US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Formetanate Hydrochloride

When EPA concluded the N-methyl carbamate cumulative risk assessment in September 2007, all tolerance reassessment and reregistration eligibility decisions for individual N-methyl carbamate pesticides were considered complete. N-methyl carbamate Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs.

Combined PDF document consists of the following:

- Completion of the Tolerance Reassessment and Final Reregistration Eligibility Decisions for the N-methyl Carbamate Pesticides (September 24, 2007)
- Formetanate Hydrochloride IRED

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: September 24, 2007

SUBJECT: Completion of the Tolerance Reassessment and Final Reregistration Eligibility Decisions for the N-methyl Carbamate Pesticides

FROM: Steven Bradbury, Ph.D., Director
Special Review and Reregistration Division
Office of Pesticide Programs

TO: Debra Edwards, Ph.D., Director
Office of Pesticide Programs

The Agency has completed its assessment of the cumulative risks from the N-methyl carbamate (NMC) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual NMC pesticides have also been subject to review through the individual chemical review process. The table below details the dates of previous decisions for the individual NMC pesticides.

Chemical	Decision Document	Date
Aldicarb	RED	9/2007
Carbaryl	IRED RED	6/2003 9/2007
Carbofuran	IRED	8/2006
Formetenate HCl	IRED	3/2006
Methiocarb	RED	3/1994
Methomyl	RED	12/1998
Oxamyl	IRED	12/2000
Pirimicarb	NA*	
Propoxur	RED	9/1997
Thiodicarb	RED	12/1998

* Pirimicarb was first registered in 1997 and therefore not subject to reregistration

EPA has concluded that, with the adoption of the risk mitigation measures evaluated in the N-methyl carbamate cumulative risk assessment, all of the N-methyl carbamate pesticide tolerances assessed in this risk assessment meet the safety standard set forth in section 408(b)(2)(a) of the FFDCA. For those tolerances, this conclusion terminates the tolerance reassessment process under section 408(q) of the FFDCA. For all of the chemicals, to the extent that the safety determination for these uses based on the cumulative risk assessment was the only remaining issue to complete the reregistration eligibility determination for a particular chemical under section 4(g)(2)(A) of FIFRA, the Agency now considers that determination (consistent with the risk mitigation measures described in the cumulative assessment) to be complete. As noted in the Introduction to the cumulative risk assessment, certain tolerances and uses were omitted from the risk assessment because EPA had previously determined that these uses or tolerances did not meet the safety standards based on their individual, aggregate risks or should be canceled for other reasons. These tolerances and uses are identified in Appendix II.A of the cumulative risk assessment. The cumulative assessment does not change the Agency's determination with respect to those uses. Should any risk mitigation measures identified in the assessment not subsequently be implemented, EPA will revise the assessment as necessary to take those residues into account.

In June 2006, the Agency determined that 144 of the N-methyl carbamate tolerances were insignificant contributors to the overall dietary exposure to the N-methyl carbamates. The uses associated with these 144 tolerances make an insignificant contribution to the overall N-methyl carbamate cumulative risk. Therefore, EPA counted these tolerances as reassessed before the final N-methyl carbamate cumulative assessment was issued. That determination is not changed by the assessment the Agency is now issuing. As noted above, EPA has now determined that those tolerances assessed in the N-methyl carbamate cumulative risk assessment meet the FFDCA safety standard and that no further risk mitigation is necessary for any of the pesticides involved in the cumulative risk assessment other than the mitigation measures identified in the individual chemical or cumulative assessments.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2007-0935).

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

March 2006
EPA 738-R-06-015

Interim Reregistration Eligibility Decision for Formetanate Hydrochloride

Interim Reregistration Eligibility Decision (IRED) Document for Formetanate Hydrochloride

Case Number 0091

Approved by: _____ Date: _____

Debra Edwards, Ph. D.
Director
Special Review and Reregistration Division

Table of Contents

Formetanate Hydrochloride Interim Reregistration Eligibility Decision Team

Biological and Economics Assessment

David Brassard

Environmental Fate and Effects Risk Assessment

Ibrahim Abdel Saheb
Richard Lee

Health Effects Risk Assessment

Danette Drew
John Doherty
Susan Stanton
Seyed Tadayon

Registration Support

Dan Kenny

Risk Management

Demson Fuller
Laura Parsons

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs

OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) interim decision regarding the reregistration eligibility of the registered uses of the insecticide formetanate hydrochloride (formetanate HCl). The Agency has conducted human health and environmental fate and effects risk assessments for formetanate HCl. EPA has determined that formetanate HCl will be eligible for reregistration and tolerances will be assessed provided the mitigation measures outlined in this document are adopted; and cumulative risks of chemicals sharing a common mechanism of toxicity do not exceed EPA's level of concern. This compound belongs to a group of pesticides called the N-methyl carbamates which share a common mechanism of toxicity. While the Agency has not yet completed its cumulative risk assessment for the N-methyl carbamates, cumulative risks of these chemicals will be considered in the future. At that time, the Agency's final tolerance reassessment and reregistration decisions for formetanate HCl and the other N-methyl carbamates will be issued. The risks from the use of formetanate HCl alone are considered in this document and mitigation decisions are included. The Agency may need to pursue further risk mitigation for formetanate HCl to address any risks identified in the cumulative assessment for the N-methyl carbamates.

Formetanate HCl is a carbamate miticide/insecticide used on apples, pears, nectarines, peaches, oranges, grapefruits, lemons, limes, tangelos, tangerines, and alfalfa grown for seed. Nectarines are the crop with the highest percent crop treated with formetanate HCl. There are no residential uses for this chemical. There are currently 10 tolerances established for formetanate HCl.

In the human health risk assessment, acute dietary risks (from both food and drinking water) exceed the Agency's level of concern. Chronic dietary risks resulting from food and drinking water exposure are below the Agency's level of concern for all population subgroups. To mitigate acute dietary risks, the registrant, Gowan Company, has agreed to delete the late season use apples from its labels.

There are some short and intermediate term risks to workers that are of concern for use of formetanate HCl which can be mitigated by prohibiting aerial applications to orchards and requiring additional protective equipment or closed cabs for handler scenarios. To address risks of concern to reentry workers, restricted entry intervals will be revised for alfalfa and deciduous fruits.

Although, ecological risks to terrestrial animals were identified as a result of formetanate HCl use, the exceedances for terrestrial animals are generally minor for this screening level assessment and risks to aquatic animals (both freshwater and estuarine/marine environments) were below EPA's level of concern. There are no indications of phytotoxicity from the use of formetanate HCl on plants; therefore, a risk assessment for plants was not conducted. The screening level assessment results in the determination that formetanate HCl will have no direct acute effects on threatened and endangered freshwater fish, invertebrates, and estuarine mollusks. Although there are some assessed ecological risks, the Agency is not proposing additional mitigation measures to reduce ecological risks at this time.

Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to EPA. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require EPA to review all tolerances for pesticides in food in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate and cumulative risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate and cumulative exposures, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment would be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Formetanate HCl is a member of the N-methyl carbamate class of pesticides. The N-methyl carbamates, as a group, have been determined to share a common mechanism of toxicity. The preliminary cumulative risk assessment for the N-methyl Carbamate Cumulative Assessment Group, which includes formetanate HCl, has been released (July 2005). The FIFRA Science Advisory Panel reviewed the preliminary cumulative risk assessment in August 2005. The revised cumulative risk assessment is currently being developed and will be released during 2006. At that time, the Agency's final tolerance reassessment reregistration decisions for formetanate HCl and the other N-methyl carbamates will be issued. The Agency may need to pursue further risk mitigation for formetanate HCl to address any risks identified in the cumulative assessment for the N-methyl carbamates.

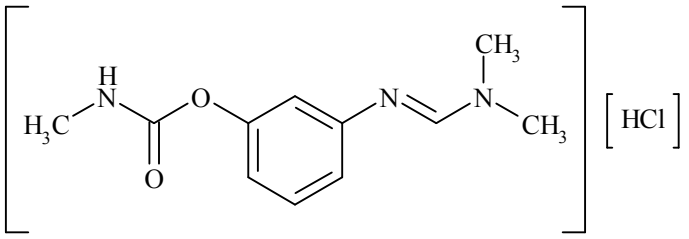
This document presents EPA's revised human health and environmental fate and effects risk assessments, its progress toward tolerance reassessment, and the interim reregistration eligibility decision for formetanate HCl. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a description of the chemical identity and a profile of the use and usage of the chemical. Section III provides a summary of the revised human health and ecological risk assessments based on data, public comments, and other information received in response to the preliminary risk

assessments. Section IV presents the Agency's interim risk management, reregistration eligibility, and tolerance reassessment decisions and rationale. Section V summarizes any data necessary to confirm the reregistration eligibility decision as well as label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The preliminary and revised risk assessments for formetanate HCl are available in the Public Docket and on the internet under docket number EPA-HQ-OPP-2004-0032.

II. Chemical Overview

A Chemical Identity

Chemical Structure:



Empirical Formula:	$C_{11}H_{16}ClN_3O_2$
Common Name:	Formetanate Hydrochloride
CAS Name:	{m-[[dimethyllamino) methylene]amino]phenyl methylcarbamate hydrochloride}
CAS Registry Number:	23422-53-9
OPP Chemical Code:	097301
Case Number:	0091
Technical or Manufacturing-Use Registrants:	Gowan Company

Formetanate HCl is a white crystalline solid with melting point of 191 - 202°C and a low vapor pressure. Formetanate HCl is highly soluble in water and only slightly soluble in organic solvents (dichloromethane, acetone, toluene, ethyl acetate, and n-hexane). For a complete review of the product chemistry for formetanate HCl, please see "*Formetanate Hydrochloride, HED Product Chemistry Chapter of the RED"* (D. Drew, 3/27/03)

B Regulatory History

Formetanate HCl was first registered in 1969. A Registration Standard was completed in 1983. An assessment was completed in 1999 for the formetanate HCl Interim Reregistration Eligibility Decision (IRED) which showed dietary risks of concern. Based on this dietary analysis, a Memorandum of Agreement (MOA) between the registrant and EPA was signed in October 1999. The MOA stipulated labeling amendments aimed at lowering application rates, increasing pre-harvest intervals and limiting uses to certain crops in an effort to reduce residues associated with formetanate HCl uses. As a result, uses on plums and prunes were cancelled, formetanate HCl use was prohibited in Florida, application timing was restricted to early season for most uses and the maximum application rate was lowered. Revised labels were approved in January and May 2000.

C. Use and Usage Profile

The following is information on the currently registered uses of formetanate HCl:

Type of Pesticide:	Miticide/Insecticide
Formulations:	Formetanate HCl is formulated as a wettable powder in water soluble packaging (92 percent active ingredient).
Methods of Application:	Formetanate HCl can be applied with aerial or ground equipment such as groundboom sprayers and airblast sprayers.
Target Organisms:	Rust mite, Thrips, European Red Mite, Two-Spotted Spider Mite, McDaniel Mite, Lygus Bug, Tentiform Leafminer, White Apple Leafhopper, and Stink Bugs
Use Sites:	Alfalfa grown for seed, Apples, Pears, Nectarines, Peaches, Grapefruit, Lemon, Lime, Orange, Tangelo, and Tangerine
Application Rates:	Formetanate HCl is labeled for use on tree fruits at 1.15 lb ai/A and on alfalfa at 0.92 lb ai/A.

