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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 9, 2000

MEMORANDUM

SUBJECT: **Phosmet** (Chemical ID No. 059201/List A Reregistration Case No. 0242). HED Revised Human Health Risk Assessment for the Reregistration Eligibility Decision Document (RED). DP Barcode No. D262365.

FROM: Christina Swartz, Chemist
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THRU: Whang Phang, Ph.D., Branch Senior Scientist
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TO: Diane Isbell/Kathy Monk (PM-52)
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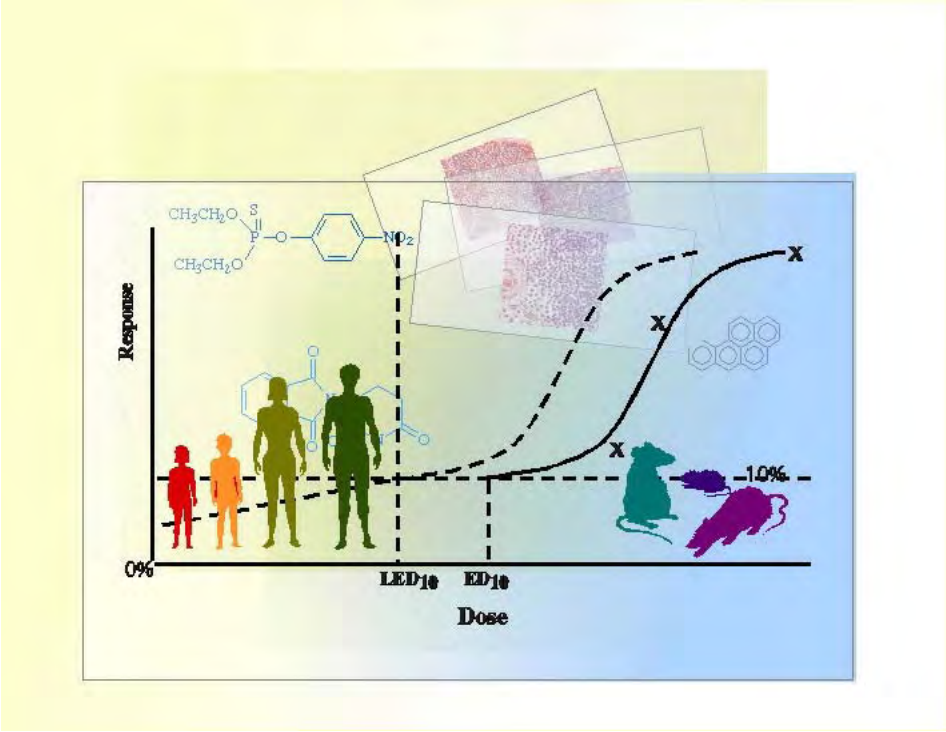
Attached is the revised human health risk assessment for phosmet prepared by Reregistration Branch 1 of the Health Effects Division. This revision incorporates data submitted by Gowan Co. and Schering-Plough Animal Health Inc. in response to the preliminary risk assessment, including acute and subchronic neurotoxicity studies and a route-specific dermal toxicity study in rats. The registrant's handler and post-application probabilistic exposure assessments were considered but have not been used to generate revised non-dietary exposure and risk estimates. Agency memos generated based on comments received during the relevant comment periods are attached. The phosmet team in HED is comprised of J. Blondell (human incident report), J. Dawson (occupational and residential risk assessment), C. Swartz (risk assessment and dietary exposure assessment), V. Dobozy (veterinary incident report) and L. Taylor (hazard assessment).

Attachment: Phosmet Revised Human Health Risk Assessment.

cc: RRB1/HED: C. Swartz, W. Phang, J. Dawson, V. Dobozy, L. Taylor,
CEB1/HED: J. Blondell
7509C:CSwartz:RRB1:CM2:Rm 722H:703 305 5877:02/02/00

HUMAN HEALTH RISK ASSESSMENT

Phosmet



U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509C)

Christina Swartz, Risk Assessor
February 9, 2000

HUMAN HEALTH RISK ASSESSMENT

Phosmet

Phase 4

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ATTACHMENTS

1.0 INTRODUCTION

The revised human health risk assessment for phosmet incorporates new studies and information submitted by registrants (Gowan Co. and Schering-Plough Animal Health Inc.) and the public, and current risk assessment techniques and policies. The hazard component of the risk has been reassessed in light of new oral acute and subchronic rat neurotoxicity studies and a 21-day rat dermal toxicity study. Probabilistic reassessment of acute dietary risk has been conducted using the DEEM™ Software; extensive monitoring data from the USDA Pesticide Data Program and the FDA Surveillance Monitoring Program; revised usage (percent crop treated) data; the hazard endpoint and dose derived from the rat acute neurotoxicity study; and the reduced (1X) FQPA Safety Factor. Chronic dietary risks were recalculated using DEEM™; monitoring data; revised usage data; the reduced FQPA factor; and, as in previous assessments, the endpoint and dose selected from a rat chronic toxicity study.

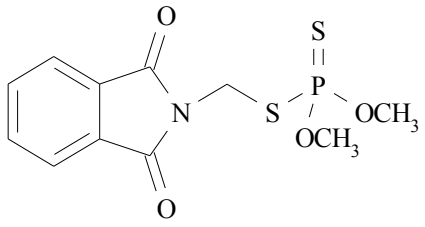
Occupational and residential risks from dermal exposure to phosmet were recalculated using the hazard endpoints and doses derived from the new route-specific rat dermal toxicity study, the new rat oral subchronic neurotoxicity study, and a rat chronic toxicity study. Occupational and residential risks from inhalation exposure were calculated using the doses and endpoints from the new acute and subchronic rat oral neurotoxicity studies and a rat chronic toxicity study. Combined margins of exposure (MOEs) were calculated for dermal and inhalation routes of exposure for both occupational workers and residential (homeowner) handlers. Post-application risks were calculated based on dermal exposure of occupational workers upon re-entry to previously treated areas, as well as for homeowners engaged in harvesting/maintenance activities following application of phosmet in home gardens. Risks were calculated for toddlers in residential settings based on dermal exposure and non-dietary ingestion (i.e., hand-to-mouth) of phosmet residues following contact with treated dogs. The revised risk assessment also considered available human and veterinary incident data.

The Environmental Fate and Effects Division (EFED) provided a qualitative assessment of the potential for phosmet residues in surface and groundwater based on environmental fate data and limited monitoring data. In addition, phosmet estimated environmental concentrations (EECs) were generated for surface and groundwater using models, including a refined (Tier II) estimate of surface water EECs. This information was used to determine the potential risk concerns associated with phosmet residues in drinking water after considering exposure to phosmet through food and in residential settings.

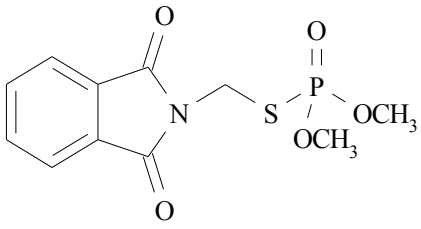
2.0 EXECUTIVE SUMMARY

The Health Effects Division (HED) of EPA's Office of Pesticide Programs has evaluated the phosmet database and conducted a revised human health risk assessment. This assessment incorporates new data and risk assessment techniques, and supersedes the 10/30/98 preliminary risk assessment. Registrant and public comments submitted in response to the preliminary risk assessment have been considered in the revised risk assessment.

Phosmet [N-mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate] is an organophosphate (OP) insecticide belonging to the phosphorodithioate subclass of organophosphates. Phosmet is marketed for both occupational (agricultural and nonagricultural) and homeowner uses to control pests including moths, beetles, weevils, lice, flies and ticks. In agricultural settings, phosmet may generally be applied within seven to 14 days of harvest. Products containing phosmet are formulated into dusts, emulsifiable concentrates and wettable powders. Phosmet and its metabolite, phosmet oxygen analog (phosmet oxon) [*N*-(mercaptomethyl) phthalimide *S*-(O,O-dimethyl phosphorothioate)], are the regulated residues of toxicological concern [refer to 40 CFR §180.261 (a) and (b)].



Phosmet



Phosmet Oxon

Toxicity, Dose-Response, and the FQPA Safety Factor

Toxic effects associated with exposure to phosmet are related to its cholinesterase-inhibiting ability via oral and dermal routes of exposure. Doses selected for human health risk assessment were the No Observed Adverse Effect Levels (NOAELs) from available toxicity studies in which brain and plasma or red blood cell (RBC) cholinesterase inhibition were observed at the next highest dose (the Lowest Observed Adverse Effects Level, or LOAEL). In addition, systemic toxicity was observed following dosing over longer durations, as evidenced by decreased food consumption and weight gain, and clinical signs associated with cholinesterase inhibition such as tremors, convulsions, unsteady gait, salivation, decreased activity, etc. in test animals.

Although several *in vitro* studies indicate phosmet is mutagenic, the mutagenic potential is not expressed *in vivo*. Phosmet is carcinogenic in mice, based on increases in liver adenomas/carcinomas in males, with a trend for adenomas/carcinomas and mammary gland tumors in females. There was no evidence of carcinogenicity in rats. Phosmet is structurally related to azinphos-methyl, another organophosphate insecticide, which has been shown to be negative in mutagenic and carcinogenic studies. After a thorough weight-of-evidence evaluation of carcinogenicity and mutagenicity data for phosmet, the HED Cancer Assessment Review Committee (CARC) concluded that there is suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential. The CARC recommended against completing a quantitative cancer risk assessment for phosmet. This recommendation is consistent with the previous recommendation to use the reference dose (RfD) approach, in which chronic risks assessed using the RfD are considered to be protective of any carcinogenic effect in addition to systemic or other chronic effects.

Acute and chronic dietary risk assessments were conducted using NOAELs selected from a rat oral acute neurotoxicity study and a chronic feeding study in rats, respectively. Following application of the appropriate uncertainty factors, the associated acute and chronic reference doses (RfDs) were 0.045 and 0.011 mg/kg/day, respectively. The Food Quality Protection Act (FQPA, 1996) requires that a 10-fold safety factor be applied during risk assessment to protect against the potential increased sensitivity of infants and children. The HED FQPA Safety Factor Committee determined that there is no increased susceptibility to infants and children, and that sufficient hazard and exposure data are available for phosmet, including the relevant developmental and reproductive toxicity studies, to justify removal of the factor (i.e., reduce it to 1X); therefore, the acute and chronic RfDs are equivalent to the respective Population Adjusted Doses (PADs) which are derived by dividing the RfD by the FQPA Safety Factor. The Agency has issued a Data Call-In (DCI) for developmental neurotoxicity studies in all organophosphates; when the studies are completed, the decision to remove the 10X factor may be revisited.

Dietary Risk Assessment

Estimated acute and chronic dietary exposure are significantly below HED's level of concern (100% PAD). Highly refined (Tier 3) acute probabilistic and chronic dietary exposure analyses were conducted, based largely on monitoring data from USDA and FDA; all available usage (percent crop treated) data and processing/cooking factors were incorporated into the assessment, and no further refinements are necessary. Estimated acute dietary exposure for the general US population (at the 99.9th percentile of exposure) corresponds to approximately 3% of the acute PAD (aPAD); the most highly exposed population subgroup is children one to six years, with 7.5 % aPAD consumed at the 99.9th percentile. Estimated chronic dietary exposure corresponds to less than 1% of the chronic PAD (cPAD) for all population subgroups. The most highly exposed population subgroup is children one to six years, with 0.7% of the chronic PAD (cPAD) consumed.

Occupational and Residential Risk Assessment

Dermal and inhalation exposures to phosmet residues in occupational and residential settings were assessed with respect to NOAELs selected from a 21-day dermal toxicity study in rats, oral acute and subchronic neurotoxicity studies in rats, and a rat chronic toxicity study. The relevant doses were used to determine risks associated with short- and intermediate-term exposures to phosmet in occupational and residential settings. Since toxic effects observed in the subchronic neurotoxicity study became more severe as the duration of exposure increased, HED defined two distinct time frames for intermediate-term exposure and risk assessment, i.e., exposures lasting seven to 30 days, and exposures lasting for more than 30 days. Based on the phosmet use pattern, chronic exposures to phosmet in occupational and residential settings are not expected.

Occupational and residential handler assessments were completed using surrogate data from the Pesticide Handlers Exposure Database, and making typical assumptions with respect to the acres treated, length of a work day, application rates, etc. There were some scenarios for which no data were available to estimate dermal and inhalation exposures associated with the pesticide application process. Although HED has risk concerns for some short- and intermediate-term occupational handler exposures, including those associated with mixing/loading/applying phosmet wettable powders, most of the risks can be mitigated through use of additional personal protective equipment (PPE) or engineering controls. Many of the occupational handler risks were below the Agency's level of concern using minimum or maximum PPE. The scenarios for which acceptable handler risks could not be attained even after the use of engineering controls include: (i) mixing/loading wettable powders for aerial application and chemigation (fruit and nut trees, grapes, vegetables, forestry, and cotton), for which calculated combined dermal and inhalation MOEs ranged from 16 to 94; and (ii) aerial application to nuts and fruit trees, for which combined MOEs ranged from 65 to 96. Although phosmet toxicity is greater via the inhalation route than the dermal route, dermal exposures contribute most significantly to the calculated combined MOEs for handlers. Detailed occupational handler risks are summarized in Attachment 1.

All residential handler exposures were considered to be short-term; calculated risks for combined dermal and inhalation exposures were below HED's level of concern, with the exception of the use of a low pressure handwand to apply wettable powders to fruit trees and ornamentals, which had combined MOEs of 42 and 83, respectively. Residential handler risks from dusting/dipping dogs were below HED's level of concern, but were based on limited dermal data, and did not include inhalation exposure. Detailed residential handler risks are presented in Attachment 2.

