiograms were taken, but only one high-dose male in the capsule study had changes which were described as "potentially" treatment-related.

EPTC, as well as other thiocarbamates (molinate, cycloate, pebulate, vernolate and butylate), have toxic effects on the central and peripheral nervous systems. With EPTC, there was an increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems of both rats and dogs. In the neurotoxicity studies in the rat, dose-related increases in the incidence of neuronal necrosis were observed in the brains after acute and subchronic exposure to EPTC. The acute delayed neurotoxicity study in the hen, however, did not reveal any delayed neurotoxicity. In both of the combined chronic toxicity/oncogenicity studies in the rat and in the chronic (capsule) study in the dog, treatment-related neuromuscular lesions were observed. In all of these studies hindquarter weakness was observed, and at necropsy evaluation, atrophy and degeneration of the skeletal muscle was observed. In the dog study, the lesions were described as Wallerian-type degeneration in the spinal cords and various peripheral nerves.

The developmental and reproductive toxicity of EPTC was evaluated. Studies in the rat and rabbit showed developmental and reproductive toxicity only in the presence of maternal or parental toxicity. In a prenatal developmental toxicity study in rats, developmental toxicity (in part, decreased fetal body weight and decreased litter size, but effects were attributed to maternal stress) was seen in the presence of marked maternal toxicity (increased mortality and decreased body weight). In a developmental toxicity study in rabbits, developmental toxicity (decreased fetal body weight) was again seen in the presence of marked maternal toxicity (in part, decreased body weight and increased mortality). In a two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in parental toxicity. However, even though there does not appear to be any concern about the reproductive or developmental toxicity of EPTC based on the studies available, the neurotoxic effects (neuronal necrosis and degeneration) warrant the need for a developmental neurotoxicity study, and therefore the retention of the 10X safety factor, as required by the Food Quality Protection Act (FQPA).

EPTC is not carcinogenic. Oncogenicity studies in both the rat and mouse did not indicate that exposure to EPTC resulted in an increased incidence of neoplastic lesions. EPTC has intrinsic genotoxicity which was not expressed in either the *in vivo* micronucleus test or the Drosophila sex-linked recessive lethal mutation assay. This is supported by lack of a carcinogenic effect in long-term studies and no genetic component in reproduction and developmental studies.

The metabolism of EPTC was evaluated in rats using ^{14}C-labeled EPTC. EPTC was rapidly absorbed and excreted; there was very little bioaccumulation. Most of the radioactivity appeared in the urine with markedly lower amounts in the feces and exhaled air. No sex differences were noted in the absorption, tissue distribution and excretion of EPTC.

In dermal absorption studies with EPTC and other thiocarbamates, EPTC was found to rapidly evaporate (volatilize) from warm skin. Based on a dermal absorption study in the rat which utilized a charcoal impregnated filter to capture vapors lost from the skin, absorption of EPTC was determined to be 5% at 10 hours.

Because of the neurotoxic effects (neuronal necrosis/degeneration), the Hazard Identification Assessment Review Committee (HIARC) recommended that a developmental neurotoxicity study in the rat be performed and recommended that the 10X uncertainty factor, as required by FQPA, be retained. Additionally, even though adequate dermal absorption studies were available, the HIARC also recommended that a 21-day dermal toxicity study in the rat be performed with technical EPTC. Because the short- and intermediate-term occupational and residential exposure scenarios are based on oral toxicity endpoints with the application of the dermal absorption factor, a 21-day dermal toxicity would better define the toxicity of EPTC by the dermal route.

3.2 Acute Toxicity

Results of acute toxicity studies, primary eye and dermal irritation studies and dermal sensitization study with EPTC technical material are summarized in Table 1. EPTC is moderately toxic (Toxicity Category III) via the oral and dermal routes and in a primary eye irritation study in rabbits, the technical was found to be slightly irritating (Toxicity Category III). EPTC is most toxic via the inhalation route (Toxicity Category II).

Table 1. Acute Toxicity of EPTC Technical Material.

Study Type	Animal	Results	Tox Cat	MRID No
81-1: Acute Oral	Rat	LD_{50} Male 1465 (1290-1663) mg/kg Female 1712 (1324-2214) mg/kg Combined 1599 (1294-1976) mg/kg	III	157868
81-2: Acute Dermal	Rabbit	LD_{50} Male > 2000 mg/kg Female > 2000 mg/kg	III	157869
81-3: Acute Inhalation	Rat	LC_{50} Combined 1.39 (0.97-2.00) mg/L	II	157870
81-4: Primary Eye Irritation	Rabbit	PIS (24hr) = 2.2 Reversed within 3 days	III	157871
81-5: Primary Dermal Irritation	Rabbit	PII = 1.4	IV	157872
81-6: Dermal Sensitization	Guinea Pig	Very slight sensitizer	N/A	157873
		Weak sensitizer (Magnusson-Kligman)	N/A	41709201

3.3 FQPA Considerations

The Health Effects Division (HED) FQPA Safety Factor Committee met on November 2, 1998 to evaluate the hazard and exposure data for EPTC and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be **retained** in assessing the risk posed by this chemical due to concern for:

- a data gap for a developmental neurotoxicity study in rats which was identified by the HIARC. A developmental neurotoxicity study will provide additional data regarding functional parameter development, potential increased susceptibility, and the effects of EPTC on the development of the fetal nervous system.

The requirement for a developmental neurotoxicity study is supported by the following:

- the severe neuropathology exhibited in acute, subchronic, and chronic studies with adult animals (acute, subchronic, and chronic exposure to EPTC produced neuronal cell necrosis of the brain in adult rats and dogs; and axonal degeneration of the spinal cord in the adult rat);

- the structure activity relationship to molinate and other thiocarbamates known to produce neurotoxicity/neuropathology;

- molinate induces neurotoxicity / neuropathology after single and multiple exposures *via* the oral, dermal, and inhalation routes across species. There is clear evidence of increased susceptibility in rat fetuses following *in utero* exposure to molinate in the prenatal developmental study. Increased susceptibility was demonstrated in the developmental neurotoxicity study in rats. Molinate was also found to be a reproductive toxicant (mice, rats, and dogs);

The Committee determined that the 10x FQPA safety factor is applicable for the following subpopulations:

Acute Dietary Assessment: All populations which include Infants and Children. The FQPA factor is appropriate for these populations due to the uncertainty regarding the effects on the developing fetal nervous system after a single exposure to EPTC. This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats.

Chronic Dietary Assessment: All populations which include Infants and Children. The FQPA factor is appropriate for these populations due to the uncertainty regarding the effects on the developing fetal nervous system after repeated exposures to EPTC. This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats.

Residential (Short-, Intermediate- and/or Long-Term) Assessment(s): All populations which include Infants and Children. The FQPA factor is appropriate for these populations since the potential for residential exposure to infants and children resulting from the use of EPTC exists and there is uncertainty regarding the effects on the developing fetal nervous system after such exposure. This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats.

3.4 Endpoint Selection

On September 17, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicological endpoints selected for acute and chronic dietary, as well as for occupational and residential (dermal and inhalation) exposure risk assessments for EPTC. The doses and toxicological endpoints selected for various exposure scenarios are summarized in Table 2.