III. Summary of Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessments form the basis of interim regulatory decisions for formetanate HCl. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2004-0032 and may be accessed on the internet at http://www.regulations.gov.

A. Human Health Risk Assessment

The Agency prepared a revised human health risk assessment, "*HED Revised Risk Assessment for Formetanate Hydrochloride,*" (D. Drew, 12/23/05) which addresses toxicology data and comments submitted during or after Phase 3 of the Public Participation Process for formetanate HCl. Specifically addressed is the July 2005 submission of a comparative cholinesterase assay study in pups and adult rats which resulted in the selection of a benchmark dose for use in this assessment. Also, an updated worker risk assessment was performed which considers a lower number of estimated acres treated per day for aerial applications to alfalfa grown for seed. A subsequent dietary analysis was conducted in January 2006 to include United States Department of Agriculture's (USDA) Pesticide Data Program (PDP) monitoring data. Data tables from this analysis are also posted in the docket.

1. Toxicity

(For a complete discussion, see sections 3.0 of the human health risk assessment.)

Formetanate HCl has high acute toxicity via the oral route, moderate acute toxicity via the inhalation route and has low acute toxicity via the dermal route. It is not an eye or skin irritant but is a dermal sensitizer.

Formetanate HCl is a carbamate pesticide, and its primary mode of toxic action is through cholinesterase inhibition (ChEI) after single or multiple exposures. In laboratory studies conducted on animals, exposure to formetanate HCl resulted in decreased plasma, whole blood and/or brain cholinesterase (ChE). In most of the toxicity studies in which ChEI was measured, it was the endpoint used to set the Lowest Observed Adverse Effect Level (LOAEL) and the No Observed Adverse Effect Level (NOAEL).

A comparative cholinesterase assay (CCA) study in neonates and adult rats was submitted in lieu of a developmental neurotoxicity study (DNT). The CCA study is appropriate because the behavioral effects in adult animals were seen at a dose 10-fold higher than the dose at which ChEI occurred. Importantly, this indicates that behavioral effects in pups measured in the DNT are likely to occur at higher doses than ChEI. Therefore, EPA determined that regulating on the ChEI endpoint would protect against potential neurotoxic effects. In order to evaluate the appropriate point of departure (PoD) for ChEI, EPA performed a benchmark dose (BMD) analysis which indicated that: (1) brain ChEI is a more sensitive endpoint then red blood cell (RBC) ChEI, (2) female pups are more sensitive than male pups, and (3) 10% ChE is the appropriate benchmark response to consider. Based on the CCA study, there was inhibition of brain ChE at all doses and the female pup brain ChEI data resulted in the lowest $BMDL_{10}$ (benchmark dose lower limit) of 0.065 mg/kg/day which was selected for the acute and chronic dietary assessments.

For the dietary assessment, EPA uses the same endpoint for all oral exposures when the acute $BMDL_{10}$ is lower than the subchronic or chronic value from longer term studies. In the case of formetanate HCl, the quick acting and reversible nature of carbamate ChE inhibition is

considered by EPA as justification for using data from the ChEI study following a single acute dose for the chronic RfD.

For the occupational risk assessment, a dermal toxicity study in rats was used to estimate occupational risks from dermal exposures. A NOAEL of 10 mg/kg/day was selected with a LOAEL of 20 mg/kg/day for ChEI in whole blood and plasma. A dermal absorption factor is not necessary for the risk assessment because a route-specific dermal toxicity study was used for formetanate HCl.

In considering the dermal endpoints, it should be noted that carbamates are relatively quick acting reversible inhibitors of cholinesterase and the subchronic and chronic studies do not usually demonstrate cumulative effects of cholinesterase inhibition. In particular, following a single dose of formetanate HCl, there is inhibition of cholinesterase that reverses shortly (in the same day) after exposure, and the consequences of inhibition (unless at extremely high doses) reverse also. Short-term exposure (up to 30 days) to formetanate HCl is regarded as multiple single-dose exposures without a cumulative effect. Thus, the NOAEL and LOAEL from the single dose study is an appropriate endpoint for the 30-day exposure scenario.

For the inhalation exposure assessment estimating occupational risks, a NOAEL of 0.1 mg/kg/day was selected from an acute neurotoxicity study with a LOAEL of 1 mg/kg/day based on plasma, whole blood and brain cholinesterase inhibition. This study was used in a previous assessment ("*HED Revised Risk Assessment for Formetanate Hydrochloride,*" June 4, 2003) and EPA determined that the occupational inhalation risk endpoint should be retained since the NOAEL of 0.1 mg/kg/day is not significantly different from BMDL of 0.065 mg/kg/day. Therefore, EPA is confident that it is not underestimating toxicity via the inhalation route. An absorption factor of 100% is assumed for exposure via the inhalation route.

There were no concerns for mutagenicity. There was no indication of a carcinogenic effect in rats or mice. Formetanate HCl is classified as a group "E" carcinogen (no evidence of carcinogenicity). There was no evidence of effects to the immune or endocrine systems.

FQPA Special Safety Factor

The FQPA safety factor is intended to provide an additional safety factor (10X) to safeguard against potential special sensitivity in infants and children to specific pesticide residues in food. Exposure to formetanate HCl did not result in developmental toxicity in either rats or rabbits or in reproductive effects in the multi-generation reproduction study. There was no indication of increased offspring susceptibility in these studies. The CCA study demonstrated that pups were more sensitive than adults to the ChEI effects of formetanate HCl. Because the endpoint is based on pup sensitivity and the formetanate HCl dietary and drinking water assessments are not expected to underestimate exposure, the special FQPA safety factor can be removed for the formetanate HCl risk assessment.

Database Uncertainty Factor

The Agency previously determined that a database uncertainty factor of 10X should be retained because a study was needed that compares the potential for formetanate HCl to inhibit cholinesterase in adult rats with neonatal rats. ("*Formetanate Hydrochloride – 4th Report of the Hazard Identification Assessment Review Committee*" May 21, 2003). The CCA study that was submitted provided the necessary data which were included in the risk assessment. Therefore, the 10X uncertainty factor was removed.

Table 1: Formetanate HCl: Summary of Toxicological Endpoints

Exposure Scenario	Dose	Endpoint for Risk Assessment
Dietary Risk Assessments		
Dietary (Acute and Chronic) General Population	$BMDL_{10}$ = 0.065 mg/kg/day UF = 100 aRfD = 0.00065 mg/kg/day cRfD = 0.00065 mg/kg/day PAD = 0.00065 mg/kg/day	$BMDL_{10}$ for female pup brain ChEI in the Comparative ChE study. The FQPA SF is removed because an endpoint based on the most sensitive effect in the most sensitive population was used. (MRID # 46618902)
(Occupational) Non-Dietary Risk Assessment		
Dermal - Occupational Short & Intermediate Term (1 - 30 days)	Dermal NOAEL= 10 mg/kg/day **MOE = 100**	Special single dose time to peak effect dermal application study (2000, MRID # 45311901). LOAEL = 20 mg/kg/day based on whole blood and plasma cholinesterase inhibition.
Inhalation Occupational Short & Intermediate Term (1 - 30 days)	Oral NOAEL = 0.1 mg/kg/day **MOE = 100**	Acute Neurotoxicity Screen (2000, MRID # 45314201) LOAEL = 1 mg/kg/day based on plasma, whole blood and brain cholinesterase inhibition. 100% absorption assumed
Cancer	Classification E: Not Likely	

2. Dietary Exposure and Risk from Food and Drinking Water

Acute probabilistic and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03) which uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CFII) from 1994-1996 and 1998.

Acute Dietary Risk Assessment for Food + Water

A partially refined, Tier 3, acute probabilistic dietary exposure assessment was conducted for all supported formetanate HCl food uses and for drinking water. Acute anticipated residues for all foods were derived using either field trial data reflecting current maximum label rates and minimum Pre-Harvest Intervals (PHI) or PDP monitoring data. Although the field trial data are limited in terms of the number of trials and residue samples, it is likely that these data result in

overestimates of dietary exposure to formetanate HCl since they reflect current maximum label rates rather than typical usage. Likewise, PDP data reflect the sampling year of 2001 when the higher pre-MOA label rates may have been used. Field trial data were used to analyze stone fruits, lemons, limes, tangelos and juice (orange and grapefruit). PDP data were used to analyze apples, pears, oranges and grapefruit. Field trial data were used for orange and grapefruit juice since PDP data reflect residues on peeled fruit and juice is extracted from whole (unpeeled) fruit. Anticipated residues were further refined using percent crop treated (%CT) data where appropriate, and, where available, processing factors.

Estimated residues in drinking water were incorporated directly into the acute assessment. The assessment was conducted using the full distribution of estimated residues in surface water generated by the PRZM-EXAMS model for the North Carolina apple crop scenario, the crop scenario resulting in the highest estimated peak surface water concentration (7.68 ppb).

The resulting acute dietary exposure and risk estimates for food and water exceed EPA's level of concern for the population subgroups, Infants and Children 1-2 years old. Acute dietary (food + water) exposure at the 99.9th percentile was estimated at 162% of the Acute Population Adjusted Dose (aPAD) for the most highly exposed population subgroup (infants). Most of the estimated acute exposure from food was determined to result from the late season uses of formetanate HCl on apples. (See Table 2).

Table 2: Results of Acute Dietary Risk Analysis[1]

Population Subgroup	Risks Including Late Season Applications on Apples (Food + Water)
General US Population	47
All Infants (< 1 year old)	162
Children 1-2 years old	119
Children 3-5 years old	93
Children 6-12 years old	51
Youth 13-19 years old	28
Adults 20-49 years old	33
Females 13-49 years old	33
Adults 50+ years old	33

[1]Risks are expressed as a percent of the aPAD. Risks > 100% of the aPAD exceed EPA's Level of Concern.

Deletion of the late season apple applications results in an acute dietary (food + water) risk of 117% of the aPAD for the most highly exposed population subgroup (infants). Analysis shows that residues from food only (excluding the late season apple residues) result in an acute dietary risk of 56% of the aPAD for infants (see Table 3). Therefore, drinking water is a large contributor to acute dietary exposure when late season uses are excluded.

Drinking water residue estimates are considered to be conservative and unrefined since residues are estimated from modeling because no water monitoring data were available to refine the assessment. Modeling estimates are based on conservative assumptions including: (1) that applications will be made at maximum application rates every year for 30 years and (2) a highly vulnerable configuration of a reservoir/watershed system is used as the application site. Additionally, for formetanate HCl, applications were modeled in an apple orchard in North

Carolina where rainfall is higher than in the west where most formetanate HCl is used.

Considering that food alone is below the Agency's level of concern for all populations, an acute dietary risk estimate of 117% of the aPAD including conservative water estimates for the exposed population of infants is also considered to be below EPA's level of concern.

Table 3: Results of Dietary Risk Analysis[1]

Population Subgroup	Risks Without Late Season Applications on Apples (Food Only)	Risks Without Late Season Applications on Apples (Food + Water)
General US Population	25	37
All Infants (< 1 year old)	56	117
Children 1-2 years old	56	69
Children 3-5 years old	51	64
Children 6-12 years old	34	41
Youth 13-19 years old	19	25
Adults 20-49 years old	16	29
Females 13-49 years old	17	31
Adults 50+ years old	17	29

[1]Risks are expressed as a percent of the aPAD

Chronic Dietary Risk Assessment for Food + Water

A partially refined, Tier 3 chronic dietary exposure assessment was also conducted for the supported food uses of formetanate HCl and for drinking water. Anticipated residues were derived using field trial data, %CT data, and, where available, processing factors.