Chemical-specific data were used to complete occupational and residential post-application risk assessments. For occupational exposures, restricted entry intervals (REIs) were calculated using the available phosmet dislodgeable foliar residue (DFR) data in conjunction with surrogate transfer coefficients and typical assumptions regarding body weight and length of a typical work day. The calculated REIs (intervals at which re-entry into treated areas would not pose unacceptable risks) were four days for scouting activities, and ranged from 18 to 58 days for other crops, including peas, blueberries, grapes, apples, pears and nuts. The longer intervals correspond to apples treated at the West Coast rate, pears and nuts. [The calculated REIs may be translated to other crops that can be treated using phosmet, depending on the similarities between use rates, the type of harvesting/maintenance activities involved, and the relevant transfer coefficients]. Risks associated with some occupational post-application exposures greater than 30 days (e.g., apple harvesting) exceed HED's level of concern, but are expected to apply to a small segment of the exposed population, such as apple and pear harvesters.

Residential post-application risks were calculated using DFR studies and a chemical-specific homeowner exposure study submitted to the Agency. In addition, the 1997 *Draft SOPs for Residential Exposure Assessment* were used to assess risks associated with toddlers coming into contact with treated dogs. HED has risk concerns for both adults and youth engaging in harvesting and maintenance activities in home gardens following phosmet application, with the exception of harvesting apples treated at the maximum East Coast rate. However, post-application risks were below HED's level of concern after one week following application, the amount of time that could be assumed to elapse between treatment and harvest in a typical home garden. HED does not have information on cultural practices in home gardens that would permit assessment of the likelihood of re-entering a treated garden within one week of application.

Residential post-application risks greatly exceed HED's level of concern for toddlers coming into contact with dogs following treatment with phosmet, regardless of the duration of exposure. Although some conservative assumptions were made based on the *Draft Residential SOPs*, chemical-specific fur dissipation data from an unpublished study, as well as the DFR data, indicate that phosmet residues persist in the environment. In addition, a moderate fur dissipation rate was assumed, which is not typically done for post-application exposures associated with pet applications, and is considered to be less conservative.

Human and veterinary incident data qualitatively support HED's conclusions with respect to occupational and residential exposure and risk. Available data suggest agricultural use of phosmet is not associated with increased risk when compared to other organophosphate and carbamate pesticides. Residential exposures to phosmet are more likely to result in treatment in a health care facility than all other organophosphate insecticides; phosmet ranked third for hospitalizations, and third for admission to intensive care units. In addition, the incident data indicate phosmet poses a much greater risk to children than other organophosphate insecticides. An analysis of the data with respect to estimated usage in homes indicates that the higher number and severity of phosmet exposure incidents is not simply due to widespread use, but may be due to highly concentrated dog dip products, which have also been associated with pet exposure incidents.

Drinking Water Assessment

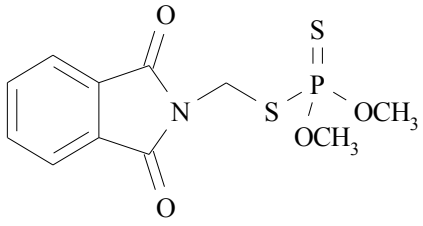
Based on the water resources assessment provided by EFED, and on estimated acute and chronic dietary exposures, phosmet residues in drinking water would not likely result in unacceptable levels of aggregate acute and chronic dietary (food + water) human health risk. Residential handler exposures were considered in concert with exposure from food. These exposures were then compared to the model estimates for surface and groundwater, which indicate that potential phosmet residues in drinking water are below HED's level of concern when considered together with exposure from food and residential pesticide application activities (home gardens/dogs). However, since residential exposures incurred during application to fruit trees/ornamentals using a low-pressure handwand were above HED's level of concern, these exposures were not aggregated; any additional exposure to phosmet through drinking water would indicate a risk concern.

Aggregate Assessment

Most residential post-application exposures were above HED's level of concern, and therefore could not be aggregated with dietary exposure to determine the level of concern for phosmet residues in drinking water. The only residential post-application scenarios with risks below the level of concern consisted of youth and adults harvesting apples (on the day of application) at the lower East Coast application rates; when these exposures are considered with exposure to phosmet in the diet, potential residues in drinking water are not of concern. The same conclusion applies to post-application exposure associated with harvesting apples at both East and West Coast rates one week following application; there is a concern for potential residues in drinking water when considered with residential post-application exposure during pear harvesting one week after application. However, based on model estimates, HED does not expect significant phosmet residues in ground and surface water for drinking water, and is therefore not particularly concerned about this component of aggregate exposure.

3.0 PHYSICAL/CHEMICAL PROPERTIES

Technical phosmet is a pink to white crystalline solid with a melting point of 66-69 C. Phosmet is slightly soluble in water (20 mg/L at 20-25 C), more soluble in ethanol and kerosene (<1.0 g/100 mL), and readily soluble in acetone, chloroform, and xylene (>100 g/100 mL). Phosmet has a relatively low vapor pressure of 3.72×10^{-7} mm Hg at 25 C. Identifying codes and characteristics are:



Phosmet

Empirical Formula: $C_{11}H_{12}NO_4PS_2$
Molecular Weight: 317.32
CAS Registry No.: 732-11-6
PC Code: 059201

4.0 HAZARD ASSESSMENT

4.1 Hazard Profile

The phosmet toxicology database is considered to be largely complete; however, confirmatory data for the 21-day dermal rat toxicity study and the rat subchronic neurotoxicity study are needed. Phosmet is a cholinesterase inhibitor and produces the associated clinical signs, such as tremors, shaking, unsteady gait, subdued mood, decreased activity, salivation, muscle weakness, convulsions in rats and rabbits [2-generation reproduction (rat) and developmental toxicity studies (rats and rabbit)] and decreased cholinesterase activity [plasma, red blood cell (RBC), brain] in rats, mice, and dogs following acute, subchronic and chronic exposures. In the acute and subchronic neurotoxicity studies, cholinesterase activity was significantly inhibited in the absence of clinical signs of cholinesterase inhibition.

In acute toxicity studies, phosmet exhibits severe toxicity *via* the oral and inhalation routes of exposure. Phosmet is not acutely toxic in rats *via* the dermal route, is non-irritating to the skin, and is not an eye irritant in the rabbit. An acceptable dermal absorption study conducted in rats indicates a dermal absorption factor of 10% is appropriate for phosmet risk assessments.

Phosmet did not cause acute delayed neurotoxicity in hens, and there was no evidence of neuropathology in the acute, subchronic and chronic studies in rats, in the chronic dog study, or the mouse long-term study. No treatment-related effects were observed on motor activity or in the functional observation battery parameters measured in the acute and subchronic neurotoxicity studies in rats. Phosmet did not produce developmental or reproductive toxicity, and there is no indication of an increased sensitivity of offspring in rats or rabbits following prenatal and/or postnatal exposure.

Adequate data have been submitted to assess mutagenic potential. Phosmet was positive in a reverse mutation assay with *Salmonella typhimurium* (with and without metabolic activation); a mouse lymphoma assay (forward mutation without activation, and chromosomal aberrations without activation but at severely toxic doses); sister chromatid exchange (SCE), with and without activation, but also at severely toxic doses; and produced morphological transformations in BALB/3T3 cells. Phosmet tested negative for mutagenicity in human fibroblasts, both with and without activation. The results of these studies are generally supported by available literature studies. Phosmet was negative for mutagenicity in the mouse bone marrow micronucleus assay; in the unscheduled DNA synthesis assay up to overtly toxic doses; and in a DNA adducts assay. In summary, phosmet is considered to cause direct effects on DNA *in vitro*, inducing mutations in bacteria and mammalian cells in the absence of exogenous metabolic activation. In the *in vivo* systems, there was no evidence of a mutagenic effect. Overall, the data indicate that phosmet has intrinsic mutagenic potential which is not expressed in whole animals.

In a mouse carcinogenicity study, phosmet caused increases in liver carcinomas/adenomas in males and increased mammary gland tumors in females. Phosmet was not carcinogenic in rats. The HED Cancer Assessment Review Committee (CARC) conducted a weight-of-evidence evaluation of the mutagenicity and carcinogenicity data for phosmet (in accordance with the 1996 draft Cancer Guidelines). Additional data regarding tumor counts in the mouse carcinogenicity study were discussed along with additional mutagenicity data submitted by the registrant. Phosmet is structurally related to azinphos-methyl, another organophosphate insecticide, which has been shown to be negative in mutagenic and carcinogenic studies. Based on all available data for phosmet, the CARC concluded that there is suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential. The CARC recommended against completing a quantitative cancer risk assessment for phosmet. This recommendation is consistent with the previous recommendation to use the reference dose (RfD) approach, in which chronic risks assessed using the RfD are considered to be protective of any carcinogenic effect in addition to systemic or other chronic effects.

Following oral administration, phosmet is rapidly absorbed in the gastrointestinal tract, distributed, metabolized, and eliminated in the urine and feces; most of the radioactivity was eliminated in the urine within 24 hours of dosing. Very low levels of radioactivity (corresponding to less than 1% of the administered dose) were found in all tissues; radioactivity was higher in liver and whole blood, and lowest in fat and bone. Phosmet does not bioaccumulate. Metabolites identified in the urine consisted of phthalamic acid conjugates; there was unidentified radioactivity in both the urine and the feces, but there was no attempt to determine if phosmet *per se* was present.

For additional details of relevant studies, refer to the Phosmet Toxicology Chapter of the Reregistration Eligibility Decision [L. Taylor memo dated 7/26/99, D257925].

4.2 Dose Response and Hazard Endpoint Selection

A summary of the phosmet toxicology studies and hazard dose and endpoint selections conducted by the HED Hazard Identification Assessment Review Committee (HIARC) is provided in the HIARC report dated 8/4/99 [L. Taylor, HED Doc.. No. 013604], and addendum dated 12/20/99 [L. Taylor, HED Doc. No. 013921]. Phosmet acute toxicity categories are presented in Table 1. These studies are not used quantitatively in the HED risk assessment, but are important for determining the need for label warnings and the level of personal protective equipment (PPE) to be used by occupational handlers. The phosmet toxicity profile is summarized in Table 2. The doses and endpoints chosen by HIARC for human health risk assessments are presented in Table 3.

Table 1 summarizes the results of acute toxicity testing for phosmet. The referenced studies satisfy the acute toxicity data requirements for phosmet.

Table 1. Phosmet Acute Toxicity.

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
870.1100/§81-1	Acute Oral - rat	00046189	LD_{50} = 113 mg/kg	II
870.1200/§81-2	Acute Dermal - rabbit	00046190	LD_{50} >5000 mg/kg	III
870.1300/§81-3	Acute Inhalation - rat	00063197	LC_{50} >0.152 mg/L	I
870.2400/§81-4	Primary Eye Irritation	00046192	moderate eye irritant	III
870.2500/§81-5	Primary Skin Irritation	00046191	not a skin irritant	IV
870.2600/§81-6	Dermal Sensitization	no study		N/A
870.6100/§81-7	Delayed Neurotoxicity	44587601	unsteadiness, subdued behavior, recumbency, salivation; no ataxia; no decreases in brain or spinal cord NTE; brain ChE decreased 63%; no neuropathology. [All hens were dosed at 600 mg/kg by oral gavage]	N/A
870.6200/§81-8	Acute Neurotoxicity	44673301	NOAEL 4.5 mg/kg LOAEL 22.5 mg/kg, based on cholinesterase inhibition [plasma, RBC, brain] and decreased motor activity in both sexes.	N/A

Table 2 summarizes the toxicity profile for technical phosmet.

Table 2. Toxicity Profile of Phosmet Technical.

Study Type	MRID No.	Results[1]	Effects
21-Day Dermal Toxicity-Rat	44795801	NOAEL (ChE Inhibition) = 15 mg/kg/day LOAEL (ChE Inhibition) = 22.5 mg/kg/day	Plasma/brain ChEI
Subchronic Neurotoxicity-Rat	44811801	NOAEL (ChE Inhibition) = Not established[2] LOAEL (ChE Inhibition) = 1.5 mg/kg/day	Whole blood and RBC ChEI (all dose groups); Plasma/brain ChEI (females)
Subchronic Feeding-Rat	00081426	NOAEL (ChE Inhibition) = 2.0 mg/kg/day LOAEL (ChE Inhibition) = 10.0 mg/kg/day	RBC/Brain ChEI
Chronic Feeding-Dog	00076436	NOAEL (systemic) = 10.0 mg/kg/day (HDT)[3] NOAEL (ChE Inhibition) = 1.0 mg/kg/day LOAEL (ChE Inhibition) = 10.0 mg/kg/day	RBC/Brain ChEI
Chronic Toxicity/ Carcinogenicity-Rat	41916401	NOAEL (systemic) = <1.1 mg/kg/day LOAEL (systemic) = ≤1.1 mg/kg/day NOAEL (ChE Inhibition) = 1.1 mg/kg/day LOAEL (ChE Inhibition) = 1.8 mg/kg/day	Systemic: fatty change in liver (males); RBC/plasma ChEI
Carcinogenicity-Mouse	00141659 00160114	NOAEL (systemic) = 1.0 mg/kg/day LOAEL (systemic) = 6.0 mg/kg/day NOAEL (ChE Inhibition) = <1 mg/kg/day LOAEL (ChE Inhibition) = 1.0 mg/kg/day Increased hepatocellular adenomas and combined adenomas/carcinomas in males; mammary gland adenocarcinomas in females.	Systemic: convulsions; Brain ChEI
Developmental Toxicity-Rat	41962902	Maternal: NOAEL = 10 mg/kg/day; LOAEL = 15 mg/kg/day Developmental: NOAEL = 15 mg/kg/day (HDT); LOAEL = Not established	Maternal: clinical signs, decreased weight gain, decreased food consumptions.
Developmental Toxicity-Rabbit	41962901	Maternal: NOAEL = 5 mg/kg/day; LOAEL = 15 mg/kg/day Developmental: NOAEL = 5 mg/kg/day; LOAEL = 15 mg/kg/day	Maternal: clinical signs, mortality, decreased weight gain. Developmental: skeletal variations

Table 2. Toxicity Profile of Phosmet Technical.

