



Pesticide Fact Sheet

Name of Chemical: PHOSMET
Reason for Issuance: REGISTRATION STANDARD
Date Issued: 10/01/86
Fact Sheet Number: 101

1. DESCRIPTION OF CHEMICAL

Generic name: N-(mercaptomethyl)
phthalimide S-(O,O-dimethyl
phosphorolithioate)

Common name: Phosmet

Trade names: Phthalofos, PMP, Appa, Imidan,
Kemlate, Prolate, R-1504

EPA Shaughnessy Code: 059201

Chemical Abstract
Service (CAS) Number: 732-11-6

Year of Initial
Registration: 1966

Pesticide Type: Insecticide-acaricide

Chemical Family: Organophosphate

U.S. Producer: Stauffer Chemical Company

2. USE PATTERNS AND FORMULATIONS

Application Sites: Terrestrial food crops (field, vegetable and orchard crops such as alfalfa, apples, almonds, apricots, blueberries, citrus, corn, cotton, grapes, nectarines, pears, peaches, pecans, plums, and potatoes); terrestrial non-food crops (nursery and ornamental crops); domestic outdoor and indoor.

Types of formulations: Dust [1% and 5% active ingredient (A.I.)], wettable powders (7.5%, 12%, 12.5%, 50%, and 70% A.I.), impregnated resins (15% A.I.) and emulsifiable concentrates [1 pound (lb.) per gallon (gal.), 3 lb/gal, and 12.5% A.I.]

Methods of Application: Foliar applications, aerial applications, animal treatments, stored commodity treatments, and impregnated materials

Usual Carrier: Water

3. SCIENT FINDINGS

Phosmet is a member of a chemical family known as the organophosphates (OPs). OP pesticides act on the nervous system by interfering with an enzyme acetylcholinesterase. This effect (known as cholinesterase inhibition) is reversible once exposure stops. There are antidotes for this type of poisoning (atropine and 2-PAM). Phosmet has a moderate to low acute oral, dermal, and eye/skin irritation toxicity. It is moderately toxic (Toxicity Category II) to humans by ingestion. Additional data (acute inhalation and dermal sensitization) is required to complete the acute toxicity profile for technical phosmet. Insufficient data exist to fully assess the subchronic dermal, mutagenicity, oncogenicity, and general metabolism of phosmet. Reentry data is necessary in order to establish permanent worker reentry intervals.

Phosmet has been classified as a "tentative" category C carcinogen. This conclusion was reached after review of a 2-year mouse oncogenicity study. Additional studies are being required to complete the oncogenic assessment of the chemical. Currently available data indicate that phosmet does not cause neurotoxic, teratogenic, or reproductive effects.

The environmental fate of phosmet is not well documented. A review of preliminary data indicates phosmet is moderately mobile to immobile in soil and hydrolyzes rapidly in soil. The physical-chemical characteristics of the chemical indicate a potential for phosmet and possibly its degradates to contaminate groundwater. Hydrolysis, soil dissipation, anaerobic soil metabolism, leaching, photodegradation, and rotational crop and reentry data are required.

Phosmet is practically non-toxic to slightly toxic to birds, and mildly toxic to mammals. It is unlikely that phosmet would be lethal to birds or mammals after a single application. Available data indicates the possibility of reproductive effects in birds and mammals due to the buildup of phosmet on avian and mammalian food items (apples, corn, cotton, and alfalfa) from repeat applications. Residue monitoring data on these food items is required to determine the magnitude of exposure. Phosmet is highly toxic to honeybees, fish, aquatic and estuarine invertebrates. Field monitoring studies are being required to determine the magnitude of exposure from the major crop uses. Additional fish and aquatic invertebrate studies are being required to complete the evaluation of hazard.

Chemical Characteristics: Information listed below references the technical grade active ingredient unless specified as the pure active ingredient (PAI).