For the chronic assessment, a single point estimate (0.08 ppb) of formetanate HCl residues in surface water was used to assess exposure from drinking water. The estimated surface water concentration represents the 90th percentile annual mean concentration generated by the PRZM-EXAMS model for the Pennsylvania apple crop scenario, the crop scenario resulting in the highest estimated annual mean concentration.

Chronic dietary risk estimates based on this analysis are below EPA's level of concern for the U.S. population and all population subgroups. Formetanate HCl mean dietary (food + water) exposure is estimated at 4.9% of the Chronic Population Adjusted Dose (cPAD) for the U.S. population and 28% of the cPAD for the most highly exposed population subgroup (infants, <1 yr. old).

3. Residential Exposure and Risk

Only agricultural uses are registered for formetanate HCl. There are no uses that would result in residential or recreational exposures. Assessments addressing residential and recreational risks are not warranted at this time.

4. Aggregate Exposure and Risk

(For a complete discussion, see Section 7 of the human health risk assessment.)

The Food Quality Protection Act (FQPA) amendments to the Federal Food, Drug and Cosmetic Act (FFDCA, Section 408(b)(2)(A) (iii)), require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures for which there is reliable information." Aggregate exposure will typically include dietary exposures (food plus drinking water), exposures from residential uses of a pesticide, and other non-occupational sources of exposure.

There are no residential uses for formetanate HCl. Therefore, when addressing aggregate exposures, only the dietary pathways of food and drinking water were considered. Since drinking water was incorporated directly into the acute and chronic dietary assessments, the dietary risk estimates discussed above reflect total estimated acute and chronic aggregate risks from formetanate HCl.

Acute aggregate exposure estimates for food and water exceed EPA's level of concern with the inclusion of late season applications to apples, but are below the level of concern without this use. Analysis for food only was 56% of the aPAD and food plus conservative water values resulted in 117% of the Population Adjusted Dose (PAD). Chronic aggregate exposure estimates for food and water are below the Agency's level of concern.

5. Occupational Exposure and Risk

(For a complete discussion, see section 7.0 of the human health risk assessment.)

People can be exposed to a pesticide while working through mixing, loading, or applying a pesticide, and reentering a treated site. Handler and worker non-cancer risks are measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a NOAEL taken from animal studies. Generally, MOEs greater than 100 do not exceed the Agency's level of concern.

For formetanate HCl, only short and intermediate-term occupational exposures are expected based on label-specified use patterns. For the occupational assessment, the dermal endpoint was selected from a dermal toxicity study in rats. The NOAEL is 10 mg/kg/day and the LOAEL is 20 mg/kg/day based on whole blood and plasma cholinesterase inhibition. The short- and intermediate-term endpoints for inhalation exposure are a NOAEL of 0.1 mg/kg/day and a LOAEL of 1 mg/kg/day based on plasma, whole blood and brain cholinesterase inhibition from an acute oral neurotoxicity study. Since an oral study was used, an inhalation absorption factor of 100% is assumed.

Occupational Handler Summary

Based on the registered use patterns, EPA has identified 7 major exposure scenarios for which there is potential occupational handler exposure during mixing, loading, and applying products containing formetanate HCl to agricultural crops. These scenarios are as follows:

(1) mixing/loading wettable powders for aerial application;
(2) mixing/loading wettable powders for airblast application;
(3) mixing/loading wettable powders for groundboom application;
(4) applying sprays with a fixed wing aircraft;
(5) applying sprays with airblast equipment;
(6) applying sprays with a groundboom sprayer; and
(7) flagging for aerial spray applications.

No chemical-specific handler exposure data were submitted, so short-term and intermediate-term dermal and inhalation exposures for handlers were developed using the Pesticide Handler Exposure Database (PHED) Version 1.1.

For occupationally exposed workers, combined MOEs (both dermal and inhalation) $\geq$100 do not exceed EPA's level of concern. No scenarios resulted in MOEs above 100 for single layer personal protective equipment (PPE); however, after a respirator was added for applicators using groundboom equipment in alfalfa for seed production, the risk was below EPA's level of concern (MOE=130). Most scenarios for applicators had MOEs above 100 at maximum PPE except for airblast applications to orchards (MOE=73) and aerial applications to alfalfa which are discussed below. Scenarios for mixing and loading for aerial applications for both orchard crops (MOE = 51) and for alfalfa grown for seed (MOE = 69) had risks above the Agency's level of concern even with engineering controls of water soluble bags.

Aerial applications to alfalfa also resulted in risk above the Agency's level of concern for applicators even when engineering controls (closed cockpits) were considered. (MOE =54). The mixing/loading and applicator scenarios for aerial application to alfalfa assumed the default acreage of 1200 acres treated per day. California pesticide application data for formetanate HCl applications to alfalfa grown for seed in 2003 showed a maximum acreage of 328 acres treated in a single day. This daily maximum was split into five separate applications. Therefore, an additional assessment was performed using a maximum estimate of 328 acres treated per day based on these data submitted by the University of California, Davis (UC Davis), Western Integrated Pest Management Center.

The following tables summarize the risks to handlers by crop type:

Table 4: Formetanate HCl: Applicator (Spray Application) Short-and Intermediate Term Exposure and Risk Estimates: Single Layer Protection + Respirator [1]

Exposure Scenarios (Scenario #)	Crop	Application Rate (lb ai/A)	Daily Area Treated	MOE
Sprays for Groundboom Application	Alfalfa for Seed	0.92	200	130

[1]A subsequent worker assessment was conducted in January 2006 for this single scenario and has been posted in the docket.

Table 5: Formetanate HCl: Applicator, Risk Estimates using Double Layer Protection, Gloves, Respirator (and Hood for Airblast Applicators Only)

Exposure Scenarios (Scenario #)	Crop	Application Rate (lb ai/A)	Daily Area Treated	MOE
Applicator				
Sprays for Airblast Application	Pome, Stone, and Citrus Fruit	1.15	40	73
Sprays for Groundboom Application	Alfalfa for Seed	0.92	200	150

Table 6: Formetanate HCl: Mixer-Loader, Applicator, Flagger Risk Estimates using Engineering Controls: Water Soluble Bags, Closed Cockpit Airplane, Closed Cab Tractors

Exposure Scenarios (Scenario #)	Crop	Application Rate (lb ai/A)	Daily Area Treated	MOE
Mixer/Loader				
Aerial Application	Alfalfa grown for seed	0.92	1200*	19
Aerial Application	Alfalfa grown for seed	0.92	328	69
Aerial Application	Pome, Stone, and Citrus Fruit	1.15	350	51
Airblast Application	Pome, Stone, and Citrus Fruit	1.15	40	450
Groundboom Application	Alfalfa grown for Seed	0.92	200	110
Applicator				
Sprays for Aerial Application	Alfalfa grown for seed	0.92	1200*	54
Sprays for Aerial Application	Alfalfa grown for seed	0.92	328	200
Sprays for Aerial Application	Pome, Stone, and Citrus Fruit	1.15	350	150
Sprays for Airblast Application	Pome, Stone, and Citrus Fruit	1.15	40	240
Sprays for Groundboom Application	Alfalfa grown for seed	0.92	200	410

Post-Application Occupational Risk

For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely reenter. The postapplication occupational risk assessment considered exposure to formetanate HCl from entering treated fields and orchards. Given the nature of activities in these locations, and that formetanate HCl is applied at various times during plant growth, contact with treated surfaces is likely. Some potential exposure scenarios include scouting, irrigation, harvesting, pruning, and thinning.

Formetanate HCl use patterns show that both short-term (1-30 days) and intermediate-term (1 month to 6 months) exposure is possible for post-application exposures, but because the endpoint and dose are the same for both exposure durations, so are the results.

No exposure data were submitted for alfalfa. Therefore, data from a citrus study was translated for alfalfa. The proposed single application rate for alfalfa is 0.92 ai/A. EPA estimated an alfalfa REI based on the formetanate HCl citrus data which considers the labeled rate of 1.15 lbs ai/A and an estimated transfer coefficient of 2,500 cm^2/hr for scouting activities.

The Agency acknowledges that the citrus residue data are not readily comparable to alfalfa residues. However, the calculated exposure using the surrogate data is being used as a screening level assessment and is considered to be a conservative estimate due to the higher rate and leaf surface area of citrus relative to alfalfa.

For worker reentry risk, the calculated REI represents the day following application on which the MOE is greater than or equal to 100. For high-end activities, MOEs were acceptable by day 10 for evergreen fruit trees (citrus), day 8 for deciduous fruit trees (pome and stone fruits), and day 9 for alfalfa.

Table 7: Formetanate HCl: Occupational Postapplication Risk Estimates

Crops	Re-entry Day with Acceptable MOEs ≥ 100	
	High exposure activities	Medium exposure activities
Alfalfa	9	6
Fruit Trees: Deciduous (Pome and Stone Fruits)	8	N/A
Fruit Trees: Evergreen (Citrus)	10	7

6. Human Incident Summary

A review of available incident reports on formetanate HCl was completed in 1997. Systemic poisoning has been reported in applicators that were not properly protected and skin rashes were reported in field workers exposed to residues. Incident data supported the need for additional personal protective equipment for those that handle formetanate HCl and reentry intervals for workers returning to orchards or fields where this active ingredient has been applied. A 2003 review of the EPA incident Data System showed no additional incident reports since 1996.

B. Ecological Risk Assessment

A summary of the Agency's environmental risk assessment for formetanate HCl is presented below. More detailed information associated with environmental risks from the use of formetanate HCl can be found in *"EFED Science Chapter for the Formetanate Hydrochloride Reregistration Eligibility Document,"* (I. Abdel-Saheb & R. Lee, October 22, 2003). The complete environmental risk assessment may be accessed in the OPP Public Docket, OPP-2004-0032.

1. Environmental Fate and Transport

(For a complete discussion, see ecological risk assessment)

Formetanate HCl is not a persistent pesticide under most normal use conditions. The primary routes of dissipation appear to be hydrolysis under neutral and alkaline conditions as well as microbial degradation. Formetanate HCl hydrolyzes with a half-life of <1 day. The soil photolysis half-life was <3 days. Metabolism data suggest that formetanate HCl is also readily biodegradable, with a half-life of <1 week.

Formetanate HCl and degradates were shown to be mobile in the laboratory. Field studies indicate that formetanate HCl degrades rapidly and generally remains within the top 6 inches of soil.

Based on the submitted volatility data (vapor pressure = 1.6 X 10^{-6} torr @ 25 C), volatilization from soils is not expected to be an important dissipation mechanism. The relatively high water solubility and low bioconcentration factors in bluegill sunfish suggest that formetanate HCl will have a low tendency to bioaccumulate in fish and other exposed organisms.

