United States
Environmental Protection
Agency

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

EPA

Pesticide Fact Sheet

Name of Chemical: DISULFOTON
Reason for Issuance:
Date Issued: Dec. 31, 1984
Fact Sheet Number: 43

1. DESCRIPTION OF CHEMICAL

Generic Name: 0,0-diethyl S-[2-(ethylthio)ethyl] phosphorodithioate

Common Name: Disulfoton

Trade Name: Di-Syston

EPA Shaughnessy Code: 032501

Chemical Abstracts Service (CAS) Number: 298-04-4

Year of Initial Registration: 1958

Pesticide Type: Insecticide/Acaricide

Chemical Family: Organophosphate

U.S. and Foreign Producers: Mobay Chemical Corp.

2. USE PATTERNS AND FORMULATIONS

Application Sites: Grain crops, nut crops, cole crops, root crops, pome, strawberry and pineapple fruits, forage, field and vegetable crops, sugarcane, seed crops, forest plantings, ornamentals, and potted plants (including houseplants)

Types of Formulations: Emulsifiable Concentrates, granulars, pelleted/tableted, and ready to use liquids

Types of Methods of Application: Soil incorporation of granulars, ground and aerial spray and granular broadcast applications

Application Rates: Range from 0.25 lbs. a.i./A to 8 lbs. a.i./A for broadcast applications and .25 oz ai.i./1000 ft. row to 10 oz. a.i./1000 foot row for band treatment; also individual potted plant soil treatment uses at various rates depending on plant and pot size.

Usual Carriers: Synthetic clays, various solvents, fertilizers

3. SCIENCE FINDINGS

Summary Science Statement

Disulfoton is very highly toxic to all mammalian systems by all routes of exposure and is assigned to Toxicity Category I, on the basis of acute toxicity requiring the most stringent labeling precautions and use restrictions. It is not considered to be oncogenic, mutagenic, or teratogenic based upon existing data. However, additional studies in a second species are being requested to fully assess oncogenic and teratogenic potential. Additional mutagenicity studies are also being required. Reproduction data is lacking and is required.

Due to the high acute toxicity and cholinesterase inhibition of disulfoton the Agency is imposing a 24-hour reentry restriction for crop uses until appropriate reentry studies and dermal absorption data are submitted and evaluated and a decision is reached whether a different time interval is more appropriate.

Data are insufficient to assess the environmental fate of disulfoton. The Agency is requesting necessary data to make this assessment and also to specifically assess whether or not disulfoton will leach into groundwater. Considering the high acute toxicity of disulfoton spray drift data are being required to measure human and non-target organism exposure resulting from spray applications and dermal and inhalation exposure data are being required to measure worker exposure in outdoor applications.

Disulfoton is very highly toxic to fish, mammals, highly toxic to birds, and moderately toxic to honey bees. Full field monitoring studies are required for the terrestrial uses to assess the exposure potential. Based on these results and on the results of the outstanding environmental fate data, chronic studies for both aquatic and terrestrial species may

be required as well as full field monitoring studies for the aquatic uses. Use precautions and restriction are being imposed in the interim to reduce potential hazards.

A number of terrestrial and aquatic endangered species have been identified as at risk from the use of a number of chemicals, including disulfoton on certain crops. This issue is currently being addressed as part of a cluster approach. Interim labeling to protect these species may be necessary if the cluster analysis is not completed by 1986.

A full tolerance reassessment cannot be completed. The previous ADI was established using a rat chronic feeding study which was found to be unacceptable. The present Provisional ADI was based on a dog chronic feeding study. The percent of the PADI utilized is 169%. A second rat chronic feeding study is required, as well as animal metabolism data to quantify and qualify disulfoton oxidation metabolites in meat, milk, poultry and eggs and residue data on numerous commodities. The Agency is requiring that when the tolerance reassessment is made, after receipt of the requested data, all tolerances are to be calculated and expressed in terms of disulfoton sulfone, the major metabolite, rather than as demeton (which is how the Agency previously expressed tolerances for disulfoton).

Chemical Characteristics

Physical State: Liquid

Color: Pale yellow

Odor: Unknown

Boiling Point: 62° C at 0.01 mm/Hg

Vapor Pressure: 1.8×10^{-4} millibars at 20° C

Flash Point: >180° F(TOC)

Toxicology Characteristics

Acute Oral: 1.9 - 6.2 mg/kg, Toxicity Category I

Acute Dermal: 3.6 - 15.9 mg/kg. Toxicity Category I

Primary Dermal Irritation: NA since chemicals toxicity would preclude testing for this requirement

Acute Inhalation: One study, which did not meet Agency standards, indicated toxicity at 0.2 mg/l, which would place it in Toxicity Category I.