Study Type	MRID No.	Results[1]		Effects
Reproductive Toxicity-Rat	41520001	Parent (ChE Inhibition)	NOAEL = Not established LOAEL = 1.5 mg/kg/day	Parent: RBC/plasma ChEI. Reproductive: decreases in live pups/litter; pup weight; lactation; and viability
		Offspring	NOAEL = 1.5 mg/kg/day LOAEL = 6.1 mg/kg/day	
Gene Mutation (Ames)	00164884	Mutagenic (±) activation		
Mouse Lymphoma	00164886	Mutagenic (forward mutation) ± activation Mutagenic (chromosomal aberration) - activation		
Chromosome Damage (SCE)	00164885	Mutagenic (±) activation		
Cell Transformation (BALB/3T3)	00164888	Mutagenic		
Mouse Micronucleus	40199401	Non-clastogenic		
DNA Repair	00164887	Non-mutagenic (±) activation		
Metabolism	41296001 41425701	Phosmet is rapidly absorbed in the gastrointestinal tract, distributed, metabolized, and eliminated in the urine and feces; most of the radioactivity was eliminated in the urine within 24 hours of dosing. Very low levels of radioactivity were found in all tissues. Phosmet does not bioaccumulate.		

[1]ChE = Cholinesterase; ChEI = Cholinesterase inhibition; RBC = Red blood cell; NOAEL = No observed adverse effects level; LOAEL = Lowest observed adverse effects level.

[2]Although the NOAEL for ChE inhibition was not established at the conclusion of the study, the HIARC later determined that at the three-week interval, the NOAEL for ChE inhibition was 1.5 mg/kg/day.

[3]HDT = Highest dose tested.

Table 3 summarizes the doses and endpoints for human health risk assessment. The doses selected from relevant studies consist of the NOAEL (no observed adverse effects level), the dose at which no toxic effects were observed in test animals. The LOAEL is the lowest dose at which the toxic effect of concern was observed in test animals. For risk assessments based on the NOAEL from studies conducted in animals, an uncertainty factor (UF) of 100X is applied, 10X for interspecies extrapolation (i.e., to account for the differences between animals and humans), and 10X for intra-species variability (i.e., to account for the differences in sensitivity between individuals in a given population).

Based on the phosmet use pattern, long-term (i.e., essentially 365 days) dermal and inhalation exposures are not anticipated, and therefore these risk assessments are not required. Intermediate-term (exposures of more than seven days to six months) endpoints and doses for occupational and residential risk assessment were specified for exposures lasting from seven to thirty days and exposures greater than 30 days. Although intermediate-term occupational and residential exposures greater than 30 days are not generally expected to occur, the registered use pattern for phosmet does not specifically preclude such exposures, and these risk assessments were deemed necessary.

Table 3. Phosmet Toxicology Endpoint Selection.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
DIETARY AND NON-DIETARY INGESTION EXPOSURES			
Acute Dietary	NOAEL=4.5 (UF =100)	Cholinesterase inhibition [plasma, RBC, brain] and decreased motor activity	Oral Acute Neurotoxicity/Rat
		Acute RfD = 0.045 mg/kg/day	
Chronic Dietary	NOAEL=1.1 (UF=100)	Cholinesterase inhibition [RBC and serum]	Oral Chronic Toxicity/ Carcinogenicity/Rat
		Chronic RfD = 0.011 mg/kg/day	
DERMAL EXPOSURES			
Short-Term Dermal (**Up to 7 days**)	NOAEL=15 (UF =100)	Cholinesterase inhibition [brain (females)/plasma (males)]	21-day Dermal Toxicity/Rat
Intermediate-Term Dermal (**>7 and ≤30 days**)	NOAEL=15 (UF=100)	Cholinesterase inhibition [brain (females)/plasma (males)]	21-day Dermal Toxicity/Rat
Intermediate-Term Dermal* (**>30 days**)	NOAEL =1.1 (UF=100)	Cholinesterase inhibition [RBC and serum]	Oral Chronic Toxicity/ Carcinogenicity/Rat
INHALATION EXPOSURES			
Short-Term Inhalation* (**Up to 7 days**)	NOAEL=4.5 (UF=100)	Cholinesterase inhibition [plasma, RBC, brain] and decreased motor activity	Oral Acute Neurotoxicity/Rat
Intermediate-Term Inhalation* (**>7 and ≤30 days**)	NOAEL=1.5 (UF=100)	Cholinesterase inhibition [brain (females)/plasma (males)]	Oral Subchronic Neurotoxicity/Rat
Intermediate-Term Inhalation* (**>30 days**)	NOAEL =1.1 (UF=100)	Cholinesterase inhibition [RBC and serum]	Oral Chronic Toxicity/ Carcinogenicity/Rat

*Appropriate route-to-route extrapolation should be performed for these risk assessments. For dermal risks, a 10% dermal absorption factor should be used to convert relevant exposure estimates to equivalent oral doses and compared to the oral NOAEL. For inhalation risks, a 100% absorption factor should be used to convert exposure estimates to equivalent oral doses and compared to the oral NOAEL.

4.3 FQPA Safety Factor

In accordance with the requirements of the Food Quality Protection Act (FQPA) of 1996, HED has evaluated the phosmet toxicology and exposure data with respect to the potential for increased sensitivity of infants and children. This evaluation included: consideration of the completeness of the toxicology data; toxic effects on fetuses and pups relative to maternal toxicity in developmental and reproductive toxicity studies, respectively; evidence of neuropathology/neurotoxicity in the required neurotoxicity studies, and the potential for underestimating exposure and risk to infants and children in the diet (food and water) and in residential settings.

The HED FQPA Safety Factor Committee has recommended the 10X FQPA safety factor be removed (reduced to 1X) for phosmet based on the following rationale [B. Tarplee memo dated 7/21/99 (HED DOC. NO. 013584)]:

i. The toxicology data base for phosmet is complete;

ii. There was no evidence of developmental effects being produced in fetuses at lower doses as compared to maternal animals nor was there evidence of an increase in severity of effects at or below maternally toxic doses following *in utero* exposure in the prenatal developmental toxicity studies in rats and rabbits;

iii. In the pre- and postnatal two-generation reproduction study in rats, there was no evidence of enhanced susceptibility in pups when compared to parental animals (i.e., effects noted in offspring occurred at maternally toxic doses or higher);

iv. There was no evidence of abnormalities in the development of the fetal nervous system in the pre- and postnatal studies submitted to the Agency; and

v. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary (food) and residential exposure and to provide a screening level drinking water exposure assessment.

5.0 EXPOSURE AND RISK ASSESSMENT

5.1 Summary of Registered Uses

Phosmet is a broad spectrum organophosphate insecticide that is marketed in formulations including dusts, soluble concentrates, emulsifiable concentrates, and wettable powders. Phosmet is used to control a variety of pests including maggots, moths, beetles, weevils and aphids in terrestrial crops including fruit and nut trees, grapes, blueberries, and field and vegetable crops. Phosmet is also used for direct animal treatments to control fleas, lice, hornflies, sarcoptic mange and ticks on cattle, swine, and dogs. There are other uses such as in forestry and for ornamentals, including residential sites, that can be treated by professional applicators. Phosmet can also be used by homeowners to treat trees and shrubs, ornamentals, pets (dogs only) and home gardens.

Phosmet can be applied using a wide array of application equipment. In agriculture, groundboom, airblast, chemigation and aerial applications can be made. Other applications are completed using handheld equipment such as low pressure handwand sprayers and backpack sprayers. Label application rates range from approximately 1 to 6 lb ai/A depending on the crop, and multiple foliar applications can be made to some crops in a growing season. Average application rates estimated by the Biologic and Economic Analysis Division (BEAD/OPP; J. Alsadek memo dated 6/99) indicate that typical application rates are likely to be lower than those specified on registered labels. Applications can generally be made up to within seven to 14 days of harvest. Post-harvest application of a dust formulation to sweet potatoes is permitted using commercial dusting equipment.

Direct dermal application to livestock is permitted via sprays and a backrubber. In addition, dogs can be treated by professionals or homeowners with a dip or a dust.

5.2 Dietary Exposure: Food

Potential dietary (food only) exposure to phosmet can occur following foliar application to food crops including pome fruits (apple and pear); stone fruits (peach; nectarine; plum, apricot); grape; kiwi; tree nuts (almond; walnut; pecan; filbert; pistachio); potato; sweet potato (foliar and post-harvest); blueberry; cherry; cotton; and peas (succulent and dried). Residues in livestock commodities could result from direct dermal application to livestock; in addition, secondary residues in livestock (excluding poultry) could potentially result from phosmet residues in alfalfa forage and other relevant livestock feed items. Although there are existing tolerances for residues in sweet corn, tomatoes and citrus, the registrant has indicated these uses will not be supported, and they have been excluded from the dietary risk assessment. Exclusion of these commodities is supported by the results of the most recent BEAD Quantitative Usage Analysis, which indicates minimal or no phosmet usage on these sites in recent years.

5.2.1 Residue Chemistry

The residue chemistry database is largely complete and is considered adequate to reassess most tolerances listed in 40 CFR §180.261. The regulated residues consist of parent phosmet [*N*-(mercaptomethyl) phthalimide *S*-(O,O-dimethyl phosphorodithioate)] and its metabolite phosmet oxygen analog (oxon) [*N*-(mercaptomethyl) phthalimide *S*-(O,O-dimethyl phosphorothioate)]. Adequate data collection and enforcement analytical methods are available to detect phosmet and its oxon in plant and livestock commodities.

Phosmet is extensively metabolized in both plants and livestock. Phosmet and its oxon were identified but did not constitute a significant portion of the total residue in plant metabolism studies. In oral metabolism studies in poultry and ruminants, phosmet *per se* was identified at a very low level only in egg yolk. In dermal metabolism studies conducted on cattle and swine, phosmet was identified as the major residue in fat, and was found at lower levels in other tissues; phosmet oxon was not identified in cattle or swine tissues. Most of the identified radioactivity consisted of phthalic acid and N-substituted derivatives of phthalimides, which are not considered to be of toxicological concern.

Reassessed tolerances for phosmet residues in most commodities are based on field trial studies in which residues were detected in crops. Tolerances for residues in nuts, cottonseed and potatoes are reassessed at the combined limits of quantitation (LOQs) for phosmet and its oxon, since no residues were detected in field trials. Tolerances for residues in meat, milk and meat by-products are also based on the combined LOQs for phosmet and the oxon; however, tolerances for residues in fat are based on residues detected in fat in oral and dermal studies. No tolerances are required for residues in poultry commodities [category 3 of 40 CFR §180.6(a)].

Available metabolism and field trial residue data indicate parent phosmet is the most significant residue in fruit; when detected, phosmet oxon residues are generally an order of magnitude less than parent residues. Storage stability data indicate that phosmet oxygen analog is relatively unstable in numerous commodities, even at very low temperatures. Available processing and residue reduction studies indicate phosmet residues are significantly reduced during cooking/canning, peeling and juicing; residues were reduced to a lesser extent during drying (e.g., raisins). Cottonseed oil was the only commodity in which phosmet residues concentrated (2X). The revised dietary exposure analyses incorporated all available processing and cooking data.

Extensive monitoring data for phosmet have been generated in numerous commodities and in multiple years by the USDA Pesticide Data Program (PDP) and the FDA Surveillance Monitoring Program. Monitoring data reflect residues in commodities closer to the point of consumption (i.e., "dinner plate") rather than the maximum residues generated in field trials, and can be used in dietary exposure analyses to determine a realistic estimate of dietary exposure and risk.

Typically, HED cannot use monitoring data which do not include all residues of toxicological concern. Although both the PDP and FDA monitoring programs reported data for parent phosmet only, these data have been used in the revised risk assessment for the following reasons: (i) field trial data indicate that oxon residues, when detected, are generally an order of magnitude lower than parent residues; (ii) residues in both PDP and FDA monitoring samples were significantly less than tolerance-level residues; and (iii) phosmet oxon is relatively unstable in numerous commodities. Using the monitoring data in acute and chronic dietary exposure analyses is not expected to underestimate risk.

The monitoring data indicate that phosmet residues in fruits, vegetables and milk are significantly lower than the established and reassessed tolerances; phosmet residues in single pears analyzed by PDP in 1998 were also significantly below field trial residues and tolerances. Additional monitoring data presented in the Michigan State University/Michigan Department of Agriculture (MSU/MDA) FQPA-Targeted Residue Study included phosmet residues in apple, peach, cherry, grape and blueberry. The data were too limited (i.e., <100 samples) to be used quantitatively, but were generally consistent with the results of FDA and PDP monitoring.

5.2.2 Dietary Risk Characterization

HED conducts two types of dietary exposure analyses. The chronic dietary exposure analysis provides an estimate of dietary risk associated with potential long-term exposure to pesticide residues in the diet. The acute dietary exposure analysis provides an estimate of dietary risk that could be associated with a single day of consumption. HED uses a tiered approach to conduct dietary exposure assessments. If dietary risk exceeds the level of concern in a lower tier of analysis, higher, more resource-intensive, tiers are used until estimated risk is below the level of concern or until the highest level of refinement possible (given the available data) has been achieved.