2. Environmental Effects

(For a complete discussion, see the ecological risk assessment)

To estimate potential ecological risks, EPA integrates the results of exposure and ecotoxicity information using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. The Agency assessed non-target ecological risks at the maximum labeled single broadcast rates of 1.15 lbs ai/A for orchard crops and 0.92 lbs ai/A for alfalfa.

a. Aquatic Organism Risk

The Agency used modeling to derive estimated environmental concentrations (EECs) for formetanate HCl in surface water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factor represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

Available acute toxicity data indicate that formetanate HCl is moderately to slightly toxic to freshwater fish and highly toxic to freshwater invertebrates on an acute basis. Chronic data for freshwater fish show that growth/development was the most sensitive endpoint. For estuarine/marine invertebrates, available acute toxicity data indicate that formetanate HCl is moderately toxic. No acute data for estuarine/marine fish or chronic data for invertebrates were available.

Aquatic Acute and Chronic Risks

Acute and chronic risks for freshwater fish and freshwater invertebrates are below the Agency's level of concern for all uses. Acute risks for estuarine/marine invertebrates were also below EPA's level of concern. Although the Agency has no toxicity data to assess risks to estuarine fish or chronic risks to estuarine invertebrates, EPA presumes that based on assessed risks to freshwater fish and invertebrates, estuarine animals are not expected to be at risk from formetanate HCl use.

b. Terrestrial Organism Risk

The Agency assessed exposure to terrestrial organisms by first predicting the amount of formetanate HCl residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various weight classes of birds and mammals. The amounts of residues on animal feed items are based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.) and the current maximum application rate for formetanate HCl which is 1.15 lbs ai/A.

Formetanate HCl is classified as highly toxic to birds on an acute basis with an LD50 value of 11.5 mg/kg and slightly toxic with an LC50 of 1413 ppm on a subacute basis. Avian reproduction data indicate that use of formetanate HCl has the potential to be of concern for chronic risks to birds. Chronic toxicity from both bobwhite quail and mallard duck studies indicate reduced eggs hatched and offspring survival at the 160 ppm treatment level.

Toxicity data for mammals indicate that formetanate HCl is highly toxic to small mammals on an acute oral basis. The chronic toxicity endpoint is based on a 52-week dog study which showed a NOAEC of 10 ppm. Clinical signs associated with this study were salivation, wheezing, heavy breathing, trembling, vomiting, coughing, and abnormal quietness.

There are no indications that formetanate HCl is phytotoxic; therefore, plant toxicity testing is considered unnecessary and a plant risk assessment has not been conducted.

The Agency generally does not conduct non-target insect risk assessments. Data indicate that formetanate HCl is practically nontoxic to bees on an acute contact basis. The acute LD_{50} of formetanate HCl is greater than 11 µg/bee. However, in the field, formetanate HCl is known to be toxic to foraging bees and, therefore, the current bee labeling statements are appropriate.

Terrestrial Acute and Chronic Risks

Birds

Acute risks to birds do not exceed the Agency's LOCs for the screening level assessment for formetanate HCl. RQs for consumption of short grass were calculated to be 0.2 for the maximum application rate to orchard fruits. All other acute RQs for birds were < 0.2 and are not of concern for nonlisted avian species. Chronic avian RQs ranged from 2 to 5 (LOC = 1) for several foodstuffs when maximum residue values were considered. For further details regarding assumptions and EECs, please see the EFED risk assessment.

Table 8: Formetanate HCl: Acute and Chronic Avian Risk Quotients

Site	App. Rate (lbs ai/A	Food Items	Acute RQ (EEC/LC50) [1]	Chronic (EEC/LC50)[2]
Citrus, Stone Fruit	1.15	Short Grass	0.20	5.21
		Tall Grass	0.09	2.39
		Broadleaf Plant/Small Insects	0.11	2.93
		Fruits/Pods/Large Insects	0.01	0.33
Alfalfa grown for seed	0.92	Short Grass	0.16	4.17
		Tall Grass	0.07	1.91
		Broadleaf Plant/Small Insects	0.09	2.34
		Seeds	0.01	0.26

[1]Based on a subacute study where the LC50 is 1413 ppm
[2]Based on a chronic study where the NOAEC is 53 ppm

Mammals

The LOC for acute risks is triggered by an RQ > 0.5. The acute RQs for orchard and alfalfa uses are above the Agency's level of concern for all weight classes (15g, 35g, and 1000g) foraging on most food categories (grass, forage, and insects) for herbivores/insectivores. Risk quotients ranged from <1 to 18. For chronic RQs, the mammalian chronic level of concern of 1.0 is exceeded for all foodstuffs at maximum application rates. Risk quotients ranged from 2 to 28. For further details regarding assumptions and EECs, please see the EFED risk assessment.

Table 9: Formetanate HCl: Mammalian Acute Risk Quotients[1]

Site and Rate in lbs ai/A	Body Weight (g)	Acute RQ		
		Short Grass	Forage & Small Insects	Large Insect
Citrus, Stone, Pome Fruit 1.15 lb ai/A	15	17.72	9.97	1.11
	35	12.31	6.92	0.77
	1000	2.80	1.57	0.17
Alfalfa 0.92 lb ai/A	15	14.17	7.97	0.89
	35	9.85	5.54	0.62
	1000	2.24	1.26	0.14

[1]Based on a rat LD50 of 14.8 mg/kg

Table 10: Formetanate HCl: Mammalian Chronic Risk Quotients[1]

Site and Rate in lbs ai/A	Chronic RQ			
	Short Grass	Tall Grass	Broadleaf Plants/insects	seeds
Citrus, Stone, Pome Fruit 1.15 lb ai/A	27.60	12.65	15.53	1.73
Alfalfa 0.92 lb ai/A	22.08	10.12	12.42	1.38

[1] Based on the NOAEC of 10 ppm from a chronic dog study.

4. Ecological Incidents

The Agency has received no reports of formetanate HCl ecological incidents.

5. Risk to Endangered Species

The Agency's screening level assessment results in the determination that formetanate HCl will have no direct acute effects on threatened and endangered freshwater fish, invertebrates, and estuarine mollusks. The preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for birds and mammals with acute RQs ranging up to 0.2 for birds and up to 18 for mammals. Chronic RQs ranged up to 5 for birds and 28 for mammals. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of formetanate HCl can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

IV. Interim Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical or manufacturing-use grade) data required to support reregistration of products containing formetanate HCl as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the dietary, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient formetanate HCl. Based on these data, the Agency has sufficient information on the human health and ecological effects of formetanate HCl to make its interim decisions as part of the tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA, pending completion of the cumulative assessment of the N-methyl carbamates class of pesticides, of which formetanate HCl is a member. Additional mitigation may be necessary after this cumulative assessment is completed. The Agency has determined that products containing formetanate HCl will be eligible for reregistration provided that (i) the risk mitigation measures outlined in this document are adopted; and (ii) label amendments are made to reflect these measures and (iii) any additional measures needed to reduce cumulative risks are adopted. Needed label changes and language are listed in Section V. Appendix A is a detailed table listing all uses that are eligible for formetanate HCl, or uses which require tolerances or tolerance consideration, that were considered for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the interim reregistration eligibility of formetanate HCl, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data or additional data necessary to confirm the decision presented here.

Based on its evaluation of formetanate HCl, the Agency has determined that formetanate HCl products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FFDCA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action

to address the risk concerns from the use of formetanate HCl. If all changes outlined in this document are incorporated into the product labels, then all current risks for formetanate HCl will be adequately mitigated for the purposes of this interim determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.5.a of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for formetanate HCl. During the public comment period on the risk assessments, which closed on May 24, 2004, the Agency received five comments: one comment from a grower, three comments from grower associations, and one from the registrant, Gowan Company. The comments by growers cited the importance of formetanate HCl in their resistance management programs to control pests, particularly thrips. Gowan commented on issues concerning both the human health and ecological risk assessments and the Agency's policies in conducting these analyses. The Agency addressed these issues and incorporated the comments, as appropriate, in the risk assessment. These comments in their entirety are available in the public docket EPA-HQ-OPP-2004-0032 at http://www regulations.gov. A detailed Response to Comments document is available in the public docket as well.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with formetanate HCl. This assessment is for this individual carbamate and does not fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the structurally-related N-methyl carbamates that have the capacity to inhibit cholinesterase enzymes. The preliminary cumulative risk assessment for the N-methyl carbamates, which includes formetanate HCl, has been released. The revised cumulative risk assessment is currently being developed and will be released during 2006. At that time, the Agency's final tolerance reassessment and reregistration decisions for formetanate HCl and the other N-methyl carbamates will be issued.

The Agency has made an interim conclusion that if the risk mitigation measures described in this document are adopted, tolerances for formetanate HCl meet the FQPA safety standards and that the aggregate exposure (from food and drinking water) is within the "risk cup." The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

b. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on formetanate HCl, there was no evidence of endocrine disruptor effects. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, formetanate HCl may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

c. Cumulative Risks

The Food Quality Protection Act of 1996 (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity with other pesticides. Formetanate HCl belongs to a group of pesticides called the N-methyl carbamates, which share a common mechanism of toxicity. The Agency has not yet completed its cumulative risk assessment for the N-methyl carbamates, but the cumulative risks of these chemicals will be considered in the future. At that time, the Agency's final tolerance reassessment decision for formetanate HCl and the other N-methyl carbamates will be issued. The Agency may need to pursue further risk mitigation for formetanate HCl to address any risks identified in the cumulative assessment for the N-methyl carbamates.

2. Interim Tolerance Summary

An interim tolerance summary and interim tolerance reassessment is presented for formetanate HCl in Table 11 below. The nature of the residue of formetanate HCl in livestock and plants has been adequately demonstrated. The residue of concern for tolerance enforcement and risk assessment is parent formetanate HCl. The tolerances levels were lowered based on limited residue data from field trials. Additional residue data are necessary to establish formetanate HCl tolerance values. At such time as the additional field trial data are received and deemed adequate these tolerance levels will be reevaluated. However, because the Agency has no dietary, drinking water, residential, or aggregate risk concerns (based on the exclusion of late season applications to apples) the data are adequate to conduct the reassessment summary for

formetanate HCl. No maximum residue limits (MRLs) for formetanate HCl have been established by Codex for any agricultural commodity.

For a detailed discussion of this section, please refer to section 860.1550, Proposed Tolerances, in the document "*Formetanate Hydrochloride HED Revised Chemistry Chapter of the RED: Summary of Analytical Chemistry & Residue Data (Phase 4*") (D. Drew, 12/14/2005). This document is located in the public docket (EPA-HQ-OPP-2004-0032 at http://www regulations.gov.)

Table 11: Formetanate HCl: Interim Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)[1]	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.276			
Apple	3	0.50	
Pear	3	0.50	
Grapefruit	4	1.5	
Lemon	4	0.60	
Lime	4	0.03	
Oranges	4	1.5	*[orange]*
Tangerine	4	0.03	
Nectarine	4	0.40	
Peach	5	0.40	
Plum, prune, fresh	2	revoke	no longer a registered use
Tolerances To Be Proposed Under 40 CFR §180.276			
Apple, wet pomace	None	1.5	
Tangelo	None	0.03	

[1] Reassessed tolerances are based on limited field trial data. When additional field trial data are received, the tolerance reassessment will be reevaluated.

D. Regulatory Rationale

1. Human Health Risk Management

a. Dietary Risk Mitigation (food and drinking water)

Acute dietary risks (from both food and drinking water) exceed the Agency's level of concern (162% of the aPAD for the most sensitive subgroup, infants). Most of the estimated acute exposure from food was determined to result from the late season use of formetanate HCl on apples.