Physical state:	Crystalline solid
Color:	White to greyish-white
Odor:	Typical phosphorodithioate
Boiling point:	Not applicable - the technical is a solid at room temperature
Flash point:	Not available in Agency files
Melting point:	72.0 - 72.7°C (PAI)

Chemical Characteristics (continued)

Specific gravity:	1.03 at 20° C
Solubility:	At 20° C, in water, 25 ppm; acetone, > 1,000 grams/liter(g/l); kerosene, 10 g/l. xylene, 200 g/l.
Stability:	Not available in Agency files

Toxicological Characteristics:

Acute toxicity. Phosmet has moderate to low acute oral, dermal, and eye/skin irritation. Phosmet, like other organophosphate chemicals, can be absorbed by inhalation and skin penetration.

Acute Oral (rat): 113-304 mg/kg.

Acute dermal (rabbit): >3,160 mg/kg

Primary eye irritation: Produced mild redness when instilled in the unwashed eyes of 3 rabbits at 24 hours after exposure. Phosmet also produced corneal opacity, redness, chemosis, and discharge in 1 of 3 rabbits. Eyes were normal within 7 days.

Inhalation: Undetermined

Primary dermal: Non-irritant

Dermal sensitization: Undetermined

Chronic toxicity:

Oncogenicity: Phosmet has been classified as a "tentative" Category C carcinogen. This conclusion was reached after review of two (a 2-year mouse and a 2-year rat) oncogenicity studies. Phosmet was associated with a significantly elevated incidence of liver tumors (adenomas, and adenomas plus carcinomas combined) in male B6C3F₁ mice at the highest dose tested. These incidences were associated with liver hyperplastic changes and a decrease in the time to tumor occurrence. In female B6C3F₁ mice, the chemical was associated only with positive dose-related trends for liver adenomas and carcinomas. A 2-year rat oncogenicity study was considered inadequate (the number of animals sacrificed at the end of the study were too small to fully evaluate tumor responses). The chemical was essentially non-mutagenic (only one positive result occurred in a limited and inadequate battery of tests) and no positive correlation with respect to oncogenicity and mutagenicity could be made with known structural analogs. After a 2-year rat oncogenicity study and additional mutagenicity studies are submitted and evaluated, the Agency will reassess the oncogenicity issue and determine if dietary and worker risk assessments are necessary.

Mutagenicity: Phosmet was evaluated in several mutagenicity assays. The chemical was found to be positive only when tested in S. typhimurium strain TA-100. No mutagenicity study of phosmet was performed in mammalian cells in culture. Additional mutagenicity studies are required.

Teratogenicity: No teratogenic effects were reported for phosmet in oral teratology studies in monkeys (NOEL = 8.0 mg/kg) and rabbits (NOEL = 60 mg/kg).

Reproductive effects: Phosmet had no adverse reproductive performance effects in a 3-generation oral reproduction study in rats. (NOEL = 80 ppm).

Neurotoxicity: Delayed neurotoxic effects were not observed at levels up to 2,050 mg/kg of phosmet. Body weight, food consumption, and egg production were significantly decreased in the 2,050 mg/kg test group.

Metabolism: Data indicates that phosmet is rapidly eliminated, with 78% being eliminated in the urine and 19% in the feces within 72 hours after administration of a single oral dose in rats. However, the major water soluble urinary metabolites have only been "tentatively" identified. A general metabolism study will be required.

Physiological and Behavioral Characteristics: Mechanism of Pesticide Action - - organophosphate cholinesterase inhibition.

Environmental Characteristics and Groundwater Concerns: Few data are available on the environmental fate of phosmet. Phosmet appears to be moderately mobile to immobile in soils ranging in texture from sand to silty clay loam. Because of phosmet's physio-chemical properties the potential exists for phosmet, and possibly its degradates, to contaminate groundwater. To date the Agency is not aware of incidents where phosmet has contaminated groundwater. To fully assess and complete the environmental fate profile of phosmet, the Agency is requiring hydrolysis, soil dissipation, anaerobic soil metabolism, leaching, photodegradation, rotational crop and reentry data.