Table 2. Summary of Doses and Endpoints Selected for EPTC Risk Assessments.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	LOAEL=200 (LDT)	Neuronal necrosis in the brain	Acute Neurotoxicity in the Rat
	UF=300 (10x,10x, 3x for lack of NOAEL)	**Acute RfD = 0.67 mg/kg/day**	
	FQPA Safety Factor Retained (10x)	**Acute PAD = 0.067 mg/kg/day**	
Chronic Dietary	NOAEL=2.5	Parental toxicity, dose-related increase in degenerative cardiomyopathy	Two-Generation Reproduction Study in the Rat
	UF=100 (10X10)	**Chronic RfD = 0.025 mg/kg/day**	
	FQPA Safety Factor Retained (10x)	**Chronic PAD = 0.0025mg/kg/day**	
Carcinogenicity (Dietary)	Not required. EPTC was not mutagenic and did not exhibit any oncogenic potential in a mouse oncogenicity study and two combined chronic toxicity/oncogenicity studies in the rat.		
Short-Term (Dermal)	Oral LOAEL=200	Neuronal necrosis in the brain.	Acute Neurotoxicity in the Rat
	UF = 300 10x, 10x, 3x for lack of a NOEL (5.0% dermal absorption) UF = 3000 for all non-occupational populations which include infants and children (FQPA Safety Factor Retained (10x)		
Intermediate-term (Dermal)[a]	Oral NOAEL = 9	Decreased body weight and relative brain weight and neuronal necrosis	90-Day Neurotoxicity Study in the Rat
	UF = 100 10x10 (5.0% dermal absorption)		
Long-Term (Dermal)	The use pattern does not indicate the need for long-term dermal risk assessment.		
Inhalation (Short and Intermediate Term)	NOAEL = 8.3 mg/m^3	Clinical signs, decreased food consumption, brain ChEI in males, and increased prothrombin times in females.	90-day Inhalation Study in the Rat
	UF = 100 10x10 (100% inhalation absorption) UF = 1000 for all non-occupational populations which include infants and children (FQPA Safety Factor Retained (10x)		
Long-Term (Inhalation)	The use pattern does not indicate the need for long-term inhalation risk assessment.		

a = The use of a 5% dermal absorption rate is required for dermal risk assessments.

Because different toxic effects were observed for dermal and inhalation dose routes, a separate margin of exposure (MOE) will be used for dermal and inhalation risk assessments.

3.5 Endocrine Disrupter Effects

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." The Agency is currently working with interested stake holders, including other government agencies, public interest groups, and industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (that is, until 8/3/99) to implement this program. At that time, EPA may require further testing of EPTC for endocrine effects.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

EPTC is a selective herbicide used to control the growth of germinating annual grassy weeds, broadleaf weeds, and some perennial weeds in alfalfa, almonds, beans, birdsfoot trefoil, citrus, clover, corn (field and sweet), cotton, garden beets, lespedeza, potatoes, safflower, sunflower, sugar beets, sweet potatoes, tomatoes, and walnuts. EPTC is also used on non-food sites such as citrus nursery stock, non-bearing orange and grapefruit orchards, evergreens, deciduous trees and shrubs, pine seedling nurseries, ornamentals, and golf course sandtraps. Potential EPTC residential use sites may include ornamentals at residences, gardens, parks, recreational areas, including shade trees, evergreens, and flower gardens; and home vegetable garden use sites may include Irish potatoes and green beans.

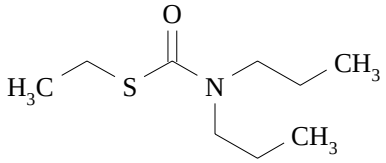
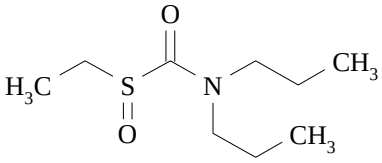
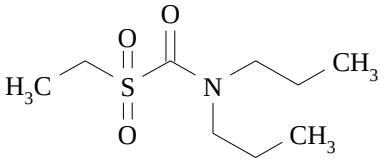
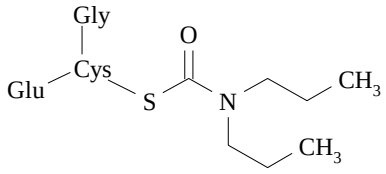
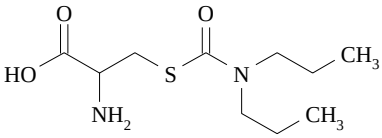
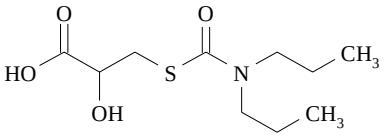
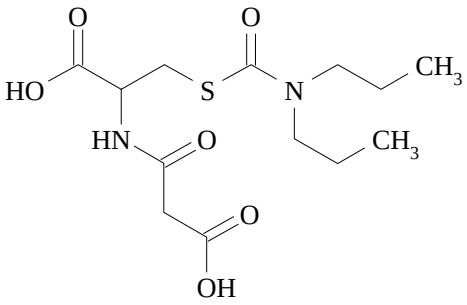
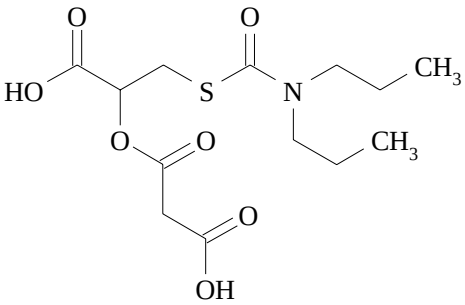
EPTC is formulated as an emulsifiable concentrate (EC) available in products containing up to 87.8% ai and as granular (G) available in products containing up to 25% ai. EPTC is typically applied as a single annual application and is usually incorporated into the soil immediately after application either mechanically or by overhead irrigation. EPTC may also be impregnated on dry bulk fertilizer and applied/ incorporated prior to planting.

There are 26 end-use products currently listed in OPP's REFS database (search conducted January 25, 1999) as active product registrations. In a letter dated July 6, 1998, Zeneca Ag Products requested voluntary cancellation of 12 of their products. The product registrations which Zeneca is supporting for reregistration are: EPA Registration Numbers 10182-172, -199, -217, -220, -223, -226, and -388. The use sites and use patterns retained on these product labels serve as the basis for this risk assessment.

4.2 Dietary Exposure

In plants, EPTC is metabolized to a variety of products via several different metabolic pathways. The major metabolic pathway of EPTC involves initial oxidation of the sulfur atom to a sulfoxide, which is oxidized further to a sulfone. The sulfone metabolite is then conjugated with glutathione and the resultant glutathione conjugate is sequentially metabolized to cysteine-; N-malonyl cysteine-; S-lactic acid-; and O-malonyl-S-lactic acid- conjugates. The second metabolic pathway of EPTC is hydroxylation of the alkyl substituents yielding: N-(2-hydroxy)propyl-; N-(3-hydroxy)propyl-; and S-(2-hydroxy)ethyl- metabolites. The chemical structures of these compounds are shown in Figure A.

Figure A. EPTC residues to be regulated and hydroxylated marker compounds in plants.

Residues to be Regulated		
EPTC 	EPTC sulfoxide 	EPTC sulfone 
Glutathione conjugate 	Cysteine conjugate 	S-Lactic acid conjugate 
N-Malonyl cysteine conjugate 	O-Malonyl S-lactic acid conjugate 	
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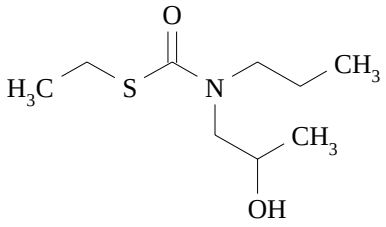
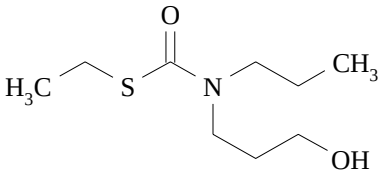
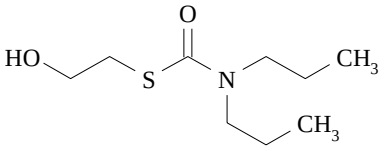
N-2-hydroxypropyl EPTC 	N-3-hydroxypropyl EPTC 	2-hydroxyethyl EPTC 

OPP has concluded that the EPTC plant residues of toxicological concern are: EPTC; EPTC sulfoxide; EPTC sulfone; and the EPTC conjugates (i.e. glutathione-; cysteine-; N-malonyl cysteine-; S-lactic acid-; and O-malonyl-S-lactic acid- conjugates). The basis for the toxicological concern of these substances is the presence of the thiocarbamate moiety. The hydroxylated EPTC plant metabolites also contain the thiocarbamate moiety. However these metabolites are formed only in low concentrations and, as such, OPP believes these residues do not contribute significantly to the total toxicity of EPTC.