In Tier 1 acute and chronic analyses, tolerance-level residues are assumed to be present in relevant commodities, and no adjustments are made to account for the percent of crop treated (%CT); default processing factors are applied. In Tier 2 analyses, there is no adjustment for %CT, but the residue input may be the highest average field trial (HAFT) value or the distribution of field trial residues (acute), or an average residue value may be used (chronic only); actual processing factors generated in residue studies may be applied. In Tier 3 analyses, adjustments are made for the percent of crop treated. These adjustments can be incorporated into the average residue in chronic analyses, or are incorporated into a residue distribution for acute analyses. Tier 3 residues may be from field trials or monitoring data; actual processing factors are applied. Finally, Tier 4 analyses incorporate available market basket survey data. Depending on the data available for relevant commodities, multiple tiers of analysis can be used in a given dietary exposure assessment.

The residues in monitoring data reflect the amount of pesticide in a 5-lb (PDP) or 20-lb (FDA) composite sample. Monitoring data are incorporated into a chronic analysis by calculating average residues, including zero residues for the percentage of the crop assumed to be not treated. In previous acute dietary exposure assessments, HED was unwilling to use monitoring data for certain commodities since the amount of pesticide in a single fruit or vegetable (e.g., an apple or potato) could be much higher than the residue in a composite sample; using the composite monitoring data residues would likely underestimate acute exposure and risk.

A new policy and statistical approach have permitted use of available monitoring data in the phosmet acute dietary exposure analysis. Commodities and food forms have been classified as non-blended (e.g., an apple or potato), partially blended (e.g., grapes, juices, blueberries and certain frozen/canned foods), or blended (e.g., cottonseed oil). In a Tier 3 acute analysis, the residues in blended commodities are incorporated as a point estimate, or average residue. For partially blended commodities, the full distribution of residues from monitoring is included in the analysis. For non-blended commodities, single-unit residues are statistically generated (de-composited) from the composite residue values. The %CT is incorporated into the distribution by adding zeros to account for the percent of the crop not treated. The statistical basis for decomposition of monitoring data is described in the H. Allender 5/26/99 paper, "Statistical Methods for Use of Composite Data in Acute Dietary Risk Assessment." The paper was presented to the Science Advisory Panel (SAP); panel members concluded that the technique would not underestimate residues in single unit commodities, and could be used to estimate acute dietary exposure in HED risk assessments.

The most recent usage (percent crop treated) data provided in the 6/99 Quantitative Usage Analysis (QUA) were incorporated into the revised dietary exposure analyses. Scientists in BEAD calculate a weighted average %CT by averaging usage across different data sources and years of data for a given crop-chemical combination. To account for differences in the extent and intensity of sampling across sources, greater weight in the average is given to data sources with larger surveys. To account for changes in usage over time, greater weight in the average is given to data from more recent years. The weighted average %CT is incorporated into chronic dietary exposure analyses, which reflect long-term consumption and exposure patterns.

In addition, BEAD scientists generate an estimated maximum, or maximum likely %CT, which corresponds to the upper 95th percent confidence interval around the weighted average %CT. This is a more conservative estimate of %CT, which is incorporated into HED's acute dietary exposure analyses to reflect the exposure and risk potentially associated with a single day of consumption.

Phosmet acute and chronic dietary exposure estimates were generated using the Dietary Exposure Evaluation Model (DEEM™) software, which incorporates consumption data from USDA's Continuing Surveys of Food Intakes for Individuals (CSFII), 1989-1991. The 1989-91 data are based on the reported consumption of more than 15,000 individuals over three consecutive days, and in total represent more than 35,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files. Consumption data are averaged for the entire US population and within population subgroups (e.g., children one to six years old) for chronic exposure assessment, but are retained as individual consumption data points for acute exposure assessment.

For chronic exposure and risk assessment, residue estimates for foods (apple) or food-forms (apple-juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the chronic Population Adjusted Dose (cPAD). For acute exposure and risk assessments, individual one-day consumption data are summed, and a food consumption distribution is generated for each population subgroup of interest. The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier 1 or Tier 2) exposure/risk assessment, or used with a residue distribution in a probabilistic (Tier 3/4, or Monte Carlo) assessment. The resulting distribution of exposures is expressed as a percentage of the acute Population Adjusted Dose (aPAD) on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita basis.

In accordance with current HED policy, when acute dietary exposure is determined using the full distribution of available residue data, per-capita risk is reported at the 99.9th percentile of exposure. If risks exceed HED's level of concern at the 99.9th percentile, and for purposes of risk characterization, additional analyses may be conducted to determine which crops or commodities are significant risk contributors.

HED has revised the terms used for expressing dietary risk since the 10/98 phosmet preliminary risk assessment was completed. An acute or chronic reference dose (aRfD or RfD) which includes the FQPA factor (1X, 3X, or 10X) is now referred to as the acute or chronic Population Adjusted Dose (aPAD or cPAD). For phosmet, the FQPA factor was removed (reduced to 1X), and therefore the aPAD and cPAD are equivalent to the acute reference dose (0.045 mg/kg/day) and the chronic reference dose (0.011 mg/kg/day), respectively. The aPAD and cPAD reflect HED's level of concern for acute and chronic dietary exposure; estimated exposures above the aPAD and cPAD may indicate a risk concern.

For the revised phosmet risk assessment, HED conducted highly refined (Tier 3) acute (probabilistic) and chronic dietary exposure analyses which were based almost entirely on the available monitoring data, and incorporated additional refinements such as processing/cooking factors and %CT. Dietary (food only) risk estimates are significantly below HED's level of concern for the general US population and all population subgroups.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, risks estimated for these subpopulations were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

5.2.2.1 Risk Estimates

The acute analysis indicates the most highly exposed population subgroup is children one to six; estimated exposure at the 99.9^{th} percentile corresponds to 7.5 % of the acute PAD (aPAD). The chronic analysis indicates less than 1% of the chronic PAD (cPAD) is consumed for all population subgroups. The most highly exposed population subgroup is children one to six years, with 0.7% of the chronic PAD (cPAD) consumed. Separate analyses that excluded commodities considered to have negligible, or zero, residues (i.e., commodities in which residues were consistently less than the limit of detection, or LOD) did not significantly reduce acute or chronic dietary exposure and risk estimates. A summary of estimated acute and chronic dietary exposure and risk is presented in Table 4.

Table 4. Phosmet Acute and Chronic Dietary Exposure and Risk Estimates.

Population Subgroup	Acute Assessment (99.9th %-ile of Exposure)		Chronic Assessment	
	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%cPAD
General US Population	0.001480	3.3	0.000036	0.3
All infants (<1 year)	0.002923	6.5	0.000034	0.3
Children 1-6 years	0.003362	7.5	0.000073	0.7
Children 7-12 years	0.002041	4.5	0.000054	0.5
Females 13-19 (not preg/nursing)	0.000907	2.0	0.000032	0.3
Females 20+ years	0.001408	3.1	0.000027	0.2
Females 13-50 years	0.001310	2.9	0.000028	0.3
Males 13-19 years	0.000704	1.6	0.000034	0.3
Males 20+ years	0.001104	2.4	0.000032	0.3

5.3 Dietary Exposure: Water

In accordance with the requirements of FQPA, HED human health risk assessments must consider the potential for exposure to pesticides in drinking water. The Environmental Fate and Effects Division (EFED/OPP) completed a water resources analysis for phosmet in conjunction with the completion of the phosmet environmental risk assessment (EFED memo dated 5/1/98). Estimates of phosmet concentrations in surface and groundwater were developed using models, since phosmet monitoring data could not be used quantitatively. The surface water model estimates were subsequently updated based on label revisions, and to incorporate average application rates (memo, S. Abel, 8/9/99).

5.3.1 Environmental Fate

Phosmet is stable to photolysis, but is subject to rapid hydrolysis in alkaline and neutral conditions, and to a much lesser degree under acidic conditions. The major route of dissipation is microbial-mediated degradation. Leaching is expected to occur in soils where microbial activity is minimal. Phosmet has a short half-life (three days) in aerobic soil conditions, and a slightly longer half-life (7 days) under anaerobic soil conditions; soil half-lives reflect both microbial degradation and hydrolysis.

Although phosmet oxon has been detected in some of the studies evaluated by EFED, the data were too limited to fully characterize its fate in the environment.

Available data indicate that the oxon is less mobile than the parent; anaerobic soil metabolism data indicate the oxon could be present in much smaller amounts than the parent and other metabolites/degradates, which consist largely of phthalimides, phthalamic acid and their conjugates. These metabolites are not considered to be of toxicological concern for the purpose of human health risk assessment.

5.3.2 Surface Water

There is a potential for contamination of surface waters with phosmet in the event of runoff- producing rain events within a few days to weeks of application. Physical properties of phosmet suggest it will enter surface water via dissolution in runoff and be adsorbed to suspended and eroding materials. Phosmet's persistence is expected to be greater in surface waters with higher residence times, such as lakes and reservoirs, than in streams and rivers; however, its persistence is also affected by factors such as pH and microbial activity. The limited fate data available for phosmet oxon suggest it does not contribute appreciably to the concentration of phosmet in surface waters.

Surface water monitoring data reported to the STORET system (1978-1994) indicate the presence of phosmet in surface waters in association with known use areas. Although the data suggest phosmet does not exceed concentrations above the very low ppb range, reported incidences could not be correlated with use pattern, were randomly allocated throughout the year, and were too limited to reflect the extent of surface water contamination. The monitoring data were not considered to be sufficiently reliable and of adequate quantity for use in drinking water assessments. Therefore, model predictions of phosmet concentrations in surface water were generated to determine if there is a concern for phosmet in surface water drinking water.

Tier II surface water estimated environmental concentrations (EECs) were calculated using the PRZM 3.1 model of an agricultural field and the EXAMS 2.97.5 model for fate and transport in surface water (PRZM-EXAMS). Crop-specific surface water concentrations were estimated based on maximum application rates and on the average application rates generated by BEAD/OPP (6/99). A Tier II EEC for a particular crop or use is based on a single site that represents a high exposure scenario for the crop or use. Weather and agricultural practices are simulated at the site for 36 years to estimate the probability of exceeding a given concentration (maximum concentration or average concentration) in a single year. Maximum EECs are calculated so that there is a 10% probability that the maximum concentration in a given year will exceed the EEC at the site; this can also be expressed as an expectation that water concentrations will exceed EECs once every 10 years. For the purpose of human health risk assessment, HED considers the maximum (peak) EECs for acute assessments, and the annual average (mean) EECs for short- and intermediate-term, as well as chronic assessments.

Use of average application rates did not significantly reduce the mean EECs since the maximum number of applications and the minimum application intervals on registered labels were assumed. However, maximum (peak) EECs were reduced for some crops, such as peaches and kiwi. The average application rates were not considered to be "typical" by EFED, and no conclusions could be drawn in terms of either efficacy or applicability to current use patterns. The EECs based on average application rates are included for the purpose of risk characterization only. The peak (maximum) and mean surface water concentrations are shown in Table 5, for both maximum and average application rates.

5.3.3 Groundwater

Available data suggest phosmet and its oxon are not expected to pose a significant threat to groundwater resources. Although phosmet has moderate mobility, it is susceptible to aerobic soil metabolism and has a short half-life. No phosmet residues were reported in monitoring data from the STORET system and the Pesticides in Groundwater Database (1981-1990), with limits of detection (LODs) ranging from 0.1 to 10 parts per billion (ppb). Phosmet usage was reported in some, but not all, of the counties in which wells were monitored. Groundwater monitoring could not be correlated with a specific use pattern or to drinking water intakes; therefore, model estimates of groundwater concentrations were prepared to determine if there is a potential concern for phosmet concentrations in groundwater.

A preliminary groundwater assessment was conducted using the Screening Groundwater model, SCI-GROW, which estimates "maximum" groundwater concentrations from application of pesticides to crops. The model is based on the fate properties of the pesticide, the annual application rate, and the existing data from small-scale groundwater monitoring studies. The model assumes that the pesticide is applied at the maximum rate in areas where the groundwater is vulnerable to contamination; however, in most cases, a considerable portion of any use area will have groundwater that is less vulnerable than areas used to derive the SCI-GROW estimates. Therefore, the resulting groundwater concentration is considered to be a high-end bounding estimate of "acute" exposure. The estimated high-end groundwater concentration of 0.4 ppb for phosmet is included in Table 5, and should be used in both acute and chronic assessments.

Table 5. Phosmet Acute and Chronic Surface and Groundwater EECs (µg/L).

Crop	Surface Water, Maximum Rates		Surface Water, Average Rates		Groundwater Acute/Chronic
	Acute (peak)	Chronic (Mean)	Acute (peak)	Chronic (Mean)	
Alfalfa	3.0	0.05	2.1	0.04	0.4
Almonds	10.3	0.07	7.8	0.05	
Apples, Eastern-high	26.7	0.20	8.7	0.07	
Apples, Eastern-low	15.6	0.08			
Apples, Western-high	11.2	0.10	3.6	0.03	
Apples, Western-low	0.4	0.01			
Berries	11.8	0.03	11.8	0.03	
Cherries	9.5	0.06	6.6	0.04	
Cotton	29.9	0.06	12.0	0.02	
Grapes	18.7	0.10	11.2	0.06	
Kiwi	137.3	1.00	69.0	0.5	
Peaches-high	16.2	0.10	8.6	0.05	
Peaches-low	8.9	0.05			
Pears	140.0	1.00	56.0	0.4	
Pecans	23.7	0.08	13.0	0.04	
Plums	8.4	0.10	5.6	0.07	
Potatoes	7.9	0.05	7.1	0.05	
Potatoes, sweet	20.6	0.08	20.6	0.08	
Walnuts	8.4	0.10	4.4	0.05	

5.3.4 Drinking Water Levels of Comparison (DWLOCs)

When dietary exposure pesticide residues in drinking water cannot be determined quantitatively, HED calculates drinking water levels of comparison (DWLOCs), which represent the maximum contribution to the human diet that may be attributed to residues of a pesticide in drinking water after dietary exposure and residential exposures are subtracted from the aPAD or cPAD, HED's levels of concern for aggregate exposure. The calculated DWLOCs are then compared to surface and groundwater EECs; if the model estimates exceed the DWLOCs for surface and groundwater, there may be a concern for dietary exposure to residues in drinking water. Acute DWLOCs consider only (one-day) food and water exposure, and there are no chronic residential exposures for phosmet; therefore the phosmet acute and chronic DWLOCs shown in Table 6 include only dietary (food and water) exposure. [Short- and intermediate-term DWLOCs are discussed following the occupational and residential exposure and risk discussion.]