Although labels specifically allow only one application per season (1.15 lbs. ai/A) for most uses, there are some late season applications permitted on labeling for pome fruits for special local concerns from California and other states located in the Northwest part of the country. Residues from these applications result in dietary risks of concern. Removing the late season use for apples resulted in a dietary risk of 56% (for food only) and 117% (food plus water) of the aPAD for infants, the most highly exposed subgroup. All other populations have

risks below EPA's level of concern (69% or less of the aPAD occupied after late season apples are removed).

Drinking water estimates are a major source of residues for formetanate dietary analysis when modeling results were used probabilistically in the acute dietary analysis. Water monitoring data are not available to estimate residues of formetanate HCl in drinking water. The availability and use of monitoring data would have resulted in a more refined estimate of drinking water exposure. The drinking water estimates used to conduct the acute assessment are considered conservative for the reasons discussed earlier in chapter 3. Therefore, the dietary risk estimate of 117% of the aPAD for infants based on food plus water is considered to be below the Agency's level of concern.

To reduce acute dietary risk the following mitigation is necessary:

- *Amend labels to prohibit late season application to apples*

Chronic dietary estimates from food plus drinking water do not result in dietary risks of concern and therefore, no mitigation is necessary to address chronic dietary risks.

b. Residential Risk Mitigation

There are no residential uses for formetanate HC1 and no residential exposure is anticipated from current uses; therefore, no mitigation is necessary at this time.

c. Occupational Risk Mitigation

There were some occupational risks identified from current labeled uses of formetanate HCl.

Formetanate HCl is currently sold only as a wettable powder packaged in water soluble bags. The Agency's handler risk assessment included scenarios which considered the protection factors for water soluble bags (an engineering control) plus maximum protective clothing and a respirator. Although this resulted in an MOE greater than 200 for mixers and loaders supporting aerial applications on alfalfa, the Agency does not recommend the use of engineering controls plus additional PPE. This calculated MOE of 200 was achieved by applying protection factors and does not actually result in significant risk reduction. Further, use of engineering controls plus maximum protection would conflict with the Worker Protection Standard (WPS). The WPS allows workers to reduce their PPE when using engineering controls, which in this case the resulting PPE would be single layer clothing, chemical resistant gloves/apron and no respirator. Although these scenarios with engineering controls and additional PPE were assessed, the results are not appropriate for regulatory purposes and are not considered here.

Handler Risks from applications to Alfalfa:

The current label requires applicators spraying alfalfa grown for seed using groundboom equipment to wear double layer PPE, eyewear, gloves, and a respirator. The risk for this

scenario did not exceed the Agency's level of concern (MOE=150). However, EPA assessed this scenario again using only single layer PPE and a respirator. The risk associated with exposure to the active ingredient was still acceptable (MOE=130).

The mixing/loading and the applicator scenarios for aerial application on alfalfa grown for seed resulted in MOEs (57 and 54, respectively) that were above the Agency's level of concern when large acreage (1200 acres treated per day) is considered.

However, data were submitted by the UC Davis, Western Integrated Pest Management Center which provided evidence of lower acreage values (328 acres treated per day) for alfalfa grown for seed. In addition, Agency data suggest that majority of the alfalfa acreage treated with formetanate HCl in the United States is in California. Therefore, this assessment was refined to reflect the lower acreage. When the new acreage is considered, the risk for aerial application on alfalfa for seed is below the Agency's level of concern (MOE=200). However, there is still a potential risk of concern for the mixer/loader scenario for aerial application (combined dermal and inhalation MOE= 69).

Although the Agency is concerned with the MOE for the mixing/loading scenario for aerial application on alfalfa grown for seed, EPA recognizes the inputs used to calculate the risk are based on conservative assumptions. The NOAEL used in the inhalation assessment was derived from an oral endpoint from an acute neurotoxicity study (0.1 mg/kg/day), and an inhalation absorption factor of 100% was used as a high end default value in lieu of an inhalation study. The Agency is requiring as a condition of this interim decision, the submission of an inhalation study which will provide a more refined estimate of the inhalation risks for workers handling formetanate HCl. The Agency believes these data will confirm the conclusion that no mitigation is appropriate for the mixer/loader scenario for aerial applications to alfalfa.

Handler Risks for Applications to Orchard Fruits:

The risk for the mixer/loader scenario using aerial application on orchard fruit exceeds EPA's level of concern using engineering controls (MOE=51). No other level of protection can be added to reduce this risk. In addition, based on Agency data, there are virtually no aerial applications of formetanate HCl to tree crops (less than 1%). Therefore, EPA has determined that aerial applications must be prohibited for orchard crops for reregistration eligibility.

The risk for applicator scenarios using airblast sprayers on orchard fruit exceeded the Agency's level of concern at Baseline PPE (MOE=19) and with double layer protection (MOE=73). When engineering controls (single layer clothing and closed cabs) are added, the risk was below the Agency's level of concern (MOE=240).

Flagger Risks for all aerial applications:

MOEs for flaggers are at an acceptable level with double layer PPE and a respirator. However, the Agency has concerns with requiring additional protective clothing for these workers due to the potential for heat stress with additional PPE. The Agency believes that most aerial applicators have either GPS systems or can use closed cabs for flagger protection.

Therefore to be eligible for reregistration, the following mitigation is required to reduce risk for handlers:

- *Revise labels to prohibit aerial application for orchard crops*.

- *Revise labels to require closed cabs for applicators using airblast sprayers on orchard fruit.*
- *Revise labels to require closed cabs for human flaggers for aerial applications.*

- *Additionally, based on results of the risk assessment for the active-ingredient, the registrant may be able to revise labels by reducing the PPE to a single layer with a PF5 respirator for applicators using groundboom equipment for alfalfa for seed, depending on end-use product toxicity.*

Post Application Risks from Alfalfa and Orchard Fruits:

Based on the formetanate HCl occupational assessment for postapplication, MOEs for high exposure activities are below levels of concern by day 10 for evergreen fruit trees, day 8 for deciduous fruit trees, and day 9 for alfalfa.

It was determined that high exposure activities (hand harvesting) are not appropriate for alfalfa, and therefore, a 6-day REI is considered appropriate to protect post application workers performing medium-exposure activities.

Therefore to be eligible for reregistration, the following mitigation is required to reduce risk for postapplication workers:

- *Revise labels to require a 10 day re-entry interval (REI) for citrus, an 8 day REI for pome and stone fruits, and a 6 day REI for alfalfa.*

2. Ecological Risk Management and Mitigation

Although the screening level ecological risk assessment shows risks of concern, the risks are relatively low in comparison with other N-methyl carbamates. For formetanate HCl, the highest RQ estimates were identified for chronic mammals when maximum estimated residues are considered (RQ's were as high as 28). Chronic risk to birds was low (highest RQ was 5). There were no risks of concern to aquatic organisms.

The Agency is not proposing additional mitigation for ecological risks at this time since considerable reductions in rates and uses were made in 1999 in accordance with the MOA. Additionally, some of the dietary and worker mitigation will result in slightly lower ecological exposures.

3. Significance of Formetanate HCl Use

There are advantages to the use of formetanate HCl as an insecticide. EPA has received comments supporting the continued use of formetanate HCl to control thrip outbreaks on stone fruit and citrus crops. USDA, private citizens, and grower organizations have expressed their need for the use of formetanate HCl as a rotational partner with other insecticides, as part of an efficacious integrated pest management program.

Formetanate HCl is a niche pesticide for growers needing the chemical to control thrips which can severely damage the skin of orchard fruits. Formetanate HCl is used extensively in California for treatment of orchard crops, particularly nectarines. Since California orchard crops are grown primarily for the fresh market, the appearance of the fruit dramatically affects the grower's ability to sell the fruit.

Alfalfa grown for seed is a relatively minor, but high value crop. Based on Agency data, approximately 48,000 acres nationally are grown for seed on an annual basis. Alfalfa growers use formetanate HCl as part of their integrated pest management programs.

4. Spray Drift

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

From its assessment of formetanate HCl, as summarized in this document, the Agency concludes that no additional drift mitigation measures are needed for formetanate HCl. The deletion of aerial application of all orchard crops from the formetanate HCl labels will reduce the potential for drift. In the future, formetanate HCl product labels may need to be revised to include additional or different drift label statements. Additionally, the Agency encourages the inclusion of best management practices on labels to reduce spray drift.

5. Endangered Species Considerations

From the screening level assessment, RQs exceeded the LOCs for endangered species for some of the representative exposure scenarios considered. The Agency's screening level assessment results in the determination that formetanate HCl will have no direct acute effects on threatened and endangered freshwater fish, invertebrates, and estuarine mollusks.

The preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for birds and mammals with RQs ranging up to 0.2 for birds and up to

18 for mammals. Chronic RQs for all uses exceeded LOCs for endangered birds using a single application (RQs for birds ranged from 2 to 5). Additionally, chronic RQs were exceeded LOCs for mammals from all uses at a single application rate (RQ's ranged from 2 to 28).

Further, potential indirect effects to any species dependent upon a species that experiences effects from use of formetanate HCl can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the IREDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this IRED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of formetanate HCl, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of formetanate HCl "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this IRED will reduce the likelihood that endangered and threatened species may be exposed to formetanate HCl at levels of concern. EPA is not requiring specific formetanate HCl label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

V. What Registrants Need to Do

The Agency has made an interim determination that formetanate HCl is eligible for reregistration provided that product specific data are submitted and the mitigation measures stated in this document are included in upcoming label submissions. In the near future, the Agency intends to issue Data Call-In (DCIs) notices requiring product specific data and generic confirmatory (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific

studies being required. Listed below is the additional generic data that the Agency intends to require.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the interim reregistration of formetanate HCl for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the interim reregistration eligibility decision documented in this RED.

830.7050	UV-Visible Absorption
830.1550	Product Identity and Composition
830.1750	Certified Limits
830.1800	Enforcement of Analytical Method
835.4100	Aerobic Soil Metabolism
835.4200	Anaerobic Soil Metabolism
860.1300	Nature of the Residue
860.1500	Crop Field Trials
870.1200	Acute Dermal Toxicity
870.1300	Acute Inhalation Toxicity
870.2500	Primary Dermal Irritation
870.3465	28-Day Inhalation Toxicity Study

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g) (2) (B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrations Response Form provided for each product. The Agency intends to issue a separate product-specific Data Call-In outlining specific data requirements.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. The specific changes and language required are presented in Table 8 below.

Existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Please refer to "Existing

Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

Labeling Changes Summary Table [Attachment III]

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride

Description	Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	AOnly for formulation into an insecticide for the following use(s) nectarines, peaches, pome fruits, citrus, and alfalfa grown for seed.@ "This product may be used only to formulate wettable powder end use products that are packaged in water soluble packets".	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	AThis product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@ AThis product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).@	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to	Precautionary Statements

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride		
	sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters."	
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] For Wettable Powder Formulations (Note: Only products packaged in water soluble bags will be eligible for reregistration)	APersonal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." AMixers, loaders, applicators, flaggers, and other handlers must wear: > Long-sleeved shirt and long pants, > Shoes plus socks, > Chemical resistant gloves and apron for mixers and other handlers exposed to the concentrate. > Applicators using groundboom equipment must wear a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C *or* -- any N, R, P, or HE filter@ "See Engineering Controls for Additional Requirements" ***Instruction to Registrant****:* Drop the AN@ type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride		
User Safety Requirements	ADiscard clothing and other absorbent materials that have been drenched or heavily contaminated with this product=s concentrate. Do not reuse them.@ "Follow manufacturers' instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for wettable powder formulations	"Engineering Controls Applicators using airblast equipment and flaggers must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must: -- wear the personal protective equipment required in the PPE section of this labeling for applicators, -- *either* wear the type of respirator specified in the PPE section of this labeling *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling, -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling, -- take off any PPE that was worn in the treated area before reentering the cab, and	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride		
	-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.@ "Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must : -- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear and the respirator as specified in the PPE section of this label. Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-5), the handler PPE requirements may be reduced or modified as specified in the WPS.@	
User Safety Recommendations	AUser Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside.	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride		
	Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.@	
Environmental Hazards	"This product is toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwaters or rinsate." "This chemical can contaminate surface water through spray applications. Under some conditions, it may also have a potential for runoff into surface water after application." "This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area. Do not allow animals to graze in treated orchard areas."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval (REI)	ADo not enter or allow worker entry into treated areas during the restricted entry interval (REI) of: 10 days for citrus 8 days for pome and stone fruits 6 days for alfalfa grown for seed"	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	APPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that	Direction for Use Agricultural Use Requirements box

Table 12: Summary of Labeling Changes for Formetanate Hydrochloride		
	has been treated, such as plants, soil, or water, is: coveralls, shoes plus socks chemical-resistant gloves made of any waterproof material@ "Notify workers of the application by warning them orally and by posting warnings signs at entrances to treated area."	
General Application Restrictions	ADo not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.@	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	"Late season applications to apples is prohibited; Only apply at petal fall" "Aerial applications to orchard crops is prohibited" "Hand harvesting for alfalfa is prohibited"	Directions for Use in the appropriate site/crop instructions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

[2] Label requirements in quotes are to be specified on the label.

VI. Appendices

Appendix A: Formetanate HCl Use Patterns Eligible for Reregistration

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Maz (lbs ai/A/Yr.)	PHI (Days)	REI (Days)	Restrictions/Comments
Alfalfa						
Aerial & Groundboom	Wettable Powder	0.92	0.92	21	6	
Apple						
Airblast	Wettable Powder	1.15	1.15	One application can be made through petal fall.	8	Late season uses are prohibited. Use of aerial application in apple orchards is prohibited.
Grapefruit,Orange						
Airblast	Wettable Powder	1.15	1.15	Applications may be made to overcropped grapefruits and Valencia oranges above one inch in diameter, provided that a preharvest interval (PHI) of 30 days is obaserved.	10	Use of aerial applications in grapefruit and orange orchards is prohibited.
Lemon, Limes, Tangelos, Tangerines						
Airblast	Wettable Powder	1.15	1.15	One application may be made prior to fruit reaching one inch in diameter.	10	Use of aerial applications in these orchards is prohibited.
Nectarine, Peach						
Airblast	Wettable Powder	1.15	1.15	One application may be made through shuck fall.	8	Use of aerial applications in nectarine and peach orchards is prohibited.
Pear						
Airblast	Wettable Powder	1.15	1.15	One application may be made through petal fall. One additional application for pears may be made in the late season to control pest in CA, OR, WA and ID upon written approval on a case-by-case basis by the State Agency responsible for enforcement of FIFRA, or authorized by that state agency.	8	Use of aerial application in pear orchards is prohibited.

Appendix B
Data Supporting Guideline Requirments for the Reregistration of Formetnate HCl

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the chemical case covered by this RED. It contains generic data requirements that apply in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703)487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

A. Terrestrial food
B. Terrestrial feed
C. Terrestrial nonfood
D. Aquatic food
E. Aquatic nonfood outdoor
F. Aquatic nonfood industrial
G. Aquatic nonfood residential
H. Greenhouse food
I. Greenhouse nonfood
J. Forestry
K. Residential
L. Indoor food
M. Indoor nonfood
N. Indoor medical
O. Indoor residential

3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each study. Normally, this is the Master Record Identification (MRID) Number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirments for the Registration of Formetanate HCl

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation
PRODUCT USE CHEMISTRY				
830.1550	61-1	Product Identity and Disclosure of Ingredients	A,B,C	Confirmatory Data Needed
830.1600	61-2A	Starting Materials and Manufacturing Process	A,B,C	00144899, 42089807, 42155401, 43489402
830.1620				
830.1650				
830.1670	61-2B	Discussion of Formation Impurities	A,B,C	00144899, 42089807, 42155401, 43489404
830.1700	62-1	Preliminary Analysis	A,B,C	00144899, 42089801, 42155401, 43489407, 43489408
830.1750	62-2	Certification of Ingredient Limits	A,B,C	Confirmatory Data Needed
830.1800	62-3	Analytical Methods to Verify the Certified Limits	A,B,C	Confirmatory Data Needed
830.6302	63-2	Color	A,B,C	00064035, 42155402
830.6303	63-3	Physical State	A,B,C	00064035, 42155402
830.6304	63-4	Odor	A,B,C	00064035, 42155402
830.6313	63-13	Stability	A,B,C	00064035, 42155402
830.6314	63-14	Oxidation/Reduction	A,B,C	00144899
830.6316	63-16	Explodability	A,B,C	00144899
830.6317	63-17	Storage Stability	A,B,C	00064035, 42155402
830.6320	63-20	Corrosion Characteristics	A,B,C	00144899
830.7000	63-12	pH	A,B,C	00142494
830.7050		UV/Visible Absorption	A,B,C	Confirmatory Data Needed
830.7200	63-5	Melting Point/Melting Range	A,B,C	00064035, 42155402
830.7300	63-7	Density/Relative Density/Bulk Density	A,B,C	00142494
830.7370	63-10	Dissociation Constant in Water	A,B,C	00142494
830.7550	63-11	Partition Coefficient (Octanol/Water)	A,B,C	00142494
830.7560				
830.7570				
830.7840	63-8	Solubility	A,B,C	00064035, 42155402
830.7860				
830.7950	63-9	Vapor Pressure	A,B,C	00064035, 42155402
ECOLOGICAL EFFECTS				
850.2100	71-1A	Acute Avian Oral, Quail/Duck	A,B,C	00077751
850.2200	71-2A	Acute Avian Dietary, Bobwhite Quail	A,B,C	00164338
850.2200	71-2B	Acute Avian Dietary, Mallard Duck	A,B,C	00164337
850.2300	71-4A	Avian Reproduction, Bobwhite Quail	A,B,C	42841001
850.2300	71-4B	Avian Reproduction, Mallard Duck	A,B,C	42841002
850.1075	72-1A	Acute Fish Toxicity, Bluegill	A,B,C	00164340
850.1075	72-1C	Acute Fish Toxicity,	A,B,C	00164339

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation
		Rainbow Trout		
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity	A,B,C	00160118
850.1025	72-3B	Acute Estuarine/Marine Toxicity, Mollusk	A,B,C	42306601
850.1035	72-3C	Acute Estuarine/Marine Toxicity, Shrimp	A,B,C	00131846
850.1300	72-4A	Daphnia Chronic Toxicity Test	A,B,C	42980601
850.1350	72-4B	Mysid (Shrimp) Chronic Toxicity	A,B,C	43228701
850.1710	72-6	Aquatic Organism Accumulation Study	A,B,C	00077656
850.3020	141-1	Honey Bee Acute Contact Toxicity	A,B,C	00077766
TOXICOLOGY				
870.3100	82-1A	90-Day Oral Toxicity – Rodent	A,B,C	42664401
870.3200	82-2	90 Day Oral Toxicity –Non-rodents	A,B,C	44948501
870.3700	83-3A	Prenatal Developmental in Rats	A,B,C	00151570
870.3700	83-3B	Prenatal Developmental in Non-rodents	A,B,C	00151571
870.3800	83-4	Reproduction and Fertility Effects	A,B,C	40411801,-02 and -03
870.4100	83-1B	Chronic Toxicity – Dogs	A,B,C	00164341
870.4200	83-2A	Carcinogenicity – Rat	A,B,C	40640901
870.4300	83-5	Carcinogenicity – Mouse	A,B,C	40707101
870.6200	81-8	Acute Neurotoxicity Screening Battery	A,B,C	45314201
870.6200	82-7	Subchronic Neurotoxicity Screening Battery	A,B,C	45314202
870.6300	83-6	Special Non-Guideline Comparative ChEI Study	A,B,C	46618901
870.7485	85-1	Metabolism and Pharmacokinetics	A,B,C	42684601,42684602,42684603,42684604, and 42909701
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	A,B,C	44151201
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B,C	00141498
835.2240	161-2	Photolysis	A,B,C	00164331, 42155403
835.2410	161-3	Photodegradation in Soil	A,B,C	00164331, 42155403
835.4100	162-1	Aerobic Soil Metabolism Study	A,B,C	Confirmatory Data Needed
835.4200	162-2	Anaerobic Soil Metabolism	A,B,C	Confirmatory Data Needed
835.1240	163-1	Soil Column Leaching	A,B,C	42089805, 43034002
835.6100	164-1	Terrestrial Field Dissipation Study	A,B,C	41192301, 41192302,
860.1950	165-4	Accumulation (Bioaccumulation) in Fish	A,B,C	00077656

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographical Citation
RESIDUE CHEMISTRY				
860.1200	171-3	Directions for Use	A,B,C	
860.1300	171-4A	Nature of Residue - Plants	A,B	Confirmatory Data Needed
860-1300	171-4B	Nature of Residue - Livestock	A,B	00164328, 00164329, 42664414, 42664417, 43329001, 43329002
860.1340	171-4C	Residue Analytical Method – Plants	A,B	00029161, 00035917, 40411802
860.1340	171-4D	Residue Analytical Method-Livestock	A,B	40557601
860.1360	171-4M	Multiresidue Methods	A,B	42664406, 42983201
860.1380	171-4E	Storage Stability Data	A,B	00077702, 40411803, 42664407, 42664408, 42723601, 43329003, 43384401, 43384405, 43610401, 43610403
Citrus Fruits Group				
860.1500	171-4K	Crop Field Trials (Grapefruit)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Lemon)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Lime)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Orange)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Tangelo)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Tangerine)	A,B	Confirmatory Data Needed
Pome Fruits Group				
860.1500	171-4K	Crop Field Trials (Apple)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Pear)	A,B	Confirmatory Data Needed
Stone Fruits Group				
860.1500	171-4K	Crop Field Trials (Nectarine)	A,B	Confirmatory Data Needed
860.1500	171-4K	Crop Field Trials (Peach)	A,B	Confirmatory Data Needed
Non-Grass Animal Feeds				
860.1500	171-4K	Crop Field Trials (Alfalfa For Seed)	A,B	40534301
Processed Food/Feed				
860.1520	171-4L	Processed Food (Apple)	A,B	00077721
860.1520	171-4L	Processed Food (Citrus)	A,B	00073455, 00077665, 00077702
Meat, Milk, Poultry, Eggs				
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry, and Eggs	A,B	41299601, 41299603
Confined Rotational Crops				
860.1850	165-1	Confined Rotational Crops	A,B,C	43170401, 43583101

C. Technical Support Documents

Appendix C. Technical Support Documents

Additional documentation in support of this IRED is maintained in the OPP Regulatory Docket, located in One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

The docket initially contained preliminary human health and ecological effects risk assessments and related documents that were published March 24, 2004. The public comment period closed sixty (60) days later on May 24, 2004. The EPA then considered comments and revised the risk assessments where appropriate. Final human health and ecological risk assessments, as well as additional support documents, will be published in the docket with this RED. These documents include the following:

Phase 3 Public Comment Documents:

HED Documents

Formetanate Hydrochloride, Addendum to Acute (Probablistic) and Chronic Dietary Exposure Assessment. 6/4/2003.