Because of the diverse structural and physiocochemical differences between these compounds, the Agency concurred with the registrant's position that development of a single enforcement analytical method that can detect each of these residues was not feasible. Because development of an enforcement analytical method for the hydroxylated metabolites was feasible, the Agency concurred with the registrant's recommendation that EPTC and its hydroxylated metabolites be used as marker residues of EPTC residues of toxicological concern (i.e., markers of EPTC, EPTC sulfoxide, sulfone and the EPTC conjugates resulting from the glutathione-S-transferase pathway).

Therefore, tolerances for EPTC residues in or on plants represent the presence of EPTC and its hydroxylated metabolites (free or conjugated). The ratio formed in plants of EPTC residues of toxicological concern to EPTC residues that will be used as markers varies from 1.5:1 (potatoes) to 13.2:1 (bean vines). OPP decided that for purposes of assessing the risks posed by EPTC, the concentration of any marker compound residues will be multiplied by 15 to estimate the concentration of residues of concern. This factor was selected to cover the high-end of the range of metabolite ratios. The tolerance expression, therefore, will now consist of residues of EPTC *per se* and the EPTC hydroxylated metabolites mentioned above. Hence, all EPTC tolerances have been reassessed based on residue data for the combined residues of EPTC and its hydroxylated metabolites.

In animals, only a single EPTC residue of toxicological concern is found in goats (EPTC-cysteine conjugate) or hens (intact EPTC) fed highly exaggerated doses of EPTC, and in either case the residue is formed in low concentration only. The Agency concludes, therefore, that residues of EPTC in animal commodities represent a Category 3 situation under 40 CFR §180.6(a): i.e., situations in which it is not possible to establish with certainty whether finite residues will be incurred under reasonable worst-case exposure scenarios, but there is no reasonable expectation of the occurrence of finite residues in animal commodities. Therefore, tolerances for residues of EPTC in animal commodities need not be established.

For the determination of residues of EPTC *per se* in or on plant commodities, the Pesticide Analytical Manual (PAM, Vol. II, Section 180.117) lists Methods A (GLC/MC (microcolorimetric) Method RR-50; level of detection (LOD) = 0.02-0.04 ppm depending on the matrix) and B (a confirmatory colorimetric procedure). The EPTC Reregistration Standard Guidance Document of 1983 concluded that the GLC/MC method is adequate for data collection and corresponding tolerance enforcement. Hence, an enforcement analytical method for detecting EPTC *per se* is available. (The GLC/MC method has not been subjected to an Agency method validation.)

For the determination of hydroxylated metabolites (free or conjugated) of EPTC in or on plant commodities, the registrant has proposed a GC/NPD method as an enforcement method. (The level of quantification (LOQ) of each hydroxylated metabolite is 0.01 ppm.) The registrant recently submitted to the Agency a description of the proposed method along with preliminary recovery data. The proposed method was reviewed by the Agency and determined to be adequate. The Agency has required an independent laboratory validation (ILV) of the proposed method in accordance with PR Notice 96-1. When a successful ILV has been received and evaluated, an Agency method trial will be conducted at the EPA Analytical Chemistry Laboratory.

Residue data from crop field trials, processing studies, and livestock feeding studies have been reviewed for the purpose of tolerance reassessment. The submitted residue data from field trial and processing studies depict combined residues of EPTC and its three hydroxylated metabolites. These data were obtained using analytical methods adequately validated for data collection. Storage stability data support

the integrity of the residue data for EPTC, but no data are currently available to delineate the stability of the hydroxy metabolites in frozen plant matrices; these data have been required. In general, field trials met the criteria for the required number of samples and were conducted in locations representative of the major growing regions specific to the crop tested. The test systems utilized representative product formulations, applied at maximum rates using application equipment in accordance with label specifications. Residues of EPTC and its three hydroxylated metabolites were nondetectable (<0.05 ppm) in the majority of samples of raw and processed commodities from the submitted field trials.

HED is recommending revocation of tolerances for certain commodities for one or more of the following reasons: (1) crop groupings are obsolete or no longer applicable thus warranting revocation of certain crop group tolerances concomitant with establishment of tolerances for individual commodities; (2) there are no longer significant livestock feed items for the commodity; and (3) currently there are no registered uses. Insufficient field trial data are available to reassess the tolerances for flaxseed, citrus, and strawberries. Existing tolerances for these commodities have been used for dietary exposure estimates.

4.3 Dietary Exposure (food source): The acute and chronic dietary exposure assessments were conducted using the Dietary Exposure and Evaluation Model (DEEM™) system. DEEM can be used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. The software contains food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992.

For EPTC, inputs to the DEEM analysis include reassessed tolerances and percent crop treated data. The tolerances published for EPTC under 40 CFR 180.117 have been reassessed (HED Residue Chemistry Chapter dated 9/25/98). The reassessed tolerance residue values, adjusted by a factor of 15 to estimate the residues of concern, have been used as the basis for a DEEM Tier 1 analysis for acute dietary exposure and a DEEM Tier 3 analysis for chronic dietary exposure. The Tier 3 analysis used average field trial residue values (adjusted for marker compounds) and also incorporated percent of crop treated data (BEAD Quantitative Usage Analysis for EPTC dated 3/10/98). Where percent crop treated estimates indicated no EPTC use, a default minimum assumption of 1% crop treated was applied. Where residues were nondetectable, one-half LOD was assumed. Data from processing studies indicate that residues of EPTC and its hydroxylated metabolites do not concentrate in the processed fractions of the tested crops except sugar beet molasses (4x concentration factor) and potato granules (1.4x). The residue file created using the DEEM ™ software for these dietary exposure analyses reflects these processing factors using a value of 1 for adjustment factor #1 (adjustment for concentration/reduction of residues in processed commodities) for commodities with no concentration. However, the concentration factor is reflected in the reassessed tolerances for sugar beet molasses (*e.g.*, the reassessed tolerance value for sugar beets is 0.1 ppm and the reassessed tolerance value for sugar beet molasses, the processed commodity, is 0.4 ppm). Also, there is a citrus processing study that is outstanding. Because the processing study for citrus has not been performed, all default concentration factors in the DEEM ™ software have been retained for citrus food items.

The Reference Dose (RfD) is derived from an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control, along with the application of uncertainty factors. The percent of the RfD is calculated as the ratio of the exposure value to the RfD (exposure/RfD x 100 = % RfD). The population adjusted dose (PAD) is an adjusted RfD reflecting the retention or reduction of the FQPA safety factor for all populations which include infants and children. For EPTC, the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD) is 0.067 mg/kg/day and 0.0025 mg/kg/day, respectively.

4.3.1 Acute Dietary Exposure Assessment

For the Tier 1 acute dietary exposure analysis of EPTC, exposure (consumption) was compared to an

acute population adjusted dose of 0.067 mg/kg/day (FQPA Safety Factor Committee Report, 11/18/98). The acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups. The analysis evaluates exposure to the chemical for each food commodity and assumes uniform distribution of EPTC in the food supply.

As shown in Table 3, the acute dietary residue contribution at the 95th percentile occupied less than 100% of the aPAD for any population subgroup and therefore does not exceed HED's level of concern. For most highly exposed subgroup, children 1-6, residue contribution occupied 87.5% of the aPAD . This Tier 1 acute analysis for EPTC is a conservative upper-bound estimate with all input residues equal to the reassessed tolerance value and the assumption that 100% of the crop is treated nationwide.

Table 3. Summary of Tier 1 EPTC Acute Dietary Exposure Analysis (Tier 1) by DEEM.