The most recent Agency guidance recommends the following DEEM™ subpopulations for use in DWLOC calculations (body weight in kg/liters of water consumed/day):

- General US population/48 states (70/2)
- Females >13 years old (60/2)
- Infants/children (10/1)

For each of the subgroups listed under females and infants/children, the most highly exposed subset (i.e., females 13+, not nursing or pregnant; or children one to six years old) should be used. The guidance suggests including the highest exposed adult subpopulation in DWLOC calculations; in the case of phosmet, either females were the adult subpopulation with the highest exposure, or the exposure for the general US population was higher than any other subpopulation containing adults. The following equations are used to calculate the acute and chronic DWLOCs.

Acute:

$$DWLOCacute\ (ug/L) = \frac{[one-day\ water\ exposure\ (mg/kg\ bw/day)\ x\ (body\ weight\ (kg))]}{[water\ consumption\ (L)\ x\ 10^{-3}\ mg/ug]}$$

$$one-day\ water\ exposure\ (mg/kg/day) = [AcutePAD - (one-day)\ food\ exposure\ (mg/kg/day)\ ]$$

Chronic:

$$DWLOC_{chronic}(ug/L) = \frac{chronic\ water\ exposure\ (mg/kg\ bw/day)\ x\ (body\ weight\ (kg))}{water\ consumption\ (L)\ x\ 10-3\ mg/ug}$$

$$chronic\ water\ exposure\ (mg/kg/day) = [Chronic\ PAD - average\ food\ exposure\ (mg/kg/day)]$$

5.3.5 Acute Dietary DWLOCs

Maximum (peak) surface water EECs for phosmet were estimated (for maximum application rates) to be 3-140 µg/L (ppb), depending on the crop/application rate modeled; the estimated high-end groundwater concentration for phosmet is 0.4 µg/L. The acute dietary DWLOCs calculated using the equations shown above range from 416-1523 µg/L (ppb). The maximum estimated concentrations of phosmet in surface and groundwater are below HED's levels of comparison for phosmet in drinking water as a contribution to acute aggregate (food + water) exposure. Therefore, HED concludes that phosmet residues in drinking water would not likely result in unacceptable levels of aggregate acute dietary (food + water) human health risk. Refer to Table 6 for details regarding calculation of acute DWLOCs.

5.3.6 Chronic Dietary DWLOCs

Mean surface water EECs for phosmet were estimated (for maximum application rates) to be 0.01-1.0 µg/L (ppb), depending on the crop/application rate modeled; the estimated high-end groundwater concentration for phosmet is 0.4 µg/L. The chronic dietary DWLOCs calculated using the equations shown above range from 110-384 µg/L (ppb). The mean concentrations of phosmet in surface and groundwater are below HED's levels of comparison for phosmet in drinking water as a contribution to chronic aggregate (food + water) exposure. Therefore, HED concludes that phosmet residues in drinking water would not likely result in unacceptable levels of aggregate chronic dietary (food + water) human health risk. Refer to Table 6 for details regarding calculation of chronic DWLOCs.

Table 6. Phosmet Acute and Chronic Dietary DWLOC (µg/L) Calculations.

Population Subgroup	Acute Food Exposure (mg/kg/day)[1]	Acute Water Exposure (mg/kg/day)[2]	Acute DWLOC (µg/L)[3]	Chronic Food Exposure (mg/kg/day)[1]	Chronic Water Exposure (mg/kg/day)[2]	Chronic DWLOC (µg/L)[3]
General US Population	0.001480	0.043520	1523	0.000036	0.010964	384
Children 1-6 years	0.003362	0.041638	416	0.000073	0.010927	110
Females 20+	0.001408	0.043592	1308			
Females 13-19				0.000032	0.010968	330

[1]Acute and chronic food exposure numbers for relevant subpopulations are shown in Table 4.

[2]Acute and chronic water exposure numbers were generated using the equations shown above; the aPAD is 0.045 mg/kg/day, and the cPAD is 0.011 mg/kg/day.

[3]Acute and chronic DWLOCs were calculated using the water exposure numbers, the population-based assumptions with respect to body weight and water consumption, and the equations shown above.

5.4 Occupational and Residential Exposure

5.4.1 Description of Occupational and Residential Use Patterns & Scenarios

The HED occupational and residential exposure and risk assessment for phosmet is based on a wide variety of occupational and residential exposure scenarios, or categories of exposures, derived from the uses described on registered labels. HED risk assessments consider several types of potentially exposed populations: handlers are those who are involved in the pesticide application process, including the preparation of spray solutions for use (i.e., referred to as mixer/loaders), and the application of the pesticide via groundboom tractor or high-pressure handwand (referred to as applicators). In addition, potential exposure and risk are considered for those who re-enter treated fields/orchards or who come into contact with treated animals following application (referred to as post-application).

Scenarios used to describe handler exposures are based on the type of application equipment used (e.g., airblast and groundboom sprayers) and the formulation involved (e.g., dust, wettable powder (WP) or emulsifiable concentrate (EC)). Post-application exposure scenarios are based on activities and tasks that might result in contact with the pesticide following application, such as harvesting/pruning or dermal contact with treated animals; in addition, the amount of the pesticide likely to be present in the environment following application is considered.

Based on the phosmet use pattern, handler and post-application occupational exposures are expected to occur; in addition, residential post-application exposure is expected to occur following occupational application in residential settings and to pets (dogs). Homeowner uses in residential settings (home/garden) are permitted on registered labels, and are expected to result in residential handler and post-application exposures, including toddlers' dermal contact with companion animals (dogs) and non-dietary ingestion resulting from hand-to-mouth activity. While the risk assessments for handlers incorporate both dermal and inhalation exposures, only dermal exposures are considered in the post-application exposure and risk assessments.

In addition to the tasks and activities associated with pesticide application and post-application exposures, HED carefully considers the expected duration and route of exposure and the associated potential toxic effects as determined in required toxicity testing for the technical active ingredient. The toxicological endpoints and doses for risk assessment are selected from available toxicity studies based on how the pesticide enters the body (e.g., orally, through the skin, or by breathing), how long the test animals were exposed, and the expected levels of exposure. These selected doses are then compared to the estimated occupational and residential exposures to calculate risks, referred to as MOEs or Margins of Exposure. The higher the MOE, the lower the risk. In general, the target (acceptable) MOE determined from toxicity studies conducted in animals is 100, which accounts for the difference in sensitivity between animals and humans and between individuals in a population.

Based on the phosmet use pattern, short-term exposures of one to seven days are expected to occur; the relevant toxicological endpoints for risk assessment were selected from a 21-day dermal toxicity study in the rat (dermal exposures) and a rat oral acute neurotoxicity study (inhalation exposures, assuming 100% absorption). Intermediate-term exposures are generally defined as those occurring from one week to several months, and may involve intermittent exposure over a period of time. In the phosmet risk assessment, intermediate-term exposures were separated into two distinct time-frames of between eight and 30 days and >30 days duration, since the results of subchronic neurotoxicity testing indicate the effects associated with exposure to phosmet become more severe over time. For exposure durations of eight to 30 days, the relevant toxicological endpoints for risk assessment were selected from a 21-day dermal toxicity study in the rat (dermal exposures) and a rat oral subchronic neurotoxicity study (inhalation exposures, assuming 100% absorption). The target (acceptable) MOE for phosmet exposures lasting eight to 30 days is 100. For intermediate-term exposures greater than 30 days, the toxicological endpoints for risk assessment (dermal exposures assuming 10% absorption, and inhalation exposures assuming 100% absorption) were selected from the rat chronic toxicity study, with a target MOE of 100. HED also considers risk associated with long-term or chronic occupational/residential exposures, i.e., those occurring every day during a year; however, no long-term or chronic exposures to phosmet are expected, based on the registered uses. Finally, non-dietary ingestion of a pesticide can occur when toddlers engaging in mouthing behaviors come into contact with treated pets (dogs in the case of phosmet). In order to assess risk from this type of exposure, HED used the endpoint and dose selected from the rat oral acute neurotoxicity study, with an acceptable MOE of 100.

Details of the assessments are provided in the "Revised Occupational and Residential Exposure aspects of the HED Chapter of the Reregistration Eligibility Document (RED)" [J. Dawson, 1/27/00, D262366], which updates the preliminary ORE assessment via inclusion of additional chemical-specific data for post-application exposures, revised use information, and new toxicological endpoints for risk assessment. Although average application rates were provided by BEAD/OPP, incorporation of these rates into the assessment did not significantly reduce estimated exposures.

A summary of the use pattern and formulation information for occupational and residential risk assessment is provided in Table 7.

Table 7. Phosmet Use Pattern/Formulation Information Relevant to ORE Assessment.

Use Sites	Formulation Type	Application Equipment (mixer/loader/applicator)	Max. Appl. Rates	Application Frequency	Typical Appl. Rates
Terrestrial Crops, Occupational					
Tree fruit/ Nut crops	WP (WSB, open bag)	Airblast; aerial; chemigation	1.5-5.95 lb ai/A[1]	<2 to <5 times/year	1.0-3.1 lb ai/A
Grapes	WP (WSB, open bag)	Airblast; over-row ground boom; aerial; and chemigation	1.5 lb ai/A	<2 to <5 times/year	1.0 lb ai/A
Field/forage fiber/small fruit/veg.	WP (WSB, open bag)	Airblast; ground boom; aerial; chemigation	0.7-1.0 lb ai/A	<2 to <5 times/year	0.4-1.0 lb ai/A
Sweet Potato (post-harvest)	Dust	Commercial dusting equipment	0.0125 lb ai/50-lb bushel		No data
Direct Animal Treatments, Occupational					
Farm Animal	EC (spray)	Low-pressure handwand; backpack sprayer; high-pressure handwand sprayer	0.4-2.0 lb ai/100 gallons spray	No data	No data
Cattle Backrubber	EC	Backrubber, soak sack, cloth	1 lb ai/50 gallons fuel oil	No data	No data
Dog/Dust	Dust	Shaker Can	0.5 g dust/kg animal weight	No data	No data
Dog/Dip	EC	Pet dipping tank	0.0076 lb ai/gallon dip solution	No data	No data

Table 7. Phosmet Use Pattern/Formulation Information Relevant to ORE Assessment.

Use Sites	Formulation Type	Application Equipment (mixer/loader/applicator)	Max. Appl. Rates	Application Frequency	Typical Appl. Rates
Ornamental/forestry/residential Use Sites, Occupational					
Non-crop areas	WP, EC	Groundboom; aerial	1.5-2.0 lb ai/A	No data	No data
Forestry and Evergreens	WP, EC	Airblast; aerial; high-pressure handwand; compressed air sprayer; bucket-pump sprayer; slide-pump sprayer; small pump sprayer; wheelbarrow sprayer	1 lb ai/A	No data	No data
Ornamentals (including fire ant)	WP, EC, SC	Low pressure handwand; airblast, backpack, high-pressure handwand. Direct application to fire ant mound	0.0075 lb ai/gallon; or 0.06 lb/gallon (airblast)	No data	No data
Pine Seedling Dip	WP, EC	Application is method is dipping by hand into open bucket	1.75 lb ai/5 gallons = 10,000 seedlings	No data	No data
Homeowner Application, Residential					
Fruits/nuts	WP	Backpack sprayer; low pressure handwand; hose-end sprayer; compressed air sprayer; small power sprayer	0.0098 lb ai/gallon, 10 gallons/tree	No data	No data
Vegetables (peas/potato)	WP	Backpack sprayer; low pressure handwand sprayer; hose-end sprayer	0.012 lb ai/100 square ft.	No data	No data
Ornamentals (including fire ant)	WP, EC, SC	Backpack sprayer; low pressure handwand sprayer; hose-end sprayer; compressed air sprayer; small power sprayer	0.0075 lb ai/gallon; Fire ant-1 packet/mound. 1 packet = 0.009 lb ai/ft^2 mound	No data	No data
Dog/dust	Dust	Shaker can	0.5 g dust/kg animal weight	No data	No data
Dog/dip	EC	Pet dipping tank	0.0076 lb ai/gallon dip	No data	No data

[1]Maximum application rates for apples are specified for East Coast (1.5 lb ai/A) and West Coast (4 lb ai/A) apples.

5.4.2 Occupational Handlers

HED completes occupational handler assessments using different levels of personal protection. Minimal protection is assumed at first, and a tiered approach to adding protective measures is used until an appropriate MOE is obtained, or until all options are exhausted. The lowest tier is defined as the baseline exposure scenario; higher tiers include measures such as personal protective equipment (PPE, e.g., gloves, extra clothing, and respirators) and engineering controls (e.g., closed cabs and closed loading systems). The most practical option for risk reduction is generally considered to be the minimal level of adequate protection identified in the risk assessment.

In the phosmet risk assessment, risks for occupational handlers, including mixer/loaders, applicators, mixer/loader/applicators, and flaggers were assessed using four distinct levels of dermal protection, including standard work clothing; standard work clothing with gloves; standard clothing with chemical-resistant gloves and an additional layer of clothing (e.g., coveralls); and engineering controls. At each level of mitigation, generic protection factors were applied to calculate exposures.

