United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington, DC 20460

540/FS-89-019

EPA Pesticide Fact Sheet

Name of Chemical: Phorate
Reason for Issuance: Registration Standard
Date Issued: December 1988
Fact Sheet Number: 34.2

1. DESCRIPTION OF CHEMICAL

Generic name: O,O-diethyl S-[(ethylthio)methyl] phosphorodithioate

Common name: Phorate

Trade Names: Thimet, AAstar and Rampart

Other Chemical Nomenclature: O,O-diethyl-S-(ethylthio) methyl phosphorodithioate and O,O-diethyl S-[(ethylthio)methyl] ester

EPA Pesticide Chemical (Shaughnessy) Number: 057201

Chemical Abstracts Service (CAS) number: 298-02-2

Year of initial registration: 1959

Pesticide type: Insecticide

Chemical family: Systemic Organophosphate

U.S. Registrants: American Cyanamid Company, Uniroyal Chemical Company Inc., Aceto Chemical Company Inc., Wilbur Ellis Co., Riverside Terra Corp., Farm Bureau Cooperative, and Platte Chemical Co.

2. USE PATTERNS AND FORMULATIONS

Application sites: Terrestrial food crop use on beans, corn (field and sweet), cotton, hops, peanuts, potatoes, sorghum, soybeans, sugar beets, sugarcane, barley and wheat.

Terrestrial non-food crop use on lilies (bulb production).

Formulations: Granular

Pests Controlled: Various leaf-feeding insects, mites, and soil insects

Methods of application: Soil and foliar applications (band, broadcast, in-furrow and drilling) using conventional ground and aerial equipment

3. SCIENCE FINDINGS

Summary Science Statement

Technical phorate is in Toxicity Category I by the oral, dermal and inhalation routes. The acute oral administration of phorate to hens did not cause a delayed neurotoxic effect. Based on results of acceptable subchronic and chronic feeding studies with rats and dogs, cholinesterase (plasma, blood or brain) is the primary target for phorate. Phorate does not produce oncogenic effects, based on results of acceptable chronic studies in rats or dogs. Phorate does not induce teratogenic effects, based on results of acceptable teratology and reproduction studies. Phorate did not cause a mutagenic response in several in vitro (microbial and mammalian cells) studies or in an in vivo dominant lethal study. Results of an acceptable metabolism study using male rats indicated that a large proportion of phorate labeled metabolites were excreted in urine and feces within 24 hours of dosing. The total radioactivity levels in tissues was low. The oxidative, phosphorylated products (metabolites of phorate which may be more potent anticholinesterase compounds through oxidative desulfuration and/or sulfide oxidation) represented a minor proportion of the phorate metabolites measured.

Based on acceptable laboratory data, technical phorate is characterized as very highly toxic to birds on an acute oral basis; highly toxic to birds on a dietary basis; very highly toxic to mammals on a dietary basis and very highly toxic to freshwater fish and aquatic invertebrates and estuarine and marine organisms on an acute toxicity basis. Results of the terrestrial field studies (Level 1) showed mortalities to avian and mammalian species. An aquatic field study (required in the 1984 Standard) is still in progress and is due in 1991.

Many of the tolerances for phorate are still not adequately supported. Additional data (residue studies, residue analytical methods, processing and cooking studies, poultry metabolism study and storage stability data) are needed before the Agency can

determine the adequacy of current tolerance levels and perform a tolerance reassessment. Based on the NOEL for brain cholinesterase in a one year dog study (0.05 mg/kg) and applying an uncertainty factor of 100, the Agency has calculated the Anticipated Residue Contribution (ARC) for the U.S. population average to be 0.000491 mg/kg/day, corresponding to 98% of the RfD. The ARC assumes residues are present at tolerance levels, but takes into account percent of crop treated, where possible. For children 1 to 6 years of age, the ARC occupies 235% of the RfD, and for non-nursing infants, the ARC occupies 331% of the RfD. The Agency is requiring processing and cooking studies to assess anticipated residue levels in meat and milk. The Agency expects that cooking and processing of meat and milk will reduce residues of phorate to levels which will be of little or no concern.