Population	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
U.S. Population	0.027156	40.53	0.052484	78.33	0.100127	149.44
All Infants <1 year	0.034682	51.76	0.058453	87.24	0.241742	360.81
Nursing Infants <1 year	0.012725	18.99	0.027757	41.43	0.410750	613.06
Non-nursing Infants <1 year	0.041815	62.41	0.063060	94.12	0.099936	149.16
Children 1-6 years	0.058633	87.51	0.096617	144.20	0.151597	226.26
Children 7-12 years	0.037088	55.36	0.066557	99.34	0.115301	172.09

4.3.2 Chronic Dietary Exposure Assessment

A chronic exposure analysis was performed using the DEEM ^{TM} exposure modeling software. The input values for the Tier 3 analysis include average residues from field trials and incorporated percent of the crop treated information from BEAD. The largest markets in terms of total pounds active ingredient are allocated to dry beans/peas (8%), corn (56%) and potatoes (6%). Exposure (consumption) was compared to the chronic population adjusted dose of 0.0025 mg/kg/day (FQPA Safety Factor Committee Report, 11/18/98).

As shown in Table 4, the chronic dietary residue contribution occupies less than 100% of the cPAD for all population subgroups and therefore does not exceed HED's level of concern. For the most highly exposed subgroup, children 1-6, the residue contribution occupies 20.6% of the cPAD. This Tier 3 chronic analysis for EPTC is a refined estimate where average residues from crop field trials and percent of crop treated data were used as inputs. For the majority of collected samples, residues of EPTC and its hydroxylated metabolites were less than the detection limit of 0.02 or 0.04 ppm depending on the matrix. Where residues were nondetectable, one-half the LOD was assumed.

Table 4. Summary of Tier 3 EPTC Chronic Dietary Exposure Analysis by DEEM.

Population Subgroup	Anticipated Residue Concentration (mg/kg/day)	Percent of Chronic PAD
U.S. Population	0.000277	11.1
All Infants (<1 year)	0.000348	13.9
Nursing Infants (<1 year)	0.000093	3.7
Non-nursing Infants (<1 year)	0.000455	18.2
Children (1-6 years)	0.000516	20.6
Children (7-12 years)	0.000387	15.5

4.3.3 Dietary Exposure (drinking water source):

The Environmental Fate and Effects Division (EFED; draft memo by James K. Wolf dated March 4, 1999) has provided an analysis of available monitoring data and a screening-level assessment using simulation models to estimate the potential concentration of EPTC in ground and surface water. EPTC is volatile and mobile in soil and does not appear to be persistent under most conditions. The metabolites of EPTC were not considered in the screening-level assessment due to a lack of environmental fate data. Although limited, there are acceptable data available indicating that metabolites of EPTC are less persistent than the parent compound.

Surface Water Modeling: The PRZM-EXAMS model predicts that EPTC surface water concentrations range from a maximum of **57.35 µg/L** to a mean of annual average of **3.44 µg/L**. These values represent upper-bound estimates of the concentrations that might be found in surface water due to use of EPTC based on simulations performed using an application rate of 3.1 lb/ai/A applied three times/year with 30-day intervals between applications. The model input for aerobic soil metabolism half-life was 77 days (ln-transformed). EPTC was assumed to be applied as a ground spray followed by a 2-inch soil incorporation. Spray drift was assumed to be 1% of the pesticide applied for ground spray and zero for granular application.

Ground Water Modeling: The SCI-GROW model predicts an estimated maximum EPTC concentration in ground water of **1.84 µg/L**. This value was estimated using the maximum application rate of 6.1 lb ai/A applied two times/year and an average half-life of 24 days (non-linear regression). Because SCI-GROW does not consider volatilization as a route of dissipation, this predicted concentration is probably an overestimate.

Ground and surface water monitoring data from at least thirty states indicate that EPTC has the potential to contaminate both ground and surface waters. The peak concentrations of EPTC in surface water estimated by PRZM/EXAMS **(6.35 to 57.35 µg/L)** corresponds reasonably well with the range of the highest surface water concentrations of EPTC observed in monitoring data (10 to 40 µg/L) although the 40 µg/L value is outside the range of the method calibration. The concentration of EPTC in ground water estimated by SCI-GROW **(1.8 µg/L)** also corresponds reasonable well with the range of the highest ground water concentrations of EPTC in observed in monitoring data (0.5 to 2.7 µg/L). Based on this analysis, EFED recommended that 10 µg/L and 1 µg/L be used as the estimates of acute and chronic drinking water levels, respectively.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. OPP uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water.
DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

4.3.3.1 DWLOCs for Chronic (Non-Cancer) Exposure

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/L (child). To calculate the DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD using the equation

$$DWLOC_{chronic} = \frac{\text{[chronic water exposure (mg/kg/day) x (body weight)]}}{\text{[consumption (L) x } 10^{-3} \text{ mg/µg]}}$$

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day)]

As shown in Table 5, the drinking water estimated concentrations in ground water (1.84 µg/L), surface water (3.44 µg/L), and EFED's recommended DWEC of 1.0 µg/L are all below HED's DWLOCs for EPTC for all population subgroups. Based on the available information, residues of EPTC in drinking water do not result in an unacceptable contribution to chronic dietary exposure at this time.

Table 5. Drinking Water Levels of Comparison for Chronic Dietary Exposure.

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (µg/L)	PRZM-EXAMS (µg/L)	SCI-GROW (µg/L)	EFED Recommended DWEC (µg/L)
Adult Male	0.0025	0.000269	0.00223	78	3.44	1.84	1.0
Adult Female	0.0025	0.000248	0.00225	68	3.44	1.84	1.0
Infants <1 yr	0.0025	0.000455	0.00205	20	3.44	1.84	1.0
Children 1-6	0.0025	0.000516	0.00198	20	3.44	1.84	1.0
Non-Hispanic Black	0.0025	0.000322	0.00218	76	3.44	1.84	1.0

4.3.3.2 DWLOCs for Acute Exposure

Acute DWLOCs were calculated based on the acute dietary (food) exposure and default body weights and water consumption figures. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/L (child). To calculate the acute DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation

$$DWLOC_{acute} = \text{[acute water exposure (mg/kg/day) x (body weight)]}$$

[consumption (L) x 10^{-3} mg/µg]

where acute water exposure (mg/kg/day) = [aPAD - acute food (mg/kg/day)].

As shown in Table 6, the drinking water estimated concentrations in ground water (1.84 µg/L) and surface water (57.35 µg/L) are below HED's DWLOCs for EPTC. HED concludes that based on the available information, modeled residues in drinking water do not indicate an unacceptable contribution to acute dietary exposure at this time.

Table 6. Drinking Water Levels of Comparison for Acute Dietary Exposure.

Population Subgroup	Acute PAD	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{acute}$ (µg/L)	PRZM EXAMS (µg/L)	SCI-GROW (µg/L)	EFED Recommended DWEC (µg/L)
Adult Male	0.067	0.027156	0.039844	1395	57.35	1.84	10
Adult Female	0.067	0.027156	0.039844	1195	57.35	1.84	10
Infants <1 yr	0.067	0.041815	0.025185	252	57.35	1.84	10
Children 1-6	0.067	0.058633	0.008367	84	57.35	1.84	10

4.3.3.4 DWLOCs for Short- and Intermediate-Term Exposure

A DWLOC for short- and intermediate-term aggregate exposure was not calculated because the dermal and inhalation risks to residential handlers alone exceeds HED's level of concern. Any contribution to exposure from residues of EPTC in water or food would result in a greater risk concern.

4.4 Non-Dietary Exposure

Occupational and residential exposure to EPTC residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities; however, the potential for postapplication occupational exposure is minimal. Because EPTC is applied as a soil directed spray or as a soil injection well before plants are mature, the potential for postapplication dermal exposure during harvest activities is minimal. Furthermore, the potential for dermal contact with EPTC-treated soil is unlikely since none of the registered use sites are believed to involve manual seed or transplant activities. *NOTE: EPTC postemergence layby application to tomatoes is made when the crop is at least 3-4 inches tall and soil incorporated using ground equipment.* In contrast to occupational workers, individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules.