Formetanate Hydrochloride: The Occupational and Residential Exposure Assessment & Recommendations for the RED. 5/21/2003.

Formetante Hydrochloride, HED Revised Chemistry Chapter of the RED: Summary of Analytical Chemistry & Residue Data. 3/27/2003.

Formetanate Hydrochloride Toxicology Chapter for the RED. 4/14/2003.

Formetanate Hydrochloride (97301) HED Product Chemistry Chapter of the RED. 3/27/2003.

Formetante Hydrochoride – 4th Report of the Hazard Identification Assessment Review Committee. 5/21/2003.

Formetanate Hydrochloride – Acute & Chronic Dietary Exposure Assessment for the RED. 4/28/2003.

HED Revised Risk Assessment for Formetanate Hydrochloride. 6/4/2003.

HED Preliminary Risk Assessment for Formetanate Hydrochloride. 4/6/1999.

Formetanate Hydrochloride – Report of the Hazard Identification Assessment Review Committee. 7/22/2002.

HED Revised Risk Assessment for Formetanate Hydrochloride. 12/23/2005.
Formetanate Hydrochloride HED Revised Chemistry Chapter of the RED: Summary of Analytical Chemistry and Residue Data. 12/14/2005.

Formetanate Hydrochloride: Revised Acute Probablistic and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision. 12/16/2005.

EFED Documents

EFED Science Chapter for the Formetanate Hydrochloride RED. 10/22/2003.

EFED Science Chapter for the Formetanate Hydrochloride RED. 8/29/1997.

Revised Tier II Drinking Water Assessment for Formetanate HCl. 3/27/2003.

Other Documents

Formetanate Hydrochloride, Addendum to the HED Revised Risk Assessment for Formetanate Hydrochloride dated May 23, 2005

D. Bibliography

Bibliography

MRID	Citation Reference
29161	Nor-Am Agricultural Products, Incorporated (1969) 332/30: Colorimetric Determination of Formetanate HC1. (Nor-Am EP-332) in Plant Material: (Schering 36 056/5 Revised). Method dated May 22, 1969. (Unpublished study received May 22, 1980 under OE2363; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:099438-B)
35917	Jenny, N.A. (1969) Gas Chromatographic Residue Determination of Formetanate HC1 (Nor-Am Carzol) in Plant Material: Report 332/41. Method dated Nov 7, 1969. (Unpublished study received Feb 1, 1973 under 3F1351; submitted by Nor-Am Agricultural Products, Inc., Naperville, Ill.; CDL:096476-F)
64035	Nor-Am Agricultural Products, Incorporated (19??) Formetanate hydrochloride. (Unpublished study received Mar 18, 1970 under 0F0961; CDL:093273-M)
73455	Morton Chemical Company (1968) ?Residues of Formetanate on Oranges, Grapefruit and Lemons|. (Compilation; unpublished study re- ceived Nov 29, 1968 under 9G0746; CDL:091290-E)
77656	Michigan State University (1968?) Residues of C^14I Formetanate-hydrochloride in Green Sunfish following a Subacute Exposure. (Unpublished study received May 18, 1973 under 2139-99; CDL: 124298-A)
77665	Nor-Am Agricultural Products, Incorporated (1975) Residues of Formetanate Hydrochloride in Citrus Treated with Carzol SP by Air. Includes method 332/30 dated May 22, 1969. (Compilation; unpublished study received Mar 12, 1975 under 2139-99; CDL: 110595-A)
77702	Nor-Am Agricultural Products, Incorporated (1970) ?Residue Data on Carzol SP in Citrus Fruits|. (Compilation; unpublished study received Apr 12, 1970 under 0F0961; CDL:091643-D)
77721	Nor-Am Agricultural Products, Incorporated (1973) Residues of Formetanate Hydrochloride in Apple Products. (Compilation; unpub- lished study, including letter dated Oct 8, 1973 from M. Lambert to Edward Gross, received Apr 25, 1973 under 3H5029; CDL: 221762-F)
77751	Nor-Am Agricultural Products, Incorporated (19??) ?Toxicity of Carzol to Bobwhite Quail and Mallard Ducks|. (Compilation; unpublished study received May 27, 1970 under 0F0989; CDL: 093298-D)
77766	Nor-Am Agricultural Products, Incorporated (1972) ?Formetanate Hy-

drochloride Residues in Almonds|. (Compilation; unpublished study received Jul 12, 1973 under 4F1419; CDL:093790-B)

131846 Rausina, G. (1975) Report to Four-day Static Aquatic Toxicity Studies with Carzol SP in Grass Shrimp and Shore Crabs: IBT No. 621-06936. (Unpublished study received Aug 11, 1983 under 2139-99; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Nor-Am Agricultural Products, Inc., Naperville, IL; CDL:250994-A)

141498 Rehme (1982) Investigation of the Hydrolysis of Carzol in Agueous Solutions: Report Nr. 36/82. Unpublished study prepared by Schering AG. 6 p.

142494 Nor-Am Chemical Co. (1984) [Chemistry Data for Formetanate HCL]. Unpublished compilation. 17 p.

144899 Nor-Am Chemical Co. (1984) [Chemistry Data for Formetanate HCL]. Unpublished compilation. 18 p.

151570 Tesh, J.; Willoughby, C.; Lambert, E.; et al. (1985) Technical For- metanate-HCl: Effects of Oral Administration (Gavage) upon Preg- nancy in the Rat (Teratology Study): LSR Report No. 84/SCE004/ 318. Unpublished study prepared by Life Science Research. 100 p.

151571 Tesh, J.; Ross, F.; Wightman, T.; et al. (1985) Technical Formeta- nate-HCl: Effects of Oral Administration (Gavage) upon Pregnancy in the Rabbit (Teratology Study): LSR Report No. 84/SCE002/319. Unpublished study prepared by Life Science Research. 95 p.

160118 Barrett, K.; Arnold, D. (1986) Determination of the Acute Toxicity of Formetanate to Daphnia magna: Report No. METAB/85/40: Study No. 59D. Unpublished study prepared by FBC Ltd. 12 p.

164328 Campbell, J.; Needham, D. (1986) Metabolism and Residues of Forme- tanate Hydrochloride in Laying Hens: Proj. ID. No. METAB/86/36. Unpublished study prepared by Schering Agrochemicals Ltd. 24 p.

164329 Campbell, J.; Needham, D. (1986) Excretion and Tissue Residues of Formetanate Hydrochloride in a Lactating Goat: Proj. ID. No. METAB/86/28. Unpublished study prepared by Schering Agrochemi- cals Ltd. 24 p.

164331 Brehm, M. (1986) Photodegradation of Formetanate Hydrochloride (...) on Soil Surfaces: Proj. ID. APC/41/86. Unpublished study prepared by Schering AG. 43 p.

164337 Roberts, N.; Fairley, C. (1986) Technical Formetanate Hydrochlo- ride: Subacute Dietary Toxicity (LC50) to the Mallard Duck: HRC Study No. FSB 187BT/851171. Unpublished study prepared by Huntingdon Research Centre. 23 p.

164338 Roberts, N.; Fairley, C. (1986) Technical Formetanate Hydrochlo- ride:

Subacute Dietary Toxicity (LC50) to the Bobwhite Quail: HRC Study No. FSB 186BT/851172. Unpublished study prepared by Huntingdon Research Centre. 22 p.

164339 Barrett, K.; Arnold, D. (1986) The Acute Toxicity of Formetanate Hydrochloride to Rainbow Trout (Salmo gairdneri): Proj. ID No. METAB/86/31. Unpublished study prepared by Schering Agrochemi- cals Ltd. 19 p.

164340 Hill, R. (1986) Determination of Acute Toxicity to Bluegill Sunfish (Lapomis macrochirus): Formetanate Hydrochloride: Proj. ID No. BL/B/2940. Unpublished study prepared by Imperial Chemical Industries Ltd. 18 p.

164341 Massey, J.; Harling, R.; Buist, D.; et al. (1986) Dietary Toxicity Study in Beagle Dogs (Final Report - Repeated Administration for 52 Weeks): Formetanate Hydrochloride: HRC Rept. No. FSB 150/ 86477. Unpublished study prepared by Huntingdon Research Centre Ltd. 278 p.

40411801 Tesh, J. (1987) T83 Technical Formetanate Hydrochloride: The Reproductive Performance of Rats Treated Continuously Through Two Successive Generations: Laboratory Project ID TOX 85002. Unpublished study prepared by Life Science Research Ltd. 1242 p.

40411802 Scheuermann, H. (1987) R155/Formetanate HCL: GLC Method of Analysis for Major Formetanate Derived Residues in Nectarines (10 970 1/87): Laboratory Project ID UPSR 32/87 PA 10 970.5/11. Unpublished study prepared by Schering AG. 28 p.

40411803 Scheuermann, H. (1987) R156 Formetanate HCL: Residues of Formetanate X HCL and Major Metabolites in Stone Fruits Follow- ing Foliar Application of CARZOL (92 SP) in the USA 1985 and 1986 (10 970 11/87): Laboratory Project ID UPSR 36/87 PA 10 970.6/11. Unpublished study prepared by Schering AG. 43 p.

40534301 Scheuermann, H. (1988) R157 Formetanate: Residue Decline of Formetanate x HCL and Major Metabolites in Alfalfa Following Foliar Application of Carzol (90SP) in the USA 1985 (10970 III/ 87): Laboratory Project ID UPSR 50/87. Unpublished study prepared by Schering AG, Germany. 52 p.

40557601 Manley, J.; Snowdon, P. (1988) R154 Formetanate: Analytical Method for the Determination of Residues of Formetanate and Major Metabolites Hydrolysing to 3-Aminophenol in Animal Tissues, Milk and Eggs by Gas Chromatography: Laboratory Project ID RESID/87/82. Unpublished study prepared by Schering Agrochemicals Limited, England. 38 p.

40640901 Mallyon, B. (1988) T87 Technical Formetanate Hydrochloride: An Eva- luation of Dietary Oncogenic and Chronic Toxicity Potential in the Rat: Final Report: Project ID: TOX 84083. Unpublished study prepared by Schering Agrochemicals Ltd. 1919 p.

40707101 Mallyon, B. (1988) T85 Technical Formetanate Hydrochloride: An Evaluation of Dietary Oncogenic Potential in the Mouse: Labora- tory Project ID: TOX/87/197-64. Unpublished study prepared by Schering Agrochemicals Ltd. 1146 p.

41192301 Scheuermann, H. (1989) W75/2 Formetanate: Dissipation of Formeta- nate X HCl and Relevant Metabolites in Soil Following Maximum Recommended Use Rates in an Orchard in the USA, 1987: Laboratory Project ID UPSR 27/89. Unpublished study prepared by Schering AG. 107 p.

41192302 Scheuermann, H. (1989) W76/2 Formetanate: Dissipation of Formeta- nate X HCl and Relevant Metabolites in Soil Following Maximum Recommended Use Rates in Alfalfa Trials in the USA 1987: Labora- tory Project ID UPSR 30/89. Unpublished study prepared by Schering AG. 187 p.