Neurotoxicity: One study was submitted which did not meet Agency standards. The study did not indicate delayed neurotoxic effects.

Oncogenicity: Two studies have been evaluated; one was acceptable and did not suggest oncogenic potential.

Teratogenicity: Two studies were evaluated; one was acceptable and the other did not fully meet the Agency standards. The chemical is not teratogenic at 0.3 mg/kg/day.

Reproduction - 2 generation: Data gap

Metabolism: The available studies suggest that disulfoton is rapidly absorbed and may undergo sequential oxidation steps that enhance anti-cholinesterase properties. Excretion is complete and rapid via urine. Major metabolites include the O-analog of disulfoton, and the sulfoxide and sulfone derivatives of both disulfoton and its O-analog. Data to further describe the nature and dynamics of this process are necessary.

Mutagenicity: Contradictory reports are available on the mutagenic potential of disulfoton. The Agency has concluded that the mutagenic potential is not adequately defined and further testing is necessary.

Physiological and Biochemical Behavioral Characteristics

Mechanism of Pesticidal Action: A plant systemic insecticide which is active by contact, ingestion, and vapor action. Disulfoton and its major metabolites are potent cholinesterase inhibitors primarily attacking acetylcholinesterase. Poisoning and death results from excessive stimulation of both the parasympathetic and central nervous systems, and the consequent myoneural junction effect as a result of acetylcholinesterase accumulation.

Symptoms of Poisoning: headache, dizziness, extreme weakness, ataxia, tiny pupils, twitching, tremor, nausea, slow heartbeat, pulmonary edema, and excessive sweating. Continual daily absorption at intermediate doses may cause influenza-like illness characterized by weakness, anorexia, and malaise.

Metabolism and Persistence in Plants and Animals:

The metabolism of disulfoton in plants is adequately understood. The major plant metabolite appears to be disulfoton sulfone. Consequently the Agency believes that the tolerances for disulfoton residues should be expressed as disulfoton sulfone.

The metabolism in animals is not well understood. More data are required to quantify and qualify animal metabolites, and to quantify plant metabolites.

Environmental Characteristics

Available data are insufficient to assess the environmental fate of disulfoton. Data gaps exist for virtually all required studies. In order to characterize the potential of the chemical to contaminate groundwater adsorption and leaching studies are being requested by the Agency.

Droplet Size Spectrum Testing and Drift Field Evaluation studies are being requested in order to determine the magnitude of exposure to non-target organisms.

Ecological Characteristics

Avian Oral:
- Mallard duck — 6.54 mg/kg
- Bobwhite Quail — 12-31 mg/kg

Avian dietary:
- Mallard duck — 510-692 ppm
- Bobwhite quail — 541-715 ppm
- ring-necked pheasant — 634 ppm

Freshwater fish:
- coldwater fish (rainbow trout) — 3.0 ppm
- warmwater fish (bluegill sunfish) — 0.039 ppm

Acute Freshwater Invertebrates: (All studies listed were not conducted according to Agency standards)

Acute Estuarine and Marine Organisms: Data gaps

Precautionary language is being required to mitigate hazards to birds, fish, and aquatic organisms. Additional labeling to protect identified endangered species may be required at a later date. Because of the lack of environmental fate and field monitoring data to quantify exposure of disulfoton to these organisms, the Agency can not quantify the hazard potential. Additional chronic toxicity studies may be required depending on the results of the environmental fate and field monitoring data.

Tolerance Assessment

The Agency is unable to complete a tolerance reassessment because of certain residue chemistry and toxicology data gaps.

Tolerances:

Commodity	Parts Per Million
alfalfa (fresh)	5.0
alfalfa (hay)	12.0
asparagus	0.1
barley (fodder, green)	5.0
barley (grain)	0.75
barley (straw)	5.0
beans (dry)	0.75
beans (lima)	0.75
beans (snap)	0.75
beans (vines)	5.0
beets, sugar (roots)	0.5
beets, sugar (tops)	2.0
broccoli	0.75
brussels sprouts	0.75
cabbage	0.75
caulifower	0.75
clover (fresh)	5.0
clover (hay)	12.0
coffee beans	0.3
corn, field (fodder)	5.0
corn, field (forage)	5.0
corn, grain	0.3
corn, pop	0.3
corn, pop (fodder)	5.0
corn, pop (forage)	5.0

Tolerances (con't):

Commodity	Parts Per Million
corn, sweet (fodder)	5.0
corn, sweet (forage)	5.0
corn, sweet, grain (kernels plus cob with husks removed)	0.3
cottonseed	0.75
hops	0.5
lettuce	0.75
oats (fodder, green)	5.0
oats (grain)	0.75
oats (straw)	5.0
peanuts	0.75
peanuts (hay)	5.0
peanuts (hull)	0.3
peas	0.75
peas (vines)	5.0
pecans	0.75
peppers	0.1
pineapples (forage)	5.0
potatoes	0.75
rice	0.75
rice (straw)	5.0
sorghum (fodder)	5.0
sorghum (forage)	5.0
sorghum (grain)	0.75
soybeans	0.1
soybeans (forage)	0.25
soybeans (hay)	0.25
spinach	0.75
sugarcane	0.3
tomatoes	0.75
wheat (fodder, green)	5.0
wheat (grain)	0.3
wheat (straw)	5.0

Based on established tolerances the theoretical maximum residue contribution (TRMC) for disulfoton residue in the human diet is calculated to be 0.2544 mg/day. The provisional acceptable daily intake (PADI) of disulfoton is 0.0025 mg/kg/day. The maximum permissable intake (MPI) for a 60 kg person is 0.15 mg/day. The percent of the ADI utilized is 169%. However a reassessment of the current tolerances based on actual constituents of the plant residues (metabolites) is necessary as well as toxicity

data on the most toxic metabolite. Conformity of U.S. tolerances with Canada and Codex Alimentaruis tolerances is withheld pending receipt and evaluation of appropriate data referred to above.

U.S. tolerances for most raw agricultural commodities are not supported by current residue data. More data are required.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

The Agency has determined that it should continue to allow the registration of disulfoton. Adequate studies are available to assess the acute toxicological effects of disulfoton to humans. None of the criteria for unreasonable adverse effects listed in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded. However, because of certain gaps in the data base a full risk assessment of disulfoton cannot be completed.

Also, a full tolerance reassessment cannot be completed because of certain residue chemistry and toxicology data gaps.

The Agency is concerned about whether or not the potential total human exposure to disulfoton and its metabolites, both from direct and indirect human contact and the exceeded ADI, poses any unacceptable hazards. To resolve this concern, additional residue, metabolism and exposure data are required, and until it is resolved no new uses will be granted.

All end-use products formulated at greater than 2% are classified for Restricted Use, pending receipt and evaluation of appropriate acute toxicity data. Acute toxicity data on products 2% and less are being required in order to determine the appropriateness of a Restricted Use classification. These steps are being taken due to the extreme toxicity of disulfoton and the lack of product specific acute toxicity data.

A federal 24-hour reentry interval is established for treated crop areas until reentry and dermal absorption data are submitted, as required, and the Agency decides on the most appropriate time interval.

Available data are insufficient to fully assess the environmental fate of disulfoton. The Agency is requesting data to determine if disulfoton will contaminate groundwater.

Toxicity data available for disulfoton indicates that it is highly toxic to aquatic, terrestrial and avian species. Data to assess the extent of the potential exposure is currently lacking and is required to complete the hazard assessment.

5. SUMMARY OF MAJOR DATA GAPS

Additional residue data on various raw agricultural and processed commodities are being required. Also additional chronic toxicity, oncogenicity, and mutagenicity data are needed to better define the long term effects of this chemical. Plant and animal metabolism, exposure, spray drift, reentry and subchronic toxicity data are required to better qualify and quantify human exposure to residues of disulfoton and its metabolites, both from dietary and non-dietary sources.

Other requirements

Acute Inhalation
Acute oral, dermal and inhalation studies on formulating intermediates and end-use products
Acute delayed neurotoxicity
Dermal absorption study
Product Integrity study
Hydrolysis study
Photodegradation studies
Soil and Water Metabolism studies
Mobility studies
Volatility studies
Dissipation studies
Accumulation studies
Large Scale Field Monitoring studies
Acute freshwater invertebrates testing
Acute estuaring and marine organisms testing
Honey bee toxicity of residues on foliage study

6. COMPLIANCE DATES FOR REVISED LABELING

-For addition of RESTRICTED USE classification to product formulations containing greater than 2% disulfoton. All such products released for shipment after September 1, 1985 must bear RESTRICTED USE labeling. All such products in the channels of trade after September 1, 1986 must be labeled for RESTRICTED USE.

-For intrastate products the Agency is requiring submission of applications for full registration of all intrastate products containing disulfoton by December 31, 1985. Holders of such intrastate products who request withdrawal or who fail to respond to the notification, may not distribute or sell the intrastate product after December 31, 1985. Products already in the channels of trade as of that date may continue to be distributed and sold by dealers and retailers until June 30, 1986. Any product found in the channels of trade after June 30, 1986 will be considered to be in violation of FIFRA sec. 12(a)(1)(A).

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