Based on toxicological criteria and potential for exposure, HED has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and for residential postapplication dermal and inadvertent oral ingestion exposure to adults and/or children.

4.4.1 Occupational Handler Exposure Scenarios

HED has identified 13 major exposure scenarios for which there is potential for occupational handler exposure during mixing, loading, and applying products containing EPTC to agricultural crops and to non-agricultural use sites. These occupational scenarios reflect a broad range of application equipment, application methods, and use sites. The scenarios were classified as short-term (1-7 days) and intermediate-term (1 week to several months) based primarily on the frequency of exposure. A long term exposure duration is not expected because applications are typically made only once per year. The estimated exposures considered baseline protection (long pants and a long-sleeved shirt, no gloves, and an open cab or tractor), additional personal protective equipment (PPE, which includes a double layer of clothing and gloves and/or a dust/mist respirator), and engineering controls (closed mixing/loading systems for liquids and granulars and enclosed cabs/trucks).

4.4.1.1 Occupational Handler Exposure Data Sources and Assumptions

An exposure assessment for each EPTC use scenario was developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

The registrant submitted a biological monitoring study conducted with cycloate (MRID 43739701). Although the Agency agreed that acceptable data from monitoring studies conducted with cycloate could be used to estimate exposure of other thiocarbamates, data from the submitted study were not used in this risk assessment. In the study, an EC formulation was mixed, loaded and applied using groundboom spray equipment mounted on either open- or closed-cab equipment, and the subjects wore a range of protective clothing during handling and application activities. PHED mixer/loader data sets for ground application of liquid formulations better represents the registered EPTC uses and resulting scenario- specific handler exposures.

4.4.1.2 Occupational Handler Risk Characterization

Because different endpoint effects were selected for the assessment of dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. MOEs for occupational handlers were derived based upon comparison of dermal exposure estimates against either a LOAEL of 200 mg/kg/day for short-term exposure or a NOAEL of 9 mg/kg/day for intermediate-term exposure. Both the short and intermediate-term LOAEL/NOAELs were from neurotoxicity studies in the rat (oral administration). Therefore, the absorbed fraction of each exposure was calculated in order to convert to an equivalent oral dose using a dermal absorption rate of 5%. MOEs were also derived based upon comparison of inhalation exposure estimates against a NOAEL of 8.3 mg/m^3 which translates to 2.17 mg/kg/day. **The uncertainty factors and target MOEs for occupational workers are 300 for short-term dermal risk, 100 for intermediate-term dermal risk, and 100 for short- and intermediate-term inhalation risk. MOEs below this level would represent a risk concern for the Agency.**
A summary of the short-term and intermediate-term risk estimates for baseline, additional PPE, and engineering controls is presented in Tables 7 and 8. Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor, except for scenario 10 which does include gloves. Additional PPE for all dermal scenarios includes double layer of clothing (50% protection factor for clothing) and chemical resistant gloves. Depending on the scenario, engineering controls include closed mixing/loading, single layer clothing, chemical resistant gloves; closed granular loading systems (98% protection factor, single layer clothing, no gloves; enclosed cab single layer clothing, no gloves; or enclosed truck (98% protection factor), single layer clothing, no gloves.

Three short-term and seven intermediate-term scenarios require PPE to mitigate dermal risks from handling and/or applying EPTC-containing products. PPE is required to mitigate risk from dermal exposure during mixing/loading EC formulations for chemigation and ground application, and for mixing/loading/applying EC formulations using hand-held equipment (a low pressure handwand).

Short-Term Risk Characterization: The estimates for short-term dermal and inhalation risks have not been combined because dermal and inhalation endpoint effects are different.

> **Dermal** exposures reflecting baseline protective clothing result in MOEs that exceed HED's level of concern for only three of 17 scenarios where MOEs ranged from 69 to 190. For these three scenarios, (1a) mixing/loading EC formulations for chemigation; (1b) mixing/loading EC formulations for ground application; and (9) mixing/loading/applying EC formulations to the soil with a low pressure handwand, additional PPE (double layer of clothing and chemical resistant gloves) are required to mitigate exposure/risk. Baseline and/or PPE exposure assessments were not performed for two scenarios because methodologies other than mechanical mixing/loading/applying are not feasible. Engineering controls are required to mitigate dermal exposure for these two scenarios (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) and (8) applying granular with aerial equipment. **Provided that EPTC short-term dermal exposures are mitigated for the above specified exposure scenarios with PPE and/or engineering controls, MOEs for dermal exposure/risk do not exceed HED's level of concern.**
>
> **Inhalation** exposures reflecting baseline protective clothing result in MOEs that exceed HED's level of concern for only three of 17 scenarios where MOEs ranged from 40 to 90. For these three scenarios: (1a) mixing/loading emulsifiable concentrate for chemigation; (2b) loading granular for aerial application; and (5) applying dry bulk fertilizer in drop type tractor drawn spreaders at 500 acres per day for all application rates, additional PPE (dust/mist respirator) are required to mitigate exposure/risk. Provided that EPTC short-term inhalation exposures are mitigated for the above specified exposure scenarios with PPE, MOEs ranging from 140 to 720 do not exceed HED's level of concern. Baseline and/or PPE exposure assessments were not performed for two scenarios because application methodologies other than mechanical mixing/loading/applying are not feasible. Therefore, engineering controls are required to mitigate inhalation exposure for these two scenarios (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) and (8) applying granular with aerial equipment. **Although engineering controls for these two scenarios decrease inhalation exposure, the estimated MOEs are 75 or 83 and exceed HED's level of concern.**

Intermediate-Term Risk Characterization: The estimates for short-term dermal and inhalation risks have not been not combined because dermal and inhalation endpoint effects are different.

> **Dermal** exposures reflecting baseline protective clothing result in MOEs that exceed HED's level of concern for seven of 17 scenarios. For these seven scenarios, (1a), (1b), (1d), (6), (9), (11), and (12) MOEs ranging from 3 to 84 require additional PPE (double layer of clothing and chemical resistant gloves) to mitigate exposure/risk. Provided that EPTC intermediate-term dermal exposures are mitigated for the above specified exposure scenarios with PPE, MOEs ranging from 150 to 5,600 do not exceed HED's level of concern. Baseline and/or PPE exposure assessments were not performed for two scenarios because application methodologies other than mechanical mixing/loading/applying are not feasible. Therefore, engineering controls are required to mitigate dermal exposure for these two scenarios: (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) and (8) applying granular with aerial equipment. **Although engineering controls for these two scenarios decrease dermal exposure, the estimated MOE of 60 for mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) exceeds HED's level of concern.**

Refer to the short-term **inhalation** exposure risk characterization above for intermediate-term inhalation exposure risk characterization; risk estimates are the same for both short- and intermediate-term inhalation exposures.

A number of issues must be considered when interpreting the results of the occupational short- and intermediate-term risk assessment. For example, the acres treated per day may vary depending on the crop and application equipment as follows:

10 acres for commercial ornamental settings using mechanical applications and 1 acre for hand held equipment except the push type granular spreader that cover 5 acres;

40 acres for citrus groves airblast and rights-of-way sprayer application;

80 acres for drop-type tractor drawn spreader and groundboom applications in an agricultural setting;

350 acres for non-forestry aerial and chemigation applications (including flaggers supporting aerial applications).

For impregnation of dry bulk fertilizer, the total amount of treated fertilizer that can be applied in one day is constant (i.e. the application rate and the area treated vary inversely). For example, 500 acres per day can be treated when fertilizer is applied at a rate of 200 lbs per acre. At a rate of 700 lbs of fertilizer per acre, only 143 acres can be treated in one work day. The number of pounds that can be mixed and loaded in one day was estimated by the number of 10-ton trucks that can be loaded per hour by one individual. Assuming that five, 10-ton trucks could be filled with treated fertilizer per hour, and that an individual works for eight hours, then 40 trucks (400 tons or 800,000 lbs) could be loaded per work day. **It must be noted that the unit exposure values for mixing/loading emulsifiable concentrate for impregnation on dry fertilizer were taken from PHED and do not reflect the actual use of the pesticide. The PHED data was determined by loading and mixing fertilizer from bags, not mechanically mixing and loading fertilizer into trucks.**

For non-agricultural uses, if more than an acre is being treated, HED assumes that a push type spreader is typically used for applying a granular or that a rights-of-way sprayer is typically used for applying a liquid. For application to golf course sandtraps, which are believed to occupy an area equivalent to the area of greens, the treated area is assumed to be about 125,000 sq. ft. using a push type spreader and 43,560 sq. ft. using a belly grinder spreader.