Based on the phosmet use pattern, a total of 23 occupational handler scenarios were identified. No chemical-specific handler exposure data were submitted for phosmet, and therefore daily dermal and inhalation handler doses were calculated using data from the *Pesticide Handlers Exposure Database (PHED), Version 1.1*. The database contains exposure values for over 1,700 monitored exposure events, which have been evaluated by the Agency in order to characterize the quality of the data. To ensure consistency in exposure assessments, the Agency has developed a series of tables of standard unit exposure values for many different types of occupational scenarios. The unit exposure values generally range from the geometric mean to the median of the available data for a given scenario.

Assumptions regarding the application rate and acres treated (including an assumption of an 8-hour workday for occupational scenarios) were used in conjunction with the PHED unit exposure values to determine phosmet handler exposures. For agricultural handler scenarios, the number of acres treated per day assumed in the phosmet risk assessment are those typically used in HED risk assessments. For pet handler exposures, HED assumed that a maximum of 8 dogs/day are dipped/dusted; risks were calculated for a range of dog body weights (5-120 lbs). In addition, HED assumed that 10% of the active ingredient applied during dipping/dusting represented the total dose; this is a standard assumption taken from the 1997 *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment*. The average body weight of an adult handler was assumed to be 70 kg, which is standard for HED risk assessments. The hose-end sprayer data were used to assess exposures associated with the fire ant mound treatment

scenario. Since there were no data to assess potential handler exposure associated with "charging" the cattle backrubber, data for open mixing of liquids were used; however, HED believes this approach may underestimate exposure, based on information submitted by the registrant, SPAH, Inc.

HED has risk concerns for occupational handlers mixing/loading wettable powders for aerial and chemigation applications to fruit/nut trees, field and vegetable crops, cotton, grapes, and ornamentals/forestry. Even after the use of engineering controls, calculated combined dermal and inhalation MOEs for mixer/loaders (for all durations of exposure) ranged from 16 to 94. Handler risks associated with mixing/loading wettable powders for groundboom and airblast applications were above HED's level of concern for certain crops/rates unless engineering controls were assumed. However, most short- and intermediate-term handler risks could be mitigated with the use of additional PPE or engineering controls.

Combined dermal and inhalation risks calculated for occupational handlers applying phosmet using airblast and groundboom sprayers were generally below HED's level of concern (i.e., MOEs >100), but engineering controls were required to attain MOEs >100 for applications to certain crops. Engineering controls (i.e., enclosed cab) were required for aerial applications; for aerial applications to nuts, use of engineering controls resulted in short- (one to seven days) and intermediate-term (>7 and ≤30 days) MOEs of 96 and 89, respectively. Intermediate-term (>30 days) exposures to aerial applicators treating fruit and nut trees had MOEs of 78 and 65, respectively. For flaggers, combined dermal and inhalation risks were below HED's level of concern for many application rates at the baseline clothing scenario; however, engineering controls were required for some flagger exposures greater than 30 days, such as those associated with applications to fruit and nut trees.

For direct animal treatments, combined dermal and inhalation risks were generally below HED's level of concern for mixer/loaders and applicators. Intermediate-term exposure durations greater than 30 days were of concern for only one scenario involving application to livestock using a high-pressure handwand, with an estimated MOE of 88. Combined dermal and inhalation risks were below HED's level of concern for handlers mixing/loading and applying phosmet to ornamentals, non-crop areas and rights-of-way.

In summary, risks for occupational handlers are above HED's level of concern for some scenarios; however, the calculated risks can generally be mitigated with additional protective measures such as engineering controls. Occupational handler risks are largely due to estimated dermal exposures; the combined dermal and inhalation MOEs were not significantly different from the dermal MOEs. There are risk concerns associated with some intermediate-term handler exposures greater than 30 days; such exposures could occur based on the phosmet use pattern, but are considered to be unlikely or infrequent, and would be limited to professional applicators. The detailed results of the occupational handler exposure and risk assessment are provided in Attachment 1.

5.4.3 Residential Handlers

Since phosmet products are labeled for homeowner use, HED completed a risk assessment for residential handlers. The tiered mitigation approach described above for occupational handlers is not considered to be appropriate for residential handlers, who lack access to and training in the use of personal protective equipment. Homeowner handler assessments are completed assuming a single clothing scenario consisting of short-sleeved shirts and short pants. In addition, homeowner handler scenarios are always considered to be short-term in nature.

A total of nine different residential handler scenarios were identified based on the phosmet use pattern. Exposure to residential handlers was considered for direct animal (dog) treatments, mixing/loading/applying wettable powders for application to terrestrial crops using a variety of hand-held equipment, and mixing/loading/applying wettable powders and liquids for application to ornamentals, also using a variety of hand-held equipment.

Since there were no chemical-specific handler data, unit exposures from PHED were used, along with data and procedures specified in the 1997 *Draft SOPs for Residential Exposure Assessment (Surrogate Exposure Table)*. For direct dermal treatments, HED assumed that one dog is dipped/dusted per day; in accordance with the *Residential SOPs*, HED assumed that 10% of the active ingredient applied during dipping/dusting represented the total handler dose. The average body weight of an adult handler was assumed to be 70 kg; although HED is aware that homeowner applications are likely to be made by young adults, range-finding calculations indicate the overall risk picture would not change for lower body weights. Limited square-footage home garden sizes were assumed, and spray applications were assumed to be 5 gallons per day.

Combined dermal and inhalation risks were below HED's level of concern (i.e., MOEs >100) for homeowners mixing/loading/applying wettable powders to peas, potatoes and fruit trees using a backpack or hose-end sprayer. Combined dermal and inhalation MOEs for mixing/loading/applying phosmet to fruit trees and ornamentals using a low-pressure handwand were 42 and 83, respectively; calculated MOEs for similar application to potatoes and peas were 230. Although handler risks for direct application to dogs (dip/dust) were below HED's level of concern, very limited data were available to assess these exposures, and the calculated MOEs did not include exposure through inhalation.

In summary, residential handler risks associated with homeowner uses of phosmet are generally below HED's level of concern; some scenarios involving the use of a low-pressure handwand exceed the level of concern. Detailed results of the residential handler exposure and risk assessment are provided in Attachment 2.

5.4.4 Post-Application (Occupational and Residential)

HED defines post-application exposures for three general populations: post-application workers, residential (homeowner) adults, and residential children. Post-application exposures are expected to occur when workers re-enter areas that have been treated; tasks associated with these exposures include agricultural harvesting and scouting, and tree surgeon or arborist activities. Residential adults are members of the general population that may be exposed to pesticide residues following treatment around their residences or in park areas and golf courses; since these exposures could occur in a variety of activities, HED generally chooses a representative activity that results in a conservative exposure estimate. Residential children may be exposed to chemicals by engaging in activities in areas previously treated with a pesticide, including parks and home gardens, and through dermal contact with treated pets. The post-application risks to residential children associated with home gardening are determined for youth (ages 10-12), while risks associated with contact with companion animals (dogs, in the case of phosmet) are assessed for toddlers.

Based on the phosmet use pattern, there is potential for post-application exposure to phosmet residues for workers, residential homeowners and residential children. Agricultural post-application scenarios assessed for phosmet consist of adults harvesting and maintaining pears, grapes, and field and vegetable crops following maximum rate applications; in addition, post-application exposures were assessed for harvesting and maintaining apples using maximum application rates for both East and West Coast apples. Residential post-application scenarios assessed for phosmet consist of adult homeowners and youth-aged children (10-12) harvesting and maintaining pears and apples at maximum application rates, and toddlers after dermal contact with treated dogs, including consideration of the hand-to-mouth dose (non-dietary ingestion).

Both short- and intermediate-term post-application exposures are expected to occur, based on the phosmet use pattern. However, as noted previously, only dermal exposures were considered in the post-application exposure assessment, since the physical properties of phosmet suggest post-application inhalation exposures would be minimal. Chemical-specific data consisting of dislodgeable foliar residue (DFR) data and a homeowner exposure study were evaluated by HED, and the results incorporated in the post-application exposure and risk assessment. All of the chemical-specific data generated for post-application exposure and risk assessment included residues of phosmet and the oxygen analog metabolite, which were assumed to be equivalent in terms of toxicity. The DFR studies conducted on citrus (used in this assessment for characterization only), grapes and pears were used to determine the level of phosmet residues on leaves that could rub off onto a person's skin, including dissipation of residues over a period of time. In determining post-application exposures, HED considers the amount of time a worker/homeowner could be engaged in an activity (e.g., harvesting). For phosmet, HED assumed workers engage in harvesting and maintenance activities for a maximum of eight hours; for homeowner exposures, HED assumed 0.67 hours harvesting/maintaining fruit trees, and a two-hour duration for exposure to companion animals (dogs).

In addition to the DFR data, HED uses scenario-specific transfer coefficients to determine exposure during a given activity. For occupational scenarios involving harvesting/maintenance of fruit trees and field and vegetable crops, surrogate transfer coefficients were used; the selected surrogate transfer coefficients are considered to be conservative, and therefore protective of any other post-application exposures, such as harvesting nuts.

For the homeowner post-application exposure scenarios, chemical-specific transfer coefficients generated in the homeowner exposure study were used; an adjustment was made for the differences in body surface areas for youth and adults, based on information found in the *Draft SOPs for Residential Exposure Assessment*. The transfer coefficients were calculated in accordance with the draft *Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines.* For intermediate-term exposures greater than 30 days (i.e., sustained exposures), the 30-day average exposure level was calculated and used in both the home garden and pet use exposure scenarios.

Post-application exposures to toddlers from contact with treated dogs (both small and large) were calculated using the *Draft SOPs for Residential Exposure Assessment* (1997), i.e., assuming a toddler body weight of 15 kg, and assuming that 20% of the pesticide applied to the animal is transferable, and that 10% of the transferable pesticide represents the dermal dose. In the case of phosmet, a moderate residue dissipation rate of 5% was assumed on treated dogs; this assumption was supported by preliminary data from a study in which residues were determined on dog fur following treatment with phosmet. Exposures evaluated consisted of dermal contact through the skin and non-dietary ingestion based on hand-to-mouth transfer during mouthing behavior. In calculating exposure, HED assumes that each time a child exhibits a mouthing behavior, all of the residues available on the treated dog transfer to the child's hands, that 50% of the residues on the hands are transferred to the mouth, and that the palmar surfaces of three fingers are placed in the child's mouth. The frequency of hand-to-mouth events was assumed to be 20 times/hour.

Occupational post-application exposures are regulated using restricted entry intervals (REIs), essentially the amount of time following pesticide application during which entry into the treated area is restricted due to post-application risk concerns. HED calculated REIs for harvesting nuts pears, grapes, apples (East and West Coast rates), blueberries and peas using daily exposures for short- and intermediate-term (<30 days) durations. In addition, an REI was calculated for scouting activities expected to occur for certain crops, such as cotton. For intermediate-term exposures lasting greater than 30 days, such as apple or pear harvesting, 30 day average exposures were used to calculate REIs.

The calculated REI for scouting activities anticipated for crops such as cotton and alfalfa is four days. The REIs calculated for short-term and intermediate-term (<30 days) exposures during harvesting of relevant crops at the maximum label rates are shown below. [The calculated REIs may be translated to other crops that can be treated using phosmet, depending on the similarities between use rates, the type of harvesting/maintenance activities involved, and the relevant transfer coefficients.] HED has risk concerns for workers entering treated areas before the corresponding elapsed time-frames (i.e., MOEs would be <100). HED emphasizes that these REIs have been calculated using chemical-specific data.

Nuts:	58 Days
Pears:	56 Days
Apples (West Coast):	52 Days
Grapes:	44 Days
Apples (East Coast):	37 Days
Blueberries:	25 Days
Peas:	18 Days

The DFR data indicate phosmet residues can be detected (well above the limit of quantitation, or LOQ) up to one month following application. For occupational post-application intermediate-term exposures of greater than 30 days duration, HED used average monthly exposure values (calculated from DFR data) for three distinct 30-day time intervals: 0-30 days, 15 to 45 days, and 30-60 days after application. The MOEs associated with these time intervals for harvesting nuts, pears, grapes, and West Coast apples were less than 100 (ranging from 4 for nuts at 0 to 30 days to 68 for grapes at 30-60 days). For harvesting East Coast apples, MOEs were <100 for all but the 30-60 day interval. For harvesting both blueberries and peas, MOEs were <100 for the 0-30 day interval, but were above 100 for the 15-45 and 30-60 day intervals. Finally, the monthly average exposures for scouting activities resulted in MOEs greater than 100, indicating post-application exposures below the level of concern.

The use of an REI is not practical for mitigation of residential post-application exposures, and therefore HED typically evaluates exposure immediately after application. This approach is considered to be appropriate for acutely toxic pesticides, such as the organophosphates. For short- and intermediate-term (<30 days) exposures to adults harvesting and maintaining apples and pears in home gardens, the calculated Day 0 (day of application) MOEs were less than 100, with the exception of apples treated at the East Coast rate. An MOE greater than 100 (i.e., not of concern) was achieved four to eight days after application. These intervals could be representative of the typical timing for re-entry in home gardens, based on the assumption that harvesting would not occur on the day of application. For short- and intermediate-term (<30 days) exposures to youth

(aged 10-12) harvesting and maintaining apples and pears, the Day 0 MOEs were similar to the Day 0 MOEs calculated for adults (i.e., less than 100), but were greater than 100 after three to six days. For harvesting East Coast apples, the Day 0 MOE for youth was calculated to be 232, which is greater than the target MOE of 100. In summary, although some of the short- and intermediate-term (<30 days) home-garden post-application exposures are of concern for both youth and adults on the day of application, risks are below HED's level of concern when typical post-application activities such as harvesting could be expected to occur.