Chemical/Physical Characteristics of the Technical Material

Chemical/Physical Characteristics:

Color: pale straw to light brown (TGAI, 2749-106); colorless to very light yellow (TGAI, 241-212 and 241-213)

Physical state: liquid

Odor: characteristic of mercaptan containing compounds

Boiling Point: 118-120 ^{0}C, 0.8 mm Hg

Specific Gravity: 1.15 at 20 ^{0}C (TGAI, 2749-106); 1.17 at 25 ^{0}C (TGAI for 241-212 and 241-213)

Solubility: 50 mg/l in water; miscible with carbon tetrachloride, vegetable oils (unspecified), xylene, and unspecified alcohols, ethers and esters

pH: 5-7 (TGAI, 2749-106); 3.56-3.81 (TGAI, 241-212 and 241-213)

Viscosity: 80 cps at 21 ^{0}C

Corrosion: non-corrosive to steel, aluminum, porcelain,

fiberglass, and phenolic resins

Toxicology Characteristics

Acute Oral: Toxicity Category I (LD_50 of 3.7 and 1.4 mg/kg in male and female rats, respectively)

Acute dermal: Toxicity Category I (LD50 of 9.3 and 3.9 mg/kg in male and female rats, respectively)

Acute inhalation: Toxicity Category I (LD50 of 60 and 11 mg/m3 for male and female rats, respectively)

Primary dermal irritation: None Available. Not required since the toxicity of phorate prohibits the administration of appropriate dosage levels.

Primary eye irritation: None Available. Not required since the toxicity of phorate prohibits the administration of appropriate dosage levels.

Skin sensitization: None available. Not required due to the high acute toxicity of the chemical.

Delayed Neurotoxicity: Did not induce delayed neurotoxicity in an acceptable study in hens.

Subchronic non-rodent study: None available. Not required since acceptable chronic data for the non-rodent are available.

Subchronic rodent study: A rat study is available. The LEL in this study was 2.0 ppm (0.1 mg/kg/day); the NOEL was 0.66 ppm (0.033 mg/kg/day).

Chronic toxicity: Dog study is available (NOEL and LEL for systemic toxicity were 50 and 250 ug/kg/day, respectively). Mouse study is available (NOEL and LEL were .45 and .9 ug/kg/day, respectively). Rat study is available (LEL was 0.05 mg/kg/day, NOEL was not determined)

Oncogenicity: The rat combined chronic toxicity and oncogenicity study did not reveal any evidence that phorate

was oncogenic under the condition of that study. Based on a reevaluation of the mouse study, the evidence does not show that an MTD was attained. Confirmatory data are required.

Mutagenicity: Phorate was negative in all areas of mutagenicity testing (gene mutation, structural chromosome aberration and tests for other genotoxic effects)

Teratogenicity: A rat study is available (LEL for developmental toxicity, based on embryotoxicity, and maternal toxicity was 0.50 mg/kg and the corresponding NOEL for each was 0.25 mg/kg). A rabbit study is available (LOEL and NOEL for maternal toxicity was 0.5 and 0.15 mg/kg, respectively. The NOEL for developmental toxicity was 1.2 mg/kg, the highest dosage administered).

Reproduction: A mouse study is available (LEL was .45 mg/kg/day and the NOEL was .23 mg/kg/day).

Metabolism: A study in male rats is available. Results indicated that a large proportion of the administered 14C was recovered in urine and feces. Oxidative, phosphorylated products only represented a minor proportion of the metabolites measured.

Environmental Characteristics

Based on the results of an acceptable leaching study, ^{14}C phorate was reported to be very mobile to mobile in loamy sand, sandy loam, silt loam, and loam soils. The 1984 Registration Standard indicated that phorate has some potential to leach through the soil and contaminate groundwater. Based on recently submitted data, phorate does not appear to be a potential leacher. However, its sulfone and sulfoxide degradates show greater persistence and mobility in soil, and therefore may have a greater leaching potential. Since data are still outstanding, the Agency cannot fully assess phorate's potential for contaminating groundwater.

Ecological Characteristics

Based on acceptable acute data, technical phorate is characterized as very highly toxic to birds on an acute oral basis, highly toxic to birds on a dietary basis, very highly toxic to mammals on a dietary basis, and very highly toxic to freshwater fish and aquatic invertebrates and estuarine and

marine organisms on an acute toxicity basis.

- Acute LD50 (mallard):
  0.62 mg/kg
- Acute LD50 (chukar):
  12.8 mg/kg
- Dietary LC50
  248 ppm (waterfowl)
  441 ppm (upland gamebids)
  28 ppm (small mammals)
- Freshwater invertebrates toxicity (96-hr LC50) for amphipods: 0.68 ppb to 9 ppb
- Fish acute toxicity (96-hr LC50) for rainbow trout: 6 to 13 ppb
- Fish acute toxicity (96-hr LC50) for bluegill sunfish: 2 ppb; 5 ppb for bass
- Estuarine fish and invertebrates (LC_{50})
  0.11 to 1.9 ppb for shrimp and 1.3 to 5.0 ppb for spot and sheepshead minnow; for mollusks (900 ppb)

Tolerance Assessment

Tolerances for residues of phorate in or on food and feed commodities are published in 40 CFR 180.206. A tolerance for residues of phorate on the processed feed commodity, dried sugarbeet pulp, is published in 21 CFR 180.590. Tolerances are expressed in terms of phorate and its cholinesterase-inhibiting metabolites.

Based on data submitted in response to the 1984 Standard, the nature of the residue in plants is adequately understood. The nature of the residue in animals not adequately understood. A poultry metabolism study is required. The available data support the established tolerances for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on potatoes, sugar beets, sugar beet tops, sugar beet pulp, and soybeans. Additional data (residue studies, processing and cooking studies, residue analytical methods, poultry metabolism study and storage stability data) are needed before the Agency can determine the adequacy of current tolerance levels and perform a tolerance reassessment.

The Agency has performed a preliminary dietary exposure analysis using tolerance level residues and percent of crop treated where possible. The ARC for phorate for the U.S. population average is 0.000491 mg/kg/day. For the U.S. population average, the ARC occupies 98% of the ADI. For children 1 to 6 years of age, the ARC occupies 235% of the ADI, and for non-nursing infants, it occupies 331% of the ADI. The ARC is based on current tolerance levels, and, where possible, on percent of crop treated. Due to the significant contribution made by milk to the diet of children and non-nursing infants,

data regarding the reduction of residues through cooking and processing are required.

4. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

- Based on a high acute toxicity of phorate to avian species and the current registered uses of phorate, there exists a high potential for adverse effects to avian species from exposure to phorate granules at or near the soil surface. This potential for exposure to phorate is demonstrated from results of Level I studies and is confirmed by bird kill incidents. The Agency is currently evaluating these data in the context of a comparative risk assessment of granular pesticides which may pose a risk to birds. Based on this assessment, regulatory action may be taken.

- The Agency is not placing phorate into Special Review at this time for hazards to aquatic organisms. Available field reports and laboratory data indicate that the concentrations of phorate in the aquatic environment resulting from the registered uses of phorate might expose aquatic species to residue levels exceeding risk criteria for Special Review. Upon receipt and evaluation of the aquatic field study (due in 1991), a determination will be made regarding further regulatory action.

- Unique warning statements required include revised and updated fish and wildlife toxicity statements, reentry statements, and protective clothing statements.

- The Agency is requiring special acute and subchronic eye studies to evaluate phorate's effect on the eye.

- The Agency will not approve significant new uses for this chemical since many of the tolerances are still not adequately supported.

- The Agency will continue to restrict the use of products containing phorate. Phorate meets the risk criteria of 40 CFR 152.170 due to acute oral and dermal toxicity and bird toxicity.

- The Agency is still unable to fully assess phorate's potential for contaminating groundwater. Upon receipt of a terrestrial field dissipation study, and other requested environmental fate data, the need for groundwater monitoring will be determined.

SUMMARY OF OUTSTANDING DATA REQUIREMENTS

Toxicology	Time Frame
Special Testing for Eye Effects	9-18 Months
Metabolism	24 "
Mouse Short-term Study	12 "

Environmental Fate/Exposure

Hydrolysis	9 Months
Photodegradation in Water	9 Months
Photodegradation on Soil	9 "
Aerobic Soil Metabolism	27 "
Anaerobic Soil Metabolism	27 "
Lab Volatility	12 "
Soil Dissipation	27 "
Confined Rotational Crop	39 "
Accumulation in Fish	12 "
Foliar Dissipation	18 "
Soil Dissipation	18 "

Fish and Wildlife

Avian Reproduction	24 Months
Estuarine/Marine Organism Testing (TEP)	12 "
Freshwater and Estuarine Fish Early Life Stage Life-Cycle Study	15 "
Freshwater and Estuarine Invertebrate Life-Cycle Study	15 "
Aquatic Organism Field Testing	January, 1991

Residue Chemistry

Residue data - Raw Agricultural Commodities	18 Months
Processing Studies	24 "
Poultry Metabolism	18 "
Cooking Studies	24 "
Storage Stability	15 "
Residue Analytical Methods	15 "

Product Chemistry

Majority of Data	9 -15 Months

6. Contact Person at EPA

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