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: FORMETANATE
Reason for Issuance:
Date Issued: September 30, 1983
Fact Sheet Number: 11

1. DESCRIPTION OF CHEMICAL

Generic Name: N,N-dimethyl-N'-[3-[[(methylamino)carbonyl] oxy]phenyl] methanimidamide monohydrochloride

Common Name: Formetanate hydrochloride(HCl)

Trade Name: Carzol

EPA Shaughnessy Code: 097301

Chemical Abstracts Service (CAS) Number: 23422-53-9

Year of Initial Registration: 1969

Pesticide Type: Acaricide/Insecticide

Chemical Family: methylcarbamate hydrochloride

U.S. and Foreign Producers: Imported into the U.S. from West Germany where it is manufactured by Schering A.G. Chemical Company. In the U.S., the sole importer and distributor of the chemical is Nor-Am Chemical Company.

2. USE PATTERNS AND FORMULATIONS

Application Sites: Citrus, pome and stone fruits and alfalfa grown-for-seed.

Types of Formulations: 92% soluble powder

Types of Methods of Application: Ground and aerial

Application Rates: Range from 0.0575 lbs. a.i./A to 1.38 lbs. a.i./A

Usual Carriers: Water

3. SCIENCE FINDINGS

Summary Science Statement

Formetanate HCl is highly toxic from an oral route of exposure. It demonstrates low toxicity from the dermal route of exposure and moderate toxicity from the inhalation route of exposure. It is considered to be an eye irritant. The chronic studies are data gaps.

Formetanate HCl appears to leach in soil and therefore has a potential for contamination of groundwater. However, available data are insufficient to fully assess the environmental fate of this chemical. A 24-hour reentry interval has been established.

This chemical is highly toxic to birds. It is slightly toxic to fish and moderately toxic to estuarine and marine organisms.

A tolerance reassessment cannot be made until the studies required to fill the toxicology data gaps have been submitted and validated. A petition for a tolerance for residues in or on alfalfa hay and alfalfa forage must be submitted. A food additive petition must be submitted for apple pomace.

Chemical Characteristics

Physical State: Crystalline solid

Color: White

Odor: Essentially odorless

Melting point: 200-202° C

Toxicology Characteristics

Acute Oral LD_{50}: 26.4 mg/kg (rat), Toxicity Category I

Acute Dermal LD_{50}: > 10,000 mg/kg (rabbit), Toxicity Category III

Primary Dermal Irritation: No irritation (rabbit), Toxicity Category IV

Primary Eye Irritation: One-fifth of the animals (rabbit) showed irritation at a 7-day observation period. The effect was considered to be presumptively not reversible in 21 days.

Acute Inhalation LC_{50}: 0.29 mg/liter (rat), Toxicity Category II

The chronic studies are data gaps. The original studies were conducted by IBT and have been determined to be invalid. No replacement studies have been submitted. A

commitment has been made by Nor-Am Chemical Company to replace the IBT studies.

A risk assessment cannot be completed at this time due to gaps in the data base.

Physiological and Biochemical Behavioral Characteristics

Mechanism of Pesticidal Action: A contact insecticide which causes reversible carbamylation of the acetylcholinesterase enzyme. Poisoning also impairs the central nervous system function.

Metabolism and Persistence in Plants and Animals: In plants, formetanate HCl is absorbed into the leaves but is not translocated to untreated areas. On the fruit, weathering and growth dilution appear to be the primary cause of the dissipation of formetanate HCl. In animals, formetanate is eliminated in the urine and feces. The major metabolic pathway involves hydrolysis to metabolites and subsequent formation of the glucuronide and ethereal sulfate conjugates of m-acetamidophenol.

Environmental Characteristics

Available data are insufficient to fully assess the environmental fate of formetanate HCl. It appears to rapidly degrade in soil under aerobic conditions. This chemical appears to leach in soil and, therefore has a potential for groundwater contamination. A 24-hour reentry interval has been established for this chemical on orchard crops.

Ecological Characteristics

Avian oral LD_{50} -
Mallard duck: 11.7 mg/kg
Bobwhite quail: 43.1 mg/kg

The avian dietary LC_{50} studies, freshwater fish LC_{50} studies and acute LC_{50} freshwater invertebrate studies are data gaps.

Formetanate HCl is characterized as highly toxic to birds. It is slightly toxic to warmwater fish and moderately toxic to estuarine and marine organisms. It is moderately toxic

to honey bees with direct contact spray, but it has very low toxicity to bees when they are exposed to residues on plants.

Tolerance Assessments

A full tolerance reassessment cannot be completed because of certain residue chemistry and toxicology data gaps. The current values for the acceptable daily intake intake(ADI) of 0.025 mg/kg/day and the maximum permissible intake(MPI) of 1.5 mg/kg/day are provisional. This is because a number of multiple dose toxicity studies submitted to establish the ADI/MPI were conducted by IBT and have been determined to be invalid. Another reassessment and recalculation will be made when the studies required to fill the toxicology data gaps are submitted and reviewed.

A petition for tolerance for residues in or on alfalfa forage and alfalfa hay must be submitted to support the alfalfa grown-for-seed use. No residue data are available. A petition for a food additive tolerace for apple pomace must be submitted.

Tolerances:

Commodity	Parts Per Million
Peaches	5
Grapefruit	4
Lemons	4
Limes	4
Nectarines	4
Oranges	4
Tangerines	4
Apples	3
Pears	3
Plums(fresh prunes)	2

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

The Agency has determined that it should continue to allow the registration of formetanate HCl. Adequate studies are available to assess the acute toxicological effects of formetanate HCl to humans. None of the criteria for unreasonable adverse effects listed in 40 CFR §162.11(a) have been met or exceeded. However, because of gaps in the data

base a full risk assessment of formetanate HCl cannot be made at this time.

A full tolerance reassessment cannot be completed because of residue chemistry and toxicology data gaps.

Available data are insufficient to fully assess the environmental fate of carbaryl. A 24-hour reentry interval has been established for formetanate HCl. This chemical appears to have the potential to contaminate groundwater.

5. SUMMARY OF MAJOR DATA GAPS

Residue data on alfalfa
Chronic feeding studies - 2 species
Oncogenicity studies - 2 species
Teratogenicity studies - 2 species
Reproduction studies - 2 species
Hydrolysis study
Mobility studies
Photodegradation studies
Dissipation studies
Avian dietary LC_{50} studies
Aquatic organism testing

6. CONTACT PERSON AT EPA

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