HED has concerns for short- and intermediate-term (<30 days) post-application risks for toddlers exposed to phosmet through dermal contact with treated dogs, as well as through non-dietary ingestion of residues associated with mouthing behaviors. The Day 0 MOEs calculated for petting small and large dogs ranged from <1 to 8, with a target MOE of 100; an MOE >100 was not achieved even after 30 days, when re-treatment could occur. For toddler mouthing behaviors, as well as for aggregate exposure to dogs (i.e., dermal + hand-to-mouth exposures) Day 0 MOEs were <1 after contact with small and large dogs, and did not go above 100 after 30 days.

HED does not have enough information to determine if intermediate-term (>30 days) exposures to phosmet occur in home gardens. However, empirical dissipation data suggest that phosmet residues persist, and that it may be possible for individuals to be exposed over an extended period of time. Therefore, monthly average exposures were calculated for adults, youth and toddlers, with a target (acceptable) MOE of 100. Intermediate-term (>30 days) post-application exposures in home gardens were below the level of concern (i.e., MOEs >100) for adults and youth harvesting apples and pears, with MOEs ranging from 104 to 387. Intermediate-term (>30 days) aggregate (i.e., dermal + hand-to-mouth) MOEs calculated for toddlers following contact with treated dogs were <1.

In summary, HED has risk concerns for post-application exposure to adults and youth in residential home gardens immediately following application of products containing phosmet; however, there is little information to determine the likelihood or extent of post-application exposure in home gardens. HED has significant risk concerns for toddlers exposed to phosmet residues following contact with treated dogs, regardless of the duration of exposure.

6.0 AGGREGATE RISK

In accordance with FQPA, HED must consider and, if possible, aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure.

For phosmet, acute and chronic aggregate risks consist of only dietary (food + water) exposures. Estimated dietary exposure and risks (acute and chronic) for phosmet are below HEDs level of concern, and the calculated acute and chronic DWLOCs are significantly lower than the EECs generated using conservative models. Therefore, phosmet aggregate acute and chronic risks are below HEDs level of concern.

Residential handler and post-application risks have been calculated for phosmet. HED has risk concerns for toddlers following dermal contact with treated dogs and oral hand-to-mouth non-dietary ingestion of phosmet residues, regardless of the duration of exposure. Calculated MOEs were <1 on the day of application and at all other intervals considered. Since the dermal and hand-to-mouth exposures for toddlers exceed HED's level of concern, these exposures were not aggregated with dietary (food + water) exposures for either short- or intermediate-term durations.

The residential handler risks calculated for phosmet consider combined dermal and inhalation exposures, for only short-term durations. Residential post-application risks (other than non-dietary ingestion) were based only on dermal exposure, and included both short- and intermediate-term (both less than and greater than 30 days) durations. Since the toxic effects associated with short-term dermal, inhalation and dietary exposures were the same (i.e., cholinesterase inhibition), and since the target (acceptable) MOEs associated with these routes of exposure were all 100, the reciprocal MOE approach was used to aggregate exposure/risk and to determine short- and intermediate-term (<30 days) DWLOCs.

The equations shown below were used to calculate phosmet short-term aggregate MOEs and DWLOCs for residential handlers; when possible, residential post-application exposures (youth and adults) were aggregated for risk-characterization purposes. Note that for post-application exposures, there is no inhalation component; in addition, there is no oral component for post-application exposures to youth and adults. Finally, intermediate-term (>30 days) post-application exposures were not aggregated, even though the associated MOEs were >100, since many of the estimated short-term post-application exposures exceeded the level of concern.

$$\text{Aggregate MOE} = \frac{1}{\frac{1}{\text{MOE}_{\text{food}}} + \frac{1}{\text{MOE}_{\text{water}}} + \frac{1}{\text{MOE}_{\text{dermal}}} + \frac{1}{\text{MOE}_{\text{inhalation}}}}$$

$$\text{MOE}_{\text{water}} = \frac{1}{\frac{1}{\text{MOE}_{\text{agg.}}} - \frac{1}{\text{MOE}_{\text{food}}} + \frac{1}{\text{MOE}_{\text{dermal}}} + \frac{1}{\text{MOE}_{\text{inhalation}}}}$$

Where the aggregate MOE_{AGG} is equal to the acceptable short-term MOE (100 for phosmet);

the MOE_{FOOD} = the acute PAD/chronic food exposure;

the MOE_{WATER} = the acute PAD/"allowable short-term water exposure" from average drinking water residues;

the MOE_{DERMAL} = short-term dermal NOAEL/dermal residential handler exposure; and

the $MOE_{INHALATION}$ = short-term inhalation NOAEL/inhalation residential handler exposure.

After calculating the value for the term "MOE_{WATER}" using the equations described above, the following equation is solved for the allowable short-term water exposure, calculated as follows:

$$\text{MOE}_{\text{water}} = \frac{\text{Acute Dietary PAD}}{\text{Allowable Short - Term Water Exposure}}$$

$$\text{Allowable Short - Term Water Exposure} = \frac{\text{Acute Dietary PAD}}{\text{MOE}_{\text{water}}}$$

Using the Short-Term Water Exposure value, the short-term DWLOC is calculated as follows:

$$\text{DWLOC(ug / L)} = \frac{\text{Short - Term Water Exposure (mg / kg / day) x Body Weight (kg)}}{\text{1E - 3 mg / ug) x Daily Drinking Water Rate (L / day)}}$$

For applications to dogs, there were no data to assess inhalation exposures, so there was no inhalation component in the calculated short-term DWLOC for these scenarios. Aggregate risks and DWLOCs were not calculated for residential handlers mixing/loading/applying wettable powders to fruit trees and ornamentals using a low pressure handwand, since the handler risks alone exceed HED's level of concern. A summary of the calculated DWLOCs for representative short-term residential handler scenarios (assuming adult applicators with a body weight of 70 kg, and 2L of water consumption per day) is shown in Table 8.

The model estimates of average concentrations of phosmet in surface and groundwater (refer to Table 5) are significantly less than the calculated residential handler DWLOCs for phosmet in drinking water as a contribution to short-term aggregate exposure. Therefore, HED concludes with reasonable certainty that phosmet residues in drinking water (when considered along with exposure through food and residential handler exposures) would not result in unacceptable levels of aggregate human health risk for most residential handlers. However, since handler risks associated with applying wettable powders to fruit trees and ornamentals exceed HEDs level of concern, any additional exposure to phosmet residues through drinking water would indicate a risk concern.

For the aggregate residential post-application exposure assessment, HED calculated DWLOCs for short-term exposures using the equations shown above (excluding inhalation exposure) and the MOEs (youth and adult) determined for Day 0 harvesting of East Coast apples, the only scenarios for which acceptable MOEs were attained on Day 0. The short-term DWLOCs calculated for post-application exposures during harvesting of East Coast apples were 7 µg/L and 6 µg/L for adults and youth, respectively. The phosmet EECs for surface and groundwater are significantly lower than these DWLOCs, indicating that residues in drinking water would not result in unacceptable levels of aggregate human health risk for these post-application exposures. However, since Day 0 MOEs for harvesting pears and West Coast apples were <100, residues in drinking water could result in a risk concern for aggregate (short-term) post-application exposures estimated for these activities.

Table 8. Summary of Short-Term DWLOCs for Residential Handlers.[1]

Scenario #, Application Equip.	Scenario Description[2]	MOE $_{DERMAL}$[3]	MOE $_{INHALATION}$[4]	MOE $_{WATER}$	Short-Term Exposure (mg/kg/day)	DWLOC (µg/L)
1	Dusting a large dog	159090.9	N/A	109	0.000414	14.5
2	Dipping a dog	1381578.9	N/A	109	0.000414	14.5
3a, backpack sprayer	M/L/A liquids to ornamentals	5490.2	280000.0	111	0.000406	14.2
3b, backpack sprayer	M/L/A WP to fruit trees	2100.8	107142.9	115	0.000392	13.7
4a, low-pressure handwand	M/L/A liquids to ornamentals	280.0	280000.0	178	0.000253	8.9
4b, low-pressure handwand	M/L/A WP to Peas & Potatoes	233.3	15909.1	206	0.000218	7.6
5a, garden hose-end sprayer	M/L/A liquids to ornamentals	933.3	884210.5	123	0.000366	12.8
5b, garden hose-end sprayer	M/L/A WP to fruit trees	357.1	338345.9	156	0.000288	10.1
6, direct application of ai via sprinkling	M/L/A SC for fire ant control	388.9	368421.1	151	0.000298	10.4

[1]Includes both dermal and inhalation exposures associated with applying phosmet in residential settings.

[2]A representative scenario having the lowest dermal MOE was chosen for each application method/formulation. M/L/A = mixer/loader/applicator; WP = wettable powder, SC = soluble concentrate.

[3]From Appendix B/Table 3 of the ORE chapter.

[4]From Appendix B/Table 3 of the ORE chapter. Note that no inhalation MOEs are provided or application to dogs, since there were no data to assess this type of exposure.

Because HED does not recommend REIs for residential post-application exposures, it is generally assumed that harvesting/maintenance activities could occur on the day of application. However, for the purpose of risk characterization, short-term DWLOCs were calculated for youth and adults harvesting fruit four to nine days following phosmet applications, the amount of time required to achieve acceptable post-application MOEs. Youth were assumed to have a body weight of 39.1 kg, and a daily water consumption of 1.5L. The results indicate the only post-application scenario with a potential concern for residues in drinking water is harvesting pears seven to nine days following phosmet application. HED notes that chemical-specific exposure data for pears were used to generate post-application exposures.

Intermediate-term (>30 days) post-application exposures were below the level of concern. Although the associated DWLOCs were not calculated, HED concludes that it is unlikely that potential additional exposure to residues in drinking water would result in unacceptable aggregate human health risk. There is insufficient information regarding phosmet use in residential settings to determine the likelihood of exposures greater than 30 days.

6.1 Incident Data Review

A review of available incident data for phosmet considered information from the OPP Incident Data System (IDS, 1992 to present), Poison Control Centers (1993-1996), the California Department of Pesticide Regulation (1982-present), and the National Pesticide Telecommunications Network (NPTN, 1984-1991). The IDS data were used to characterize occupational and non-occupational exposures, as well as exposure to children. The PCC data consider largely residential incidents, including those involving exposures in children. The California DPR data focused largely on agricultural incidents, and the NPTN data consisted of largely residential exposures, either following contact with treated pets, or upon entry into previously treated areas. In addition, several literature studies were discussed, two of which described an exposure incident in detail, and one which consisted of a telephone survey of animal groomers/veterinary workers, boarding kennels, etc., to determine the type of products used, PPE used, and incidents associated with exposure to flea control products.

Available data suggest agricultural use of phosmet is not associated with increased risk when compared to other organophosphate and carbamate pesticides. However, HED has concerns for exposures associated with treatment of companion animals (dogs). The majority of the serious cases reported in the incident data involved systemic illnesses to pet owners, groomers and veterinary assistants. The available survey data suggest that label recommendations regarding the use of PPE are not routinely observed; in cases where actual poisonings have been reported, symptoms have persisted for months or even years. Pet groomers and homeowners with several dogs, who may repeatedly dip their animals may be at a greater risk for illness due to repeated exposure to phosmet. In two case studies, clinical signs of exposure were observed even though normal red blood cell cholinesterase levels were measured.

Residential exposures to phosmet are more likely to result in treatment in a health care facility than all other organophosphate insecticides; phosmet ranked third for hospitalizations, and first for admission to intensive care units. In addition, the incident data indicate phosmet poses a much greater risk to children than other organophosphate insecticides. An analysis of the data with respect to estimated usage in homes indicates that the higher number and severity of phosmet exposure incidents is not simply due to widespread use. The increased number of incidents may be due to the manner in which phosmet is sold, in a highly concentrated dog dip product. Veterinary incident data include many documented pet incidents associated with the more concentrated dog dip products. Labels have been amended to discourage application to certain dog breeds, and to smaller dogs.

7.0 ENDOCRINE DISRUPTOR 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...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disruptor Screening Program was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of phosmet and its end-use products for endocrine effects may be required.

8.0 CUMULATIVE EXPOSURE AND RISK

The current risk assessment considers risk associated with exposure to phosmet. EPA has determined that phosmet has a common mechanism of toxicity with other organophosphate insecticides, and therefore a cumulative risk assessment may be required. The Agency is in the process of developing methodology to conduct cumulative risk assessments; a cumulative risk assessment for phosmet will be considered when this methodology is available.

9.0 DATA NEEDS

9.1 Toxicology

- 21-Day Dermal Toxicity. The submitted 21-day dermal toxicity study [MRID 44795801] is considered to be acceptable, and satisfies the guideline requirement [870.3200] for a 21-day dermal toxicity study; however, the use of a control group run specifically to obtain cholinesterase data for comparison with the phosmet-treated groups in the study is inappropriate. In order to verify the NOAEL, historical control data for cholinesterase activity [plasma and brain] must be submitted; in addition, the registrant should conduct a statistical analysis of the combined control cholinesterase data.

- Subchronic Neurotoxicity. To confirm the lack of neuropathology for phosmet, additional data are required to fully characterize the severity of the digestion chambers (lesions) in the sciatic and peroneal nerves observed in high-dose male rats. Specifically, the registrant should provide data concerning the number of fibers affected in each case, compared with the same information for historical controls. Incidence of these and similar lesions in historical controls should be fully described.

9.2 Residue Chemistry

Additional data required to support the reassessed tolerances include:

- Label amendments, including specification of maximum seasonal rates and number of applications for some crops;

- Representative storage stability studies for phosmet oxon in an oil seed or nut matrix;

- Geographically representative field trial residue data for blueberry;

- Residue data for cotton gin byproducts (a new requirement under OPPTS 860.1500); and

- Residue data supporting post-harvest dust application to sweet potato.

10.0 SUPPORTING DOCUMENTATION

The conclusions from the following supporting (attached) documents have been incorporated into the phosmet revised human health risk assessment:

"Phosmet - Review of Incident Reports for ProTICall® Derma-Dip (Reg. No. 773-79)," [V. Dobozy memorandum dated 4/17/97, DP Barcode No. D234382].

"Revised Product and Residue Chemistry Chapters of the HED RED," [C. Swartz memorandum dated 11/23/98, DP Barcode No. D250029].

"Review of Phosmet Incident Reports," [J. Blondell memorandum dated 12/7/98, DP Barcode No. D251247].

"Phosmet-Report of the FQPA Safety Factor Committee," [B. Tarplee memorandum dated 7/21/99].

"Phosmet Toxicology Chapter for the HED RED," [L. Taylor memorandum dated 7/26/99, DP Barcode No. D257925, HED Document No. 013586].

"HED Response to Public Comments on the Preliminary Human Health Risk Assessment," [C. Swartz memorandum dated 7/29/99, DP Barcode No. D258140].

"HED Review of the Gowan Co. Probabilistic (Monte Carlo) Acute Dietary Exposure and Risk Assessment," [C. Swartz memorandum dated 7/30/99, DP Barcode No. D254657].

"Phosmet: Revised Report of the Hazard Identification Assessment Review Committee," [L. Taylor memorandum dated 8/4/99, HED Document No. 013604].

"Phosmet Tier II EECs," [S. Abel memorandum dated 8/9/99].

"Phosmet: Revised Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment," [C. Swartz memorandum dated 9/8/99, DP Barcode No. D258080].

"The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Document (RED) for Phosmet," [J. Dawson memorandum dated 1/27/00, DP Barcode No. D262366].

"Cancer Assessment Document: Evaluation of the Carcinogenic Potential of Phosmet (3rd Review)," [S. Diwan memorandum dated 9/30/99].

"Phosmet: Revised Report of the Hazard Identification Assessment Review Committee," [L. Taylor memorandum dated 12/20/99, HED Document No. 013921].

ATTACHMENTS

Attachment 1. Summary of Occupational Handler Exposure and Risk Assessments.

Notes for the Following Table:

MOE = Margin of Exposure; reflects combined dermal and inhalation MOEs.
PF = Protection Factor
WP = Wettable Powder
SC = Soluble Concentrate

MOEs for all levels of personal protection assessed, as well as the assumptions used (e.g., acres treated/day, body weight, etc.) are described in detail in Appendix A of the 1/27/00 J. Dawson ORE chapter, D262366.

Scenario Number and Description	Crop Type or Target	Short-Term Exposures ≤7 days		Intermediate-Term Exposures >7 and ≤30 days		Intermediate-Term Exposures >30 days	
		Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE
Occupational Mixer/loaders (M/L)							
1a) M/L liquids for high-pressure handwand applications (including right-of-way)	Livestock (lower rate)	Single layer gloves	9700	Single layer gloves	7500	Single layer gloves	5500
	Livestock (higher rate)	Single layer gloves	1900	Single layer gloves	1500	Single layer gloves	1100
	Ornamentals	Baseline	120	Baseline	120	Single layer gloves	7300
1b) M/L liquids for airblast application	Ornamentals	Baseline	120	Baseline	120	Single layer gloves	7300
2a) M/L WP for Aerial/Chemigation Applications	Nut Trees (6 lb/A)	Engineering Controls	23	Engineering Controls	22	Engineering Controls	16
	Fruit Trees (5 lb/A)	Engineering Controls	28	Engineering Controls	26	Engineering Controls	19
	Fruit/Nut Trees (3 lb/A)	Engineering Controls	46	Engineering Controls	43	Engineering Controls	31
	Grape/Veg. (1.5 lb/A)	Engineering Controls	92	Engineering Controls	86	Engineering Controls	63
	Grape/Tree Fruit(1 lb/A)	Engineering Controls	140	Engineering Controls	130	Engineering Controls	94
	Cotton	Engineering Controls	150	Engineering Controls	140	Engineering Controls	100
	Forestry	Engineering Controls	40	Engineering Controls	37	Engineering Controls	27

Attachment 1. Summary of Occupational Handler Exposure and Risk Assessments.

Scenario Number and Description	Crop Type or Target	Short-Term Exposures ≤7 days		Intermediate-Term Exposures >7 and ≤30 days		Intermediate-Term Exposures >30 days	
		Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE
2b) M/L WP for Groundboom Applications	Non-crop/field perim.	Single layer gloves	170	Single layer gloves+PF5 Respirator	200	Single layer gloves+PF5 Respirator	150
	Grape/Veg. (1.5 lb/A)	Engineering Controls	400	Engineering Controls	370	Engineering Controls	270
	Grape/Tree Fruit(1 lb/A)	Engineering Controls	600	Engineering Controls	560	Engineering Controls	410
	Cotton	Single layer gloves	105	Single layer gloves+PF5 Respirator	130	Single layer gloves+PF10 Respirator	110
2c) M/L WP for Airblast Applications	Nut Trees (6 lb/A)	Engineering Controls	200	Engineering Controls	190	Engineering Controls	140
	Fruit Trees (5 lb/A)	Engineering Controls	240	Engineering Controls	220	Engineering Controls	160
	Fruit/Nut Trees (3 lb/A)	Engineering Controls	400	Engineering Controls	370	Engineering Controls	270
	Grape/Veg. (1.5 lb/A)	Double layer gloves+PF5 Respirator	110	Double layer gloves+PF10 Respirator	100	Engineering Controls	550
	Grape/Tree Fruit(1 lb/A)	Double layer gloves+PF5 Respirator	130	Double layer gloves+PF5 Respirator	120	Double layer gloves+PF10 Respirator	110
	Ornamentals	Single layer gloves	1100	Single layer gloves	580	Single layer gloves	430
2d) M/L WP for High Pressure Handwand Applications	Ornamentals	Single layer gloves	1100	Single layer gloves	580	Single layer gloves	430
2e) M/L WP for Treating Pine Seedlings	Pine Seedlings	Single layer gloves+PF5 Respirator	150	Single layer gloves+PF5 Respirator	120	Single layer gloves+PF10 Respirator	100

Attachment 1. Summary of Occupational Handler Exposure and Risk Assessments.

Scenario Number and Description	Crop Type or Target	Short-Term Exposures ≤7 days		Intermediate-Term Exposures >7 and ≤30 days		Intermediate-Term Exposures >30 days	
		Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE
Occupational Applicators							
3) Applying Sprays w/Airblast Sprayer	Nut Trees (6 lb/A)	Engineering Controls	220	Engineering Controls	190	Engineering Controls	140
	Fruit Trees (5 lb/A)	Engineering Controls	260	Engineering Controls	220	Engineering Controls	160
	Fruit/Nut Trees (3 lb/A)	Engineering Controls	430	Engineering Controls	370	Engineering Controls	270
	Grape/Veg. (1.5 lb/A)	Engineering Controls	850	Engineering Controls	740	Engineering Controls	540
	Grape/Tree Fruit(1 lb/A)	Single layer gloves	100	Single layer gloves+PF5 Respirator	100	Engineering Controls	820
	Ornamentals	Baseline	930	Baseline	860	Baseline	630
4) Applying Sprays w/Groundboom Sprayer	Non-crop/field perim.	Baseline	3200	Baseline	2400	Baseline	1800
	Grape/Veg. (1.5 lb/A)	Baseline	530	Baseline	410	Baseline	300
	Grape/Tree Fruit(1 lb/A)	Baseline	800	Baseline	610	Baseline	450
	Cotton	Baseline	2000	Baseline	1500	Baseline	1100
5) Aerial Application of Sprays (fixed-wing aircraft, helicopter)	Nut Trees (6 lb/A)	Engineering Controls	96	Engineering Controls	89	Engineering Controls	65
	Fruit Trees (5 lb/A)	Engineering Controls	110	Engineering Controls	100	Engineering Controls	78
	Fruit/Nut Trees (3 lb/A)	Engineering Controls	190	Engineering Controls	180	Engineering Controls	130
	Grape/Veg. (1.5 lb/A)	Engineering Controls	380	Engineering Controls	350	Engineering Controls	260
	Grape/Tree Fruit(1 lb/A)	Engineering Controls	570	Engineering Controls	530	Engineering Controls	390
	Cotton	Engineering Controls	630	Engineering Controls	580	Engineering Controls	420
	Forestry	Engineering Controls	170	Engineering Controls	150	Engineering Controls	110

Attachment 1. Summary of Occupational Handler Exposure and Risk Assessments.

Scenario Number and Description	Crop Type or Target	Short-Term Exposures ≤7 days		Intermediate-Term Exposures >7 and ≤30 days		Intermediate-Term Exposures >30 days	
		Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE
6) Applying w/High Pressure Handwand	Livestock (lower rate)	Baseline	130	Baseline	100	Single layer Gloves	130
	Livestock (higher rate)	Double layer gloves+PF5 Respirator	130	Double layer gloves+PF5 Respirator	100	Double layer gloves+PF10 Respirator	88
	Ornamentals	Baseline	170	Baseline	140	Baseline	100
7) Applying w/Right-of-way Sprayer	Ornamentals	Baseline	270	Baseline	260	Baseline	190
8) Dipping Pine Seedlings	Pine Seedlings	No data	--	No data	--	No data	--
Occupational Mixer/loader/applicators (M/L/A)							
9) M/L/A w/Power Duster	Sweet Potatoes	No data	--	No data	--	No data	--
10) Dusting an Animal	Dog	No data	--	No data	--	No data	--
11) Dipping an Animal	Dog	No data	--	No data	--	No data	--
12) Use of a Cattle Backrubber	Cattle	Baseline	360	Baseline	360	Baseline	260
13a) M/L/A liquids w/Backpack Sprayer	Livestock (lower rate)	Single layer gloves	1000	Single layer gloves	940	Single layer gloves	690
	Livestock (higher rate)	Single layer gloves	200	Single layer gloves	190	Single layer gloves	140
	Ornamentals	Single layer gloves	1350	Single layer gloves	1250	Single layer gloves	920
13b) M/L/A WP w/Backpack Sprayer	Ornamentals	Single layer gloves	1350	Single layer gloves	1250	Single layer gloves	920

Attachment 1. Summary of Occupational Handler Exposure and Risk Assessments.

Scenario Number and Description	Crop Type or Target	Short-Term Exposures ≤7 days		Intermediate-Term Exposures >7 and ≤30 days		Intermediate-Term Exposures >30 days	
		Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE	Level of Personal Protection Assumed	MOE
14a) M/L/A liquids w/Low Pressure Handwand	Livestock (lower rate)	Single layer gloves	4950	Single layer gloves	3600	Single layer gloves	2600
	Livestock (higher rate)	Single layer gloves	990	Single layer gloves	720	Single layer gloves	530
	Ornamentals	Single layer gloves	6600	Single layer gloves	4800	Single layer gloves	3500
14b) M/L/A WP w/Low Pressure Handwand	Ornamentals	Single layer gloves	290	Single layer gloves	180	Single layer gloves	130
15) M/L/A SC for sprinkling	Fire Ants	Baseline	160	Baseline	160	Baseline	120
Occupational Flaggers							
16) Flagging for Aerial Spray Applications	Nut Trees (6 lb/A)	Engineering Controls	2100	Engineering Controls	1700	Engineering Controls	1300
	Fruit Trees (5 lb/A)	Engineering Controls	2500	Engineering Controls	2100	Engineering Controls	1500
	Fruit/Nut Trees (3 lb/A)	Engineering Controls	4100	Engineering Controls	3400	Engineering Controls	2500
	Grape/Veg. (1.5 lb/A)	Baseline	160	Baseline	140	Baseline	100
	Grape/Tree Fruit(1 lb/A)	Baseline	250	Baseline	200	Baseline	150
	Cotton	Baseline	270	Baseline	230	Baseline	170
	Forestry	Engineering Controls	3600	Engineering Controls	3000	Engineering Controls	2200

Attachment 2. Summary of Residential Handler Exposure and Risk Assessments.

Notes for the Following Table:

MOE= Margin of Exposure; reflects combined dermal and inhalation MOEs, unless otherwise indicated.
WP= Wettable Powder
SC= Soluble Concentrate

The assumptions used (e.g., amount handled, body weight, etc.) are described in detail in Appendix B of the 1/27/00 J. Dawson ORE chapter, D262366.

Scenario Description	Crop Type or Target	Combined Short-term MOE
1) Dusting an Animal	Dog (low rate)	>100,000 (Dermal only)
	Dog (high rate)	>100,000 (Dermal only)
2) Dipping a Dog	Dog	>100,000 (Dermal only)
3a) Mixing/loading/applying liquids w/Backpack sprayer	Ornamentals	5385
3b) Mixing/loading/applying WP w/Backpack sprayer	Ornamentals	4039
	Peas	11218
	Potatoes	11218
	Fruit Trees	2060
4a) Mixing/loading/applying liquids w/Low pressure handwand	Ornamentals	280
4b) Mixing/loading/applying WP w/Low pressure handwand	Ornamentals	83
	Peas	230
	Potatoes	230
	Fruit Trees	42
5a) Mixing/loading/applying liquids w/Garden hose-end sprayer	Ornamentals	932
5b) Mixing/loading/applying WP w/Garden hose-end sprayer	Ornamentals	699
	Peas	1942
	Potatoes	1942
	Fruit Trees	357
6) Mixing/loading/applying SC for sprinkling	Fire Ant	389

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