Ecological Characteristics:

Avian acute toxicity:	Mallard duck -	2009 mg/kg
Avian dietary toxicity:	Bobwhite quail -	501 ppm
	Japanese quail -	2000 ppm
	Mallard duck -	>5000 ppm
Avian reproduction:	Bobwhite quail -	60-150 ppm
	Mallard duck -	25-60 ppm
Fish:	Rainbow trout -	230 ppb
	Bluegill sunfish -	70 ppb
Aquatic invertebrates:	<u>Daphnia magna</u> -	5.6 ppb
	<u>Gamma fasciatus</u> -	2.0 - 4.2 ppb

Sufficient data are available to characterize technical phosmet as very highly toxic to warmwater fish and highly toxic to coldwater fish. The chemical is also very highly toxic to aquatic and estuarine invertebrates. Monitoring data in runoff water following terrestrial applications of phosmet is being required to complete the hazard assessment.

Phosmet is practically non-toxic to slightly toxic to birds and mammals. Phosmet may cause reproductive impairment in birds and mammals due to a buildup of residues on avian food items. Residue monitoring of avian and mammalian food items (apples, corn, cotton, and alfalfa) will be required to complete an evaluation of the reproductive hazards.

Phosmet is very highly toxic to honeybees and displays extended residual toxicity.

Endangered Species: Use on apple and pear orchards, alfalfa, corn, and cotton crops, could place endangered species in the vicinity of treated areas at risk. Also two endangered insect species in the vicinity of food crop uses in certain counties of California could be threatened. Residue monitoring data will be required to aid in completion of the assessment of hazards to endangered species.

Tolerance Assessment: Tolerances have been established for residues of phosmet in raw agricultural commodities, meat, fat and meat byproducts (40 CFR 180.261) and in processed food (21 CFR 193.279) for phosmet and its oxygen analog at levels ranging from 0.1 to 40.0 ppm.

The metabolism of phosmet in plants and animals is not adequately understood. Additional residue data and metabolism data will be required to reassess the adequacy of existing tolerances and to issue new tolerances. Processing studies are also being required for potatoes, apples, plums, peaches, grapes, field corn grain, and cottonseed.

The acceptable daily intake (ADI) for humans was based on a 2-year chronic feeding study in rats. The ADI in humans was calculated to be 0.02 mg/kg/day and the maximum permitted intake (MPI) is equal to 1.2 mg/kg/day with a NOEL of 40 ppm and a safety factor of 100. Using these calculations the percent utilization of the ADI would be 98.29 percent. Since virtually all of the ADI has been used up by the TMRC and the Agency is aware of a potential oncogenic response to phosmet, new tolerances and/or new uses will not be issued if they contribute significantly to the TMRC and/or result in a significant increase in the dietary exposure.

Reported Pesticide Incidents: In the period from 1978 to 1979, 67 incidents involving a flea dip formulation (Paramite) of phosmet were reported to the Agency. Of these 67 incidents, 39 involved cats only, 16 involved dogs only, 2 involved cats and dogs, 8 involved human reactions, and 2 involved dogs and human reactions. Reported mortalities from these incidents were 20 cats (one leukemic) and 12 dogs. Additional incidents of adverse animal reactions (primarily cats) involving the same formulation have been reported up through 1985. The Agency is re-evaluating the use of phosmet on pets.

ESTABLISHED PHOSMET TOLERANCES

<u>Commodity</u>	<u>Parts Per Million</u>
Alfalfa	40.0
Almond, hulls	10.0
Apples	10.0
Apricots	5.0
Blueberries	10.0
Cattle, fat	0.2
Cattle, meat	0.2
Cattle, mby	0.2
Cherries	10.0
Citrus fruits	5.0
Corn, fresh (including sweet K + 6 WHR)	0.5
Corn, fodder	10.0
Corn, forage	10.0
Corn, grain	0.5
Cottonseed	0.1
Cranberries	10.0
Goats, fat	0.2
Goats, mby	0.2
Goats, meat	0.2
Grapes	10.0
Hogs, fat	0.2
Hogs, mby	0.2
Hogs, meat	0.2
Horses, fat	0.2
Horses, mby	0.2
Horses, meat	0.2
Kiwi fruit	25.0
Nectarines	5.0
Nuts	0.1
Peaches	10.0
Pears	10.0
Peas	0.5
Peas, forage	10.0
Peas, hay	10.0
Plums (fresh prunes)	5.0
Potatoes	0.1
Sheep, fat	0.2
Sheep, mby	0.2
Sheep, meat	0.2
Sweet potatoes	10.0
Tomatoes	2.0
Cottonseed oil	0.2

4. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

- No referral to Special Review is being made at this time. A repeat rat oncogenicity study and additional mutagenicity studies must be submitted. The Agency will reassess the oncogenicity issue and determine if dietary and worker carcinogenicity risk assessments are necessary. The available data also indicate that phosmet is highly toxic to fish. Terrestrial residue analysis and aquatic runoff modeling indicate that certain use patterns could result in exposure of certain aquatic organisms to hazardous levels of the pesticide. Additional data are needed before the Agency can complete a full assessment of this hazard potential.
- The Agency will reassess the adequacy of the existing tolerances after required metabolism data and residue data are submitted.
- New tolerances and uses will be issued on a case-by-case basis.
- The tolerance expression for phosmet under 40 CFR 180.261 will be amended by deleting the reference to "cholinesterase-inhibiting" residues.
- The Agency has determined that endangered species label restrictions are necessary in order to prevent unreasonable adverse effects on the environment.
- In the absence of reports of fish kills following phosmet application and actual field monitoring data, the Agency will not restrict certain uses of phosmet to certified applicators, but has determined, based on the high toxicity of phosmet to aquatic organisms, that precautionary labeling will be required. The restricted use classification may be required if additional studies indicate that phosmet use poses risks to aquatic organisms that could be mitigated by increased controls in application.
- The Agency is imposing a 24-hour reentry interval. Foliar dissipation data are required on crops whose propagation requires human tasks that involve substantial, prolonged human contact.
- Protective clothing is required for mixers/loaders and applicators.
- The Agency will analyze the safety and efficacy data of a phosmet flea dip formulation (Paramite) to determine if further regulatory action is warranted. A warning statement indicating that improper dilution of the product could cause serious injury to pets is being required.
- The Agency has determined that the tolerance for cranberries should be revoked because there are no registered uses for phosmet on cranberries.
- The Agency is requiring processing data for the following agricultural commodities: potatoes, apples, plums, peaches, grapes, field corn grain, and cottonseed.

- The Agency is not requiring a rotational crop restriction. If required data demonstrate that follow-up crops take up phosmet residues from soil, rotational crop restrictions or tolerances in those crops may be necessary.
- The Agency is not imposing a ground water advisory statement on phosmet labeling at this time, but is requiring data to fully characterize the potential of this chemical to reach ground water.
- While data gaps are being filled, currently registered end-use products containing phosmet as the sole active ingredient may be sold, distributed, and used, subject to the terms and conditions specified in the Registration Standard.

5. SUMMARY OF MAJOR DATA GAPS

Product Chemistry

Product Chemistry	Feb. 1987
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Residue Chemistry

Plant/Livestock Metabolism	Feb. 1988
Plant/Animal Residues	Feb. 1988
Storage Stability	Feb. 1988

Environmental Fate

Hydrolysis/Photodegradation	-	July 1987
Mobility Studies		Sept. 1987
Accumulation (Rotational) Crops		Dec. 1989
Glove Permeability		Mar. 1987 - protocol
		Nov. 1987 - final report
Anaerobic Soil Metabolism		Dec. 1988
Soil Dissipation		Dec. 1988

Toxicology

Acute Inhalation Toxicity (rat)	July 1987
Dermal Sensitization	July 1987
21-Day Dermal (rabbit)	Sept. 1987
Oncogenicity (rat)	Nov. 1990
Gene Mutation	July 1987
Structural Chromosome Aberration	Sept. 1987
Other Genotoxic Effects	Sept. 1987
General Metabolism	Sept. 1988

Ecological Effects

Acute Toxicity to Freshwater Invertebrates	July 1987
Acute Toxicity to Estuarine and Marine Organisms	Sept. 1987
Fish Early Life Stage and Aquatic Invertebrate Life Cycle	Dec. 1987
Field Monitoring (avian, aquatic, and mammalian)	Feb. 1988

6. CONTACT PERSON AT EPA

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