Incident Reports

HED has reviewed the OPP Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) data bases for reported incident information for EPTC. Of the 19 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995), 17 involved use of EPTC alone and were judged to be responsible for the health effects. Eye and skin illnesses were the most commonly reported effects. Based on these reports, exposure to EPTC can lead to skin and eye illnesses such as skin rashes and conjunctivitis. HED recommends that appropriate protective clothing to protect the eyes and skin be worn by occupational workers who may have extensive exposure from handling EPTC. If workers are likely to be exposed to irrigation water treated with EPTC, they should be warned of its treatment by posting or verbal warnings.

4.4.1.3 Occupational Postapplication Exposure

Because EPTC is applied to the soil directly and is soil incorporated well before the plants are mature, OPP has concluded that there is a low potential for occupational postapplication exposure when pre-emergent herbicides are used. The timing of the application of EPTC greatly reduces the potential for postapplication

exposure. Also, most agricultural operations mechanically plant seeds early in the season, which minimizes the potential for contact. *NOTE: EPTC postemergence layby application to tomatoes is made when the crop is at least 3-4 inches tall and soil incorporated using ground equipment.*
Minimal exposure during harvesting or any other late season activities, is expected since the chemical is applied pre-emergent. Therefore, OPP does not require a postapplication occupational exposure assessment for EPTC.

The restricted entry interval (REI) is 12 hours, with the exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

4.4.2. Residential Handler Exposure

Potential EPTC residential use sites may include ornamentals at residences, gardens, parks, recreational areas, including shade trees, evergreens, and flower gardens; and home vegetable garden use sites may include Irish potatoes and green beans.

EPTC is typically applied only to bare soil once before planting or after weeding under crops or ornamentals followed by soil incorporation. Examples of typical usage of a granular formulation in the home garden would include preplant application and incorporation with a rototiller, postplant application incorporated into the soils to a depth of 2-3 inches using a hand rake or hoe, and weed control in established trees and shrubs by incorporation into the top 6 inches of soil. EPTC granular formulations are packaged for the residential market in 50 lb bags.

Residential handler exposure to EPTC residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities. The exposure duration of these activities was classified as short-term (1-7 days) because EPTC is usually applied only once per year.

4.4.2.1 Residential Handler Exposure Scenarios

The EPA has determined that there is potential exposure to residential mixer, loader, and applicators during the usual use-patterns associated with EPTC. Based on the use patterns, seven major residential exposures were identified for EPTC. Three involve mixing/loading/applying sprays with low pressure hand wand, a hose-end sprayer, or a back pack sprayer. Four involve loading/applying granulars with a push-type spreader, a belly grinder spreader, by hand/spoon, or applying granulars with a shaker can.

4.4.2.2 Residential Handler Exposure Data Sources and Assumptions

Residential handler exposure assessments were completed by HED assuming an exposure scenario for homeowners wearing the following attire: short sleeved shirt, short pants, shoes and socks, and no gloves or respirator. PHED values used to estimate daily unit exposure values were taken from the *Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 1997).*

The area treated per day was assumed to be 0.25 acre for a low pressure hand wand, a hose-end sprayer and a backpack sprayer or 10,000 square feet for a push type spreader, bellygrinder spreader, shaker can and hand/spoon application. Calculations were made using the maximum application rates for crops as stated on the available EPTC labels. Application rates represent the range of exposure levels associated with the various use patterns.

4.4.2.3 Residential Handler Risk Characterization

Because different endpoint effects were selected for the assessment of dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. MOEs for residential handlers were derived based upon comparison of dermal exposure estimates against a LOAEL of 200 mg/kg/day for short-term exposure. The short-term LOAEL is from a neurotoxicity study in the rat (oral administration). Therefore, the absorbed fraction of each dose was calculated in order to convert to an equivalent oral dose using a dermal absorption factor of 5%. MOEs were also derived based upon comparison of inhalation exposure estimates against a NOAEL of 8.3 mg/m^3 which translates to 2.17 mg/kg/day. **The uncertainty factors and target MOEs for residential populations (including the 10x FQPA safety factor) are 3000 for short-term dermal risk and 1000 for short-term inhalation risk.**

Short-term Risk Characterization: The estimates for short-term dermal and inhalation risks have not been combined because dermal and inhalation endpoint toxicity effects are different.

Dermal exposures result in margin of exposure (MOE) values that exceed HED's level of concern for four of the seven residential handler scenarios where MOEs range from 94 to 1,800.

- (1) Mixing/loading/applying emulsifiable concentrate with a low pressure hand wand for all application rates.
- (2) Mixing/loading/applying emulsifiable concentrate with a hose-end sprayer at the maximum application rate of 15.0 lbs ai/A for ornamentals.
- (5) Loading/applying granular with bellygrinder spreader on ornamentals.
- (6) Loading/applying granular with by hand/spoon for all application rates.

Inhalation exposures result in margin of exposure (MOE) values that exceed HED's level of concern for two of the seven residential handler scenarios where MOEs ranged from 94 to 710.

- (5) Loading/applying granular with bellygrinder spreader on ornamentals at the maximum application rate of 15.0 lbs ai/A for ornamentals.
- (6) Loading/applying granular with by hand/spoon for all application rates.

It should be noted that the estimated MOEs for applying granular formulations with a spoon are based on unit exposure values in PHED for applying granular formulations by hand without glove protection.

In general, use of EPTC at application rates typically prescribed (6 lb ai/A) for control on annual weeds in vegetable gardens do not exceed HED's level of concern for the residential handler. Risk estimates exceeding HED's level of concern are based on exposures from maximum rates (15 lb ai/A) prescribed to control perennial weeds in ornamental gardens and when application is made using a belly grinder or a hand-held spoon.

4.4.3 Residential Postapplication Exposures and Risks

EPA has determined that there are potential postapplication exposures to residents entering treated areas around ornamentals and in gardens. In contrast to occupational workers, there is a potential for postapplication residential dermal exposure because individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules. For residential postapplication activities, the

exposure duration is expected to be short-term (1 to 7 days).

4.4.3.1 Postapplication Exposure Scenarios

The scenarios likely to result in postapplication exposures are as follows:

- Dermal exposure from residue on gardens (adult and youth);
- Ingestion of granules in treated areas (toddler);
- Incidental ingestion of soil from pesticide-treated residential areas (toddler).

4.4.3.2 Data Sources and Assumptions for Postapplication Exposure Calculations

The equations and assumptions used for each of the scenarios were taken from the *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments* guidance document, and are given below. The following general assumptions were made for all scenarios:

- On the day of application, it was assumed that 20 percent of the application rate is available from the soil as dislodgeable residue.

- The assumed ingestion rate for dry pesticide formulations (i.e., granules) is 0.27 grams/day for toddlers age 3 years. This is based on the assumption that if 6.0 pounds of product were applied to a 1,000 square feet of land, the amount of product per square foot would be 2.7 g/ft^2. The toddler would consume one-tenth of the product available in a square foot.

- Postapplication was assessed on the same day the pesticide is applied because it was assumed that the homeowner could enter the garden immediately after application. Therefore, postapplication exposures were based on day 0.

- Adults were assumed to weigh 70 kg. The average body weight for a 10 to 12 year old youth is 39.1 kg. This represents the median value for males and females at ages 10, 11, and 12 years old. The 1 to 6 year old toddler is assumed to weigh 15 kg.

4.4.3.3 Residential Postapplication Risk Characterization

A summary of the calculations of short-term dermal risk is presented in Table 10. MOEs do not exceed HED's level of concern for dermal exposure in treated gardens or inadvertent soil ingestion in treated areas where MOEs range from 6,000 to 260,000. However, the estimated incidental ingestion of granules in treated areas by a toddler based on standard assumptions from the Residential SOPs results in an MOE of 480 which greatly exceeds HED's level of concern. While it is HED's policy to routinely conduct screening level assessments for incidental ingestion of granules from treated areas, HED believes a toddler's exposure to EPTC granules may be outside the scope of concern because of the formulation particle size. HED recommends that the registrant provide quantitative information on the number of particles per gram (or particles per area) of formulated product applicable to the current inert carrier material for the 2.3% granular formulation.

4.4.4 Cumulative Exposure

For risk assessment purposes, HED has not assumed that EPTC has a common mechanism of toxicity with any other chemicals.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

5.1 Acute Aggregate Risk

Acute aggregate risk estimates do not exceed HED's level of concern. The aggregate acute dietary risk estimates include exposure to EPTC residues in food and water. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern based on an upper-bound analysis using tolerance-level residues and assuming 100% of crop treated, represents 87.5% of the acute PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to all other groups represents less than 62.4% of the acute PAD. Using conservative screening-level models, the estimated maximum peak concentrations of EPTC in surface water is 57 µg/L. This estimated peak concentration is less than HED's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate acute dietary risk. Based on the available information, HED concludes with reasonable certainty that no harm to any population will result from acute dietary exposure to EPTC.

5.2 Short- and Intermediate-Term Aggregate Risks

Short-term aggregate risk estimates exceed HED's level of concern. Currently registered uses of EPTC in residential settings result in dermal, inhalation, and inadvertent oral exposures that alone exceed HED's level of concern. Any additional exposure through food or drinking water would contribute to an already unacceptable risk estimate
.

5.3 Chronic (Non-Cancer) Aggregate Risk

Chronic (non-cancer) aggregate risk estimates do not exceed HED's level of concern. The aggregate chronic dietary risk estimates include exposure to EPTC residues in food and water. No chronic residential use scenarios were identified. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern based on a Tier 3 refinement using average residues from field trial and percent of crop treated data, represents 20.6% of the chronic PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to all other groups represents less than 18.2% of the chronic PAD. Using conservative screening-level models, the estimated maximum 1-in-10 year annual average of EPTC in surface water is 3.44 µg/L. This estimated average concentration is less than HED's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate chronic dietary risk. Based on the available information, HED concludes with reasonable certainty that no harm to any population will result from chronic dietary exposure to EPTC.

6.0 DATA NEEDS

Additional data requirements have been identified in the attached Science Chapters and are summarized here.

Toxicology Data for OPPTS Guidelines:

83.6 Developmental neurotoxicity study in the rat

In addition to the requirement for a developmental neurotoxicity study in the rat, the HIARC recommended that the following studies be performed:

82.2 21-day dermal toxicity study with technical EPTC
85.1 Metabolism study.

Product and Residue Chemistry Data for OPPTS Guidelines:

860.1200 Direction for Use
860.1340 Residue Analytical Methods - Plant Commodities
860.1360 Multiresidue Methods
860.1380 Storage Stability Data
860.1500 Crop Field Trials: Citrus Fruits Group; Cotton, seed and gin byproducts; flaxseed; fallow land.
860.1520 Processed Food/Feed: Citrus fruit

Occupational Exposure Data for OPPTS Guidelines

- The need for additional data will be determined when HED and SRRD consider risk mitigation/regulatory options.

Table 7. Summary of Occupational Handler Dermal Risk for EPTC at Baseline, with PPE, and Engineering Controls

Exposure Scenario (Scenario #)	Short-Term MOE = 300			Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	Baseline	PPE	Engineering Controls	
MIXER/LOADER EXPOSURE							
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	69	12,000	N/A	3	529	N/A	The number of acres treated/day (350) is a major driver for this exposure.
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	200-1,600	≥34,000	N/A	9-72	≥1,500	N/A	A 6 lb ai/A max rate and the number of acres treated/day (80) for ag crops (other than citrus, cotton, ornamentals) results in the highest exposures.
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System) (1c)	N/A	N/A	≥68,000	N/A	N/A	60-430	Additional mitigation can be achieved by reduction in the amount handled/day or additional information on this use.
Mixing/Loading Emulsifiable Concentrate for Handgun (Hydraulic Sprayer) Application (1d)	≥400	N/A	N/A	18-72	≥3,100	N/A	A 6 lb ai/A max rate and the number of acres treated (40) for non-bearing citrus results in the highest exposures.
Loading Granular in Drop-TypeTractor Drawn Spreader (2a)	≥69,000	N/A	N/A	≥3,100	N/A	N/A	N/A
Loading Granular with Aerial Equipment (2b)	24,000	N/A	N/A	1,100	N/A	N/A	N/A
APPLICATOR EXPOSURES							
Applying Spray to the Soil with a Groundboom Sprayer (3)	≥42,000	N/A	N/A	≥2,000	N/A	N/A	N/A
Applying Spray to the Soil with an Airblast Sprayer (4)	≥3,200	N/A	N/A	≥150	N/A	N/A	N/A
Applying Dry Bulk Fertilizer in Drop Type Tractor Drawn Spreader (5)	≥9,000	N/A	N/A	≥420	N/A	N/A	N/A
Applying Spray to the Soil with Handgun (Rights-of-Way Sprayer) Application (6)	≥900	N/A	N/A	40-160	180-720	N/A	A 6 lb ai/A max rate and the number of acres treated (40) for non-bearing citrus results in the highest exposures.
Applying Granular with a Drop-Type Tractor Drawn Spreader (7)	≥59,000	N/A	N/A	≥2,700	N/A	N/A	N/A
Applying Granular with Aerial Equipment (8)	N/A	N/A	125,000	N/A	N/A	5,600	N/A
MIXER/LOADER/APPLICATOR EXPOSURES							
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (9)	190-470	≥50,000	N/A	8-21	≥2,300	N/A	Exposure is activity driven; the unit exposure value for handheld equipment is high. Low confidence in hand/dermal baseline and PPE data; no PF applied.

Exposure Scenario (Scenario #)	Short-Term MOE = 300			Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	Baseline	PPE	Engineering Controls	
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil a with Backpack Sprayer (10)	≥7,500	N/A	N/A	≥340	N/A	N/A	N/A
Loading/Applying Granular with a Push-Type Spreader (11)	≥1,300	N/A	N/A	58-300	≥230	N/A	A 15 lb ai/A max rate on ornamentals results in the highest exposures.
Loading/Applying Granular with a Bellygrinder Spreader (12)	≥1,900	N/A	N/A	84-250	≥150	N/A	A 15 lb ai/A max rate on ornamentals results in the highest exposures.
FLAGGER EXPOSURE							
Flagging Granular Applications (13)	72,000	N/A	N/A	3,200	N/A	N/A	N/A

Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor, except scenario 10 that also includes gloves. Additional PPE for all dermal scenarios includes double layer of clothing (50% protection factor for clothing) and chemical resistant gloves. Engineering controls includes closed mixing/loading, single layer clothing, chemical resistant gloves (scenarios 1a/1b/1d), lock and load (98% protection factor, single layer clothing, no gloves (scenarios 2a/2b), enclosed cab single layer clothing, no gloves (scenarios 3,4,5,7,8), enclosed truck (98% protection factor), single layer clothing, no gloves (scenario 14). Application rates are based on the maximum application rates listed on the EPTC labels. Amount handled per day are from EPA estimates of acres treated, or square feet treated in a 8-hour work day.

Three short-term and seven intermediate-term scenarios require PPE to mitigate dermal risks from handling and/or applying EPTC-containing products. PPE is required to mitigate risk from dermal exposure during mixing/loading EC formulations for chemigation and ground application, and for mixing/loading/applying EC formulations using hand-held equipment (a low pressure handwand).

Table 8. Summary of Occupational Handler Inhalation Risk for EPTC at Baseline, with PPE, and Engineering Controls

Exposure Scenario (Scenario #)	Short- and Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	
MIXER/LOADER EXPOSURE				
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	90	450	N/A	Exposure is driven by the amount handled; more acreage can be treated by chemigation than with vehicles.
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	≥260	N/A	N/A	
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System) (1c)	N/A	N/A	75-350	The highest application rate and 200 lb fertilizer/day results in the highest exposure.
Mixing/Loading Emulsifiable Concentrate for Handgun (Hydraulic Sprayer) Application (1d)	≥530	N/A	N/A	
Loading Granular in Drop-TypeTractor Drawn Spreader (2a)	≥170	N/A	N/A	
Loading Granular with Aerial Equipment (2b)	64	320	N/A	Exposure is driven by the amount handled; more acreage can be treated via aircraft than with ground vehicles.
APPLICATOR EXPOSURES				
Applying Spray to the Soil with a Groundboom Sprayer (3)	≥430	N/A	N/A	
Applying Spray to the Soil with an Airblast Sprayer (4)	≥140	N/A	N/A	
Applying Dry Bulk Fertilizer in Drop Type Tractor Drawn Spreader (5)	40-300	≥210	N/A	The 6 lb/A rate results in the greatest exposure.
Applying Spray to the Soil with Handgun (Rights-of-Way Sprayer) Application (6)	≥160	N/A	N/A	
Applying Granular with a Drop-Type Tractor Drawn Spreader (7)	≥230	N/A	N/A	
Applying Granular with Aerial Equipment (8)	N/A	N/A	83	Alfalfa 350A - low confidence in hand/dermal & inhalation data.
MIXER/LOADER/APPLICATOR EXPOSURES				
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (9)	≥340	N/A	N/A	
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil a with Backpack Sprayer (10)	≥340	N/A	N/A	
Loading/Applying Granular with a Push-Type Spreader (11)	≥320	N/A	N/A	
Loading/Applying Granular with a Bellygrinder Spreader (12)	≥160	N/A	N/A	
FLAGGER EXPOSURE				
Flagging Granular Applications (13)	720	N/A	N/A	

Baseline inhalation unit exposure represents no respirator. Application rates are based on the maximum application rates listed on the EPTC labels. Amount handled per day are from EPA estimates of acres treated, or square feet treated in a 8-hour work day.

Table 9. Residential Handler Short-term Dermal and Inhalation Risk to EPTC at Baseline.

Exposure Scenario (Scenario. #)	Crop/Use	Rate	Baseline Dermal (Target MOE = 3000)		Baseline Inhalation (Target MOE = 1000)	
			Daily Dose (mg/kg/day)[a]	Short-term MOE[b]	Daily Dose (mg/kg/day)[c]	Short-term MOE[e]
MIXER/LOADER/APPLICATOR EXPOSURE						
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (1)	Ornamentals	typical	0.11	1,900	0.00064	3,400
		maximum	0.27	750	0.0016	1,400
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Hose-end Sprayer (2)	Ornamentals	typical	0.032	6,200	0.00020	11,000
		maximum	0.080	2,500	0.00051	4,300
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Backpack Sprayer (3)	Ornamentals	typical	0.0055	37,000	0.00064	3,400
		maximum	0.014	15,000	0.0016	1,400
Loading/Applying Granular with a Push-Type Spreader (4)	Ornamentals	typical	0.0030	68,000	0.00012	18,000
		maximum	0.0074	27,000	0.00031	7,000
	Garden Use		0.0015	130,000	0.00006	34,000
Loading/Applying Granular with a Bellygrinder Spreader (5)	Ornamentals	typical	0.11	1,800	0.0012	1,800
		maximum	0.27	740	0.0031	710
	Garden Use		0.06	3,500	0.0006	3,400
Loading/Applying Granular by Hand/Spoon (6)	Ornamentals	typical	0.42	470	0.0093	230
		maximum	1.06	190	0.023	94
	Garden Use		0.22	910	0.005	450
Applying Granular Shaker Can (7)	Ornamentals	typical	no data	no data	no data	no data
		maximum	no data	no data	no data	no data

Footnotes:

a Daily Dermal Dose (mg/kg/day) = (Daily Dermal Exposure (mg/day) / Body Weight (70 kg)) x Absorption Factor (5%).
b Short-term Dermal MOE = LOAEL (200 mg/kg/day) / Daily Dermal Dose (mg/kg/day) . The acceptable MOE value is 3000.
c Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day) / Body weight (70kg).
d Short-term Inhalation MOE = NOAEL (2.17 mg/kg/day) / Daily Inhalation Dose (mg/kg/day). The acceptable value is 1000.

Table 10. EPTC Residential Postapplication Scenarios and Estimated Risks.

Exposure Scenario (Scenario #)	Receptor	Application Rate Per Treatment (AR) (lbs ai/A)	DFR_t (µg/cm^2)[a]	SR_t (µg/g)[b]	Transfer Coefficient (Tc) (cm^2/hr)	Exposure Time (ET) (hrs/day)	Dermal Adsorption (%)	IgR (g/day) or (mg/day)[c]	F (ai)	BW (kg)	ADD (mg/kg/day)[d]	MOE[e]
Dermal Exposure from Pesticide Residue on Gardens	Adults	3.1	6.95	_	10,000	0.67	5	_	_	70	0.0333	6,000
	Youth				5,000					39.1	0.0298	6,700
Eating Granules in Treated Areas	Toddler	_	_	_	_	_	_	0.27	0.023	15	0.0835	480
Soil Ingestion in Treated Areas	Toddler	15	_	114	_	_	_	100	_	15	0.0007	260,000

Footnotes

[a] Dislodgeable foliar residue (µg/cm^2) = [AR (lbs ai/A) * fraction ai retained on foliage (20%) * 4.54E+8 µg/lb * 2.47E-8 A/cm^2]

[b] Soil residue (µg/g) = [AR (lbs ai/A) * fraction ai retained on soil (20%/cm) * 4.54E+8 µg/lb * 2.47E-8 A/cm^2 * 0.67 cm^3/g soil]

[c] Ingestion rate: g/day for granular ingestion, and mg/day for incidental soil ingestion.

[d] Average daily dose (ADD) (mg/kg/day)

Dermal exposure: = [DFR (µg/cm^2) * Tc (cm^2/hr) * mg/1,000 µg * ET (hrs/day) * absorption factor (1.0)] / [BW (kg)];

Hand-to-mouth: = [DFR (µg/cm^2) * SA (cm^2/event) * FQ (events/hr) * mg/1,000 µg * ET (2 hrs/day)] / [BW (kg)];

Granular ingestion: = [F * IgR (g/day) * 1,000 mg/g] / [BW (kg)]; and

Incidental soil ingestion: = [SRt (µg/g) * IgR (mg/day) * g/1,000,000 µg] / [BW (kg)].

[e] MOE = LOAEL (200 mg/kg/day) / ADD.

ATTACHMENTS (041401)

Report of the Hazard Identification Assessment Review Committee. Fricke/Rowland (10/23/98)
Report of the FQPA Safety Factor Committee. Brenda Tarplee (11/18/98)
Product Chemistry Chapter. Ken W. Dockter (05/05/98; D245001)
Residue Chemistry Chapter. Stephen C. DeVito (09/25/98; D245000)
EPTC anticipated Residues. Stephen C. DeVito (03/11/99; D254210)
Toxicology Chapter. Robert F. Fricke (01/21/99; D244999)
Occupational and Residential Exposure Assessment. Renee Sandvig (01/06/99; D244998)
Dietary Exposure and Risk Estimates for Reregistration. Carol Christensen (02/18/99)
Addendum: Chronic Dietary Exposure Analysis for EPTC Using Anticipated Residues (03/23/99; D254454)
Incident Report. Jerome Blondell and Monica Spann (06/23/98; D247064)

cc Without Attachments: P. Deschamp, Caswell File