41299601 Roberts, N.; Cameron, D.; Emerson, E. (1988) R163A Formetanate Hydrochloride: Residues in Milk & Tissues of Dairy Cows--Animal Phase: Lab Project Number RESID/88/44; FSB 275/861445; 101/05/001. Unpublished study prepared by Huntingdon Research Centre. 23 p.

41299603 Manley, J.; Snowdon, P. (1989) C49 Formetanate: Analytical Method for the Determination of Dietary Concentrations of Formetanate Hydrochloride in Maize Oil by High Performance Liquid Chromatography: Lab Project Number RESID/88/46; 101/01/002. Unpublished study prepared by Schering Agrochemicals Ltd. 20 p.

42089801 Muller, T.; Steib, C.; Lehne, V. (1991) Formetanate Hydrochloride: Product Chemistry: Lab Project Number: C-55: C-56: C-57. Unpub- lished study prepared by Schering AG. 83 p.

42089805 Forster, V. (1990) W-83, Formetanate Hydrochloride: The Sorption of Formetanate Hydrochloride on German Standard Soils 2.1 and 2.3 and Schering Soils 175 and 179: Lab Project Number: 62/90-PA 10 970.7/18. Unpublished study prepared by Schering AG. 40 p.

42089807 Vukich, J. (1991) Formetanate Hydrochloride: Preliminary Discussion of Proposed Alternative Manufacturing Process: Lab Project Numb- er. Unpublished study prepared by Nor-Am Chemical Co. 38 p.

42155401 Steib, C.; Muller, T.; Klehr, M.; et al. (1991) Formetanate Hydrochloride: Product Chemistry: Lab Project Number: C-53: C-61: C-8. Unpublished study prepared by Schering Ag. 306 p.

42155402 Steib, C.; Muller, T.; Lehne, V. (1991) Formetanate Hydrochloride: Product Chemistry: Lab Project Number: C-62: C-65: C-59. Unpublished study prepared by Schering Ag. 153 p.

42155403 Brehm, M. (1991) W67, Addendum 1--Formetanate-HCL: Photodegradation of Formetanate Hydrochloride (...) on Soil Surfaces: Lab Project Number: 00164331. Unpublished study prepared by Schering Ag. 28 p.

42306601 Sved, D.; Smith, G. (1992) Formetanate Hydrochloride: a 96-Hour Shell Deposition Test with the Eastern Oyster (Crassostrea virginica): Final Report: Lab Project Number: 244A-103: W-90. Unpublished study prepared by Wildlife Intl. 41 p.

42664401 Wason, S. (1992) Investigational Study into the Effects on Acetylo-cholinesterase in the Rat following Treatment for 3 Months: T97 Formetanate: Technical Formetanate Hydrochloride: Lab Project Nos. 020901: TOX/91/197-71: 91/197-71. Unpublished study pre- pared by Schering Agrochemical Ltd. 77 p.

42664406 Bowman, M. (1992) Testing of Formetanate HCL (R187) through U.S. FDA Multiresidue Methods: U.S.A., 1992: Lab Project Number: MCB-NOR-AM/MR-5: Y-92R-03. Unpublished study prepared by M.C. Bowman & Associates. 76 p.

42664407 Wrede-Rucker, A. (1992) Stability of Formetanate X HCL and its Metabolite ZK 10 714 during Deep Freeze Storage in Peaches: Interim Report: (R191 Formetanate HCL): Lab Project Number: U/R 43/92: 020906: PF-R 92 029. Unpublished study prepared by Schering AG. 27 p.

42664408 Wrede-Rucker, A. (1992) Stability of Formetanate HCL and its Metabolite ZK 10 714 during Deep Freeze Storage in Apples: Interim Report: (R191 Formetanate HCL): Lab Project Number: U/R/ 45/92: 020907. Unpublished study prepared by Schering AG. 27 p.

42664410 Brady, S. (1992) At-harvest Formetanate-derived Residues in or on Nectarines following Treatment with Carzol SP (Aerial and Ground) at Maximum Use Rates: USA, 1991: Lab Project Number: Y-91R-01. Unpublished study prepared by NOR-AM Chemical Co. 42 p.

42664414 Reynolds, C. (1993) The Nature of the Residues of Formetanate HCL in the Edible Tissues and Milk of a Cow following Oral Administration for 7 days at a Dose Equivalent of 30 ppm in the Diet: Lab Project Number: TOX 92/197-76: 020910: T0X 91044. Unpublished study prepared by Schering Agrochemical Ltd. 170 p.

42664417 Reynolds, C. (1992) The Excretion and Distribution of Formetanate HCL and its Metabolites in the Laying Hen following Daily Oral Administration at a Dose Rate Equivalent to 10 ppm in the Diet: Lab Project Number: TOX 92/197-74: 020911: TOX 91045. Unpublished study prepared by Schering Agrochemical Ltd. 27 p.

42684601 O'Boyle, F. (1993) M-18: The Distribution and Excretion of Radiolabelled Residues in the Rat Following Oral Dosing with (carbon 14)-Formetanate Hydrochloride at 10 mg/kg Body Weight: Lab Project Number: TOX/92/197-75: TOX 91043A: M-18. Unpublished study prepared by Schering Agrochemicals Ltd. 16 p.

42684602 Elson, L. (1993) M-17: The Metabolism of Formetanate HC1 in the Rat: Lab

Project Number: SMS 437A/921189: TOX 91043: TOX/92/197-78. Unpublished study prepared by Huntingdon Research Center, Ltd. 65 p.

42684603 O'Boyle, F. (1993) M-24: The Metabolism of Formetanate Hydrochloride in the Rat Following Oral Dosing at 10 mg/kg Body Weight: Lab Project Number: TOX/93/197-79: TOX/91330: M-24. Unpublished study prepared by Schering Agrochemicals Ltd. 60 p.

42684604 Girkin, R. (1993) M-25: The Metabolism of Formetanate Hydrochloride in the Rat Following Dosing with (carbon 14)-Formetanate Hydrochloride at 0.1 mg/kg Body Weight: Lab Project Number: SMS 437B/930480: TOX 91043: M-25. Unpublished study prepared by Huntingdon Research Center, Ltd. 49 p.

42841001 Mansell, P. (1993) Technical Formetanate HCl: Bobwhite Quail Dietary Reproduction and Tolerance Studies: Lab Project Number: SMS 351: SMS 309/93057: TOX 91041. Unpublished study prepared by Huntingdon Research Center, Ltd. 263 p.

42841002 Mansell, P. (1993) Technical Formetanate HCl: Mallard Duck Dietary Reproduction and Tolerance Studies: Lab Project Number: SMS 352: SMS 310/930571: TOX 91040. Unpublished study prepared by Huntingdon Research Center, Ltd. 216 p.

42723601 Scheuermann, H. (1990) Stability of Formetanate X HCl in Alfalfa during Deep Freeze Storage: Lab Project Number: UPSR 56/90: 4010. Unpublished study prepared by Schering AG. 20 p.

42983201 Williams, L. (1993) Testing of Formetanate.HCL Through Protocol A of US FDA Multiresidue Methods: Lab Project Number: Y-92R-08. Unpublished study prepared by NOR-AM Chemical Co. 26 p.

42909701 O'Boyle, F.; Elson, L.; Girkin, R. (1993) Supplement 1: Metabolism of Formetanate Hydrochloride in the Rat: Lab Project Number: M-18: M-17: M-24. Unpublished study prepared by NOR-AM Chemical Co. 34 p.

42980601 Kelly, I.; Schupner, J. (1993) Formetanate W-91, Supplement 1: The Toxicity of Formetanate-HCL Early Life Stages of Fathead Minnow, Pimephales promelas, in a Flow Through System: Lab Project Number: 501Y. Unpublished study prepared by NOR-AM Chemical Co. 32 p.

43034002 Bruhl, R. (1986) W65-Formetanate HCl: Mobility of Formetanate Hydrochloride in a Sandy Loam After Aging (Schering Soil No. 152): Lab Project Number: UPSR 26/86-PA 36 056: 26/86-PA 36 056.73/6. Unpublished study prepared by Schering Ag. 23 p.

43170401 Smith, S. (1994) Uptake of (carbon 14)-Formetanate Residues in Soil by Rotational Crops under Confined Conditions: Lab Project Number: 503Y. Unpublished study prepared by Nor-Am Chemical Co. 167 p.

43228701 Fischer, R.; Young, B.; Schupner, J. (1994) Supplement 2: A Daphnia magna

21-Day Reproduction Study of Formetanate--HCl Technical in a Flow Through System: Lab Project Number: 500 Y. Unpublished study prepared by NOR-AM Chemical Co. 8 p.

43329001 Reynolds, C. (1994) The Nature of Residues of Formetanate HCl in the Edible Tissues and Milk of a Cow Following Oral Administration for 7 Days at a Dose Equivalent of 30 ppm in the Diet: M19-Addendum 1: Lab Project Number: TOX/92/197/76. Unpublished study prepared by Schering Agrochemicals Ltd. 99 p.

43329002 O'Boyle, F. (1994) The Nature of Residues of Formetanate HCl in the Edible Tissues of the Laying Hen Following Oral Administration for 14 Days at a Dose Equivalent to 10 ppm in the Diet: M20-Addendum 1: Lab Project Number: TOX/92/197/77. Unpublished study prepared by Schering Agrochemicals Ltd. 69 p.

43329003 Czochor, L. (1994) Response to EPA Review of Formetanate Hydrochloride Storage Stability Data Base. Unpublished study prepared by AgrEvo USA Co. 17 p.

43384401 Wrede, A. (1994) Formetanate HCl R165-Addendum to Report: Residues of Formetanate x HCl and Major Metabolites in Citrus Following Application of CARZOL 92 SP in the USA 1988: Lab Project Number: UPSR 89/88: PF-R88056. Unpublished study prepared by Schering AG and Hoechst Schering AgrEvo GmbH. 13 p.

43384405 Wrede, A. (1994) Formetanate HCl R179-Addendum to Report: Residues of Formetanate x HCl and Major Metabolites in Citrus Following Application of CARZOL 92 SP in the USA 1989: Lab Project Number: UPSR 11/90: PF-R90007. Unpublished study prepared by Schering AG and Hoechst Schering AgrEvo GmbH. 13 p.

43489402 Cichy, M. (1994) Formetanate Hydrochloride: Description of Beginning Materials and Manufacturing Process: Report Number C73: Lab Project Number: 94/030. Unpublished study prepared by Hoechst Schering AgrEvo GmbH. 59 p.

43489404 Cichy, M. (1994) Formetanate Hydrochloride: Discussion of the Formation of Impurities: Report Number C74: Lab Project Number: 94/034. Unpublished study prepared by Hoechst Schering AgrEvo GmbH. 19 p.

43489407 Mueller, H.; Laass, H.; Cichy, M. (1994) Formetanate Hydrochloride--Preliminary Analysis of 5 Product Samples: Report Number C72 and Amendment: Lab Project Number: 94 02420 55: 94/029. Unpublished study prepared by Hoechst Schering AgrEvo GmbH. 28 p.

43489408 Repenthin, W. (1994) Determination of the Total Content of N-Nitroso Compounds in Formetanate-HCl: Report Number C75: Lