

SEPA Pesticide **Fact Sheet**

Name of Chemical: TERBUFOS

Reason for Issuance: REGISTRATION STANDARD AMENDMENT / CLASSIFICATION FOR RESTRICTED USE

Date Issued: Feb. 1, 1985

Fact Sheet Number:

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1. Description of Chemical

Generic name: S-[[(1,1-dimethyl-ethyl)thio]methyl] 0,0-

diethyl phosphorodithioate

Common name: Terbufos Trade name: Counter

EPA Shaughnessy code: 105001

Chemical Abstracts Service (CAS) number: 13071-79-9

Year of initial registration: 1974 Pesticide type: insecticide-nematicide

Chemical family: organophosphate

U.S. and foreign producer: American Cyanamid Company

Use Patterns and Formulations

Application sites: Corn, sugar beets, and grain sorghum Types of formulations: granular Types and methods of application: soil incorporation Application rates: vary according to formulation and crop Usual carriers: Confidential Business Information

Science Findings 3.

Summary science statement:

Terbufos is highly toxic to humans, fish and wildlife. Due to a number of major data gaps, the Agency cannot complete a full risk assessment until the data required under this Standard have been submitted and reviewed.

Reassessment of established tolerances must await receipt and evaluation of required toxicological studies. Available chronic toxicity studies are only supplementary data, and a "No Observable Effect Level" (NOEL) cannot be established at this time, and a maximum permissible intake (MPI) cannot be calculated.

Chemical characteristics:

Terbufos, an organophosphate, is a clear slightly brown liquid. It is relatively stable in water under neutral or slightly acidic conditions but is subject to hydrolysis under alkaline conditions. It decomposed on prolonged heating at temperatures greater than 120°C. does not present any unusual handling hazards.

Toxicology characteristics:

Current available toxicology studies on terbufos are as follows:

- Oral LD₅₀ in rats: from 1.3 to 1.57 mg/kg in females and 1.6 to 1.74 mg/kg in males (Tox category I)
- Dermal LD50 in male rate: 1.0 mg/kg (Tox category I)
- Eye irritation: due to the high acute toxicity of the chemical and the rapid death of animals, eye irritation scores were not reported
- Dermal irritation: due to the high acute toxicity of the chemical and the rapid death of animals, skin irritation scores were not reported

Symptoms of acute cholinesterase inhibition were reported in all acute studies.

- Multigeneration reproduction study in rats: NOEL of 0.25 ppm and LEL of 1.0 ppm based on noted increase in the percentage of litters with offspring death in each of the three generations as compared to the controls.
- Chronic feeding/oncogenicity in rats: both the ChE NOEL and the systemic NOEL appear to be lower than 0.25 ppm (LDT). The oncogenic potential of terbufos could not be assessed because too few animals of each group were histologically examined. Exophthalmus was noted in treated females in a dose-related fashion during the first year. This effect appeared to subside during the second year of the study.
- 6-month chronic feeding in dogs: a ChE of 0.0025 mg/kg/ day for both plasma and red blood cells cholinesterase inhibition. However, it is not clear how the dosage was mixed with the feed and how homogeneous the distribution of the test substance was in the diet. Also, the raw data were not available. A one-year study is now required.
- 18-month oncogenicity in mice: the oncogenic potential of terbufos could not be determined because too few animals were histologically examined. Dose-related exophthalmia was noted in treated males during the first year. This effect subsided in the second year.
- Two 90-day subchronic feeding studies in rats: both studies reflected a ChE NOEL of 0.25 ppm; one study reflected a systemic NOEL of 0.25 ppm. A systemic NOEL could not be determined for the other study because histological data were not reported.

- 28-day feeding study in dogs: only one dose (0.05 mg/kg) was tested at 6 and 7 days/week exposure. Both groups of animals showed similar levels of ChE activities with plasma ChE being significantly inhibited (79% inhibition) while no inhibition was observed in RBCChE activity.
- 30-day dermal study in rabbits: systemic NOEL was determined to be 0.02 mg/k for the technical material.
- Acute delayed neurotoxicity in hens: terbufos did not produce signs of neurotoxicity after the second 21day dosing period using the technical material at 40 mg/kg (the LD₅₀ dosage).
- Mutagenicity: the Ames test on bacterial system was performed with and without microsomal activation with negative results.

Additional data are needed to fully assess the toxicity of terbufos.

Environmental characteristics:

Based on available data, terbufos is not expected to leach into ground water. However, additional data are needed to fully assess the environmental fate of terbufos.

Ecological characteristics:

The following data are available:

- Avian oral LD50: 28.6 mg/kg (highly toxic)
- Avian dietary LC50: 143 ppm (highly toxic)
- Fish LC50: 0.77-3.8 ppb (bluegill sunfish); 9.4-20.0 ppb (trout)
- Aquatic invertebrate LC50: 0.31 ppb for Daphnia magna (very highly toxic)

The Agency is requiring further monitoring of water, sediment, and fish; in ponds adjacent to treated fields, to fully assess the potential hazard to nontarget aquatic species. Avian and mammalian field testing are required to assess the potential hazard to terrestrial organisms.

Efficacy review results:

None required.

Tolerance assessments:

Tolerances have been established, under 40 CFR 180.352, for combined residues of terbufos and its cholinesterase-inhibiting metabolites in or on the following raw agricultural commodities:

Commodity	PPM
Beets, sugar; roots	0.05 negligible residues (N)
Beets, sugar; tops	0.1
Corn, field; fodder,	0.5
forage	
Corn, pop; fodder, forage	0.5
Corn, grain	0.05(N)
Corn, sweet (kernel + cob	0.05(N)
with husk removed)	
Corn, sweet; fodder, forage	0.5
Sorghum; fodder, forage	0.5
Sorghum; grain	0.05

There are currently no food or feed addivitve tolerances and it has been determined that none are required for food and/or feed byproducts of these commodities.

There are no tolerances for meat, milk, poultry and eggs, nor are any required since there is no reasonable expectation of finite residues occuring in these foods from feed use of the raw agricultural commodity including their processing byproducts. Request for new livestock feed crops, however, may require tolerances for meat, milk, poultry and eggs.

The established tolerances for terbufos are presently expressed in terms of terbufos and its cholinesterase-inhibiting metabolites without specifying the latter as phosphorylated metabolites. The Agency will proceed towards revising 40 CFR 180.352 by changing the wording to read "....terbufos and its phosphorylated (cholinesterase inhibiting) metabolites".

Reassessment of the established terbufos tolerances must await receipt and evaluation of pertinent toxicological studies. Available chronic toxicity studies are only supplementary data and thus may not be used as a basis for tolerance assessment. Consequently, a "No Observable Effect Level" (NOEL) cannot be established at this time, hence a maximum permissible intake (MPI) cannot be calculated.

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The Pesticide Incident Monitoring System (PIMS) reports through June, 1981, include 31 reports involving terbufos, of which 19 involved terbufos alone. Of these 19 incidents, 9 involved humans, 8 involved domestic livestock and 2 involved wildlife. No human fatalities resulted. In those human exposure incidents which were reported with some detail, it appears that carelessness or negligence were important factors. In two of these incidents, the granular pesticide was reported to have been handled with bare hands during loading and application procedures.

In those instances involving livestock, one resulted in the death of about 600 cattle, another in the death of 127 cattle. The accidental contamination of livestock feed was reported as the cause in these incidents.

The two wildlife instances involved fish kills which were reportedly due to runoff from treated fields. Only one included analysis of the water samples. Though the sampling agnecy was unable to test for terbufos, no evidence of organophosphorus compounds was found in the sampled water.

Careless and/or negligence appear to have been important factors in most incidents. Strict adherence to proper storage and application techniques as prescribed in the label directions and precautions will minimize the risk of potential adverse effects to humans and domestic animals.

4. Summary of Regulatory Position and Rationale:

Use classification: Based on the acute oral and dermal toxicity, granular end-use products containing 15% or more terbufos are classified for "Restricted Use". All such products released for shipment on September 1, 1985, or thereafter, must be labeled for restricted use. Similarly, all such products which are in channels of trade on or after September 1, 1986 must bear restricted use labeling.

Restrictions: end-use products formulated from manufacturinguse products under the standard must be granular formulations for ground incorporated application only.

Unique warning statements:

- Labeling of manufacturing-use products must contain the following statements:

"Wear protective clothing, rubber gloves and goggles."

- "Wear a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provision of 30 CFR Part 11 for organic phosphate protection."
- Labeling of end-use products must contain the statements:
 - "Restricted Use"
 - "Wear protective clothing, gloves and goggles."
 - "Not for use or storage in or around the home."

5. Summary of major data gaps:

- Toxicology: inhalation LC₅₀, 2 chronic feeding studies, 2 oncogenicity studies, 2 teratogenicity studies, and additional mutagenicity studies. These studies must be submitted no later than June, 1986.
- Wildlife and Aquatic Organisms: avian reproduction, simulated and actual field testing mammals and birds, fish early life stage and aquatic invertebrate life-cycle; and acute LC₅₀ for estuarine and marine organisms. These studies must be submitted no later than June, 1986.
- Environmental Fate: photodegradation in water, lab volatitily study, rotational crop field study, and monitoring studies (soil and water, sediment and fish). These studies must be submitted no later than June, 1986.

6. Contact Person at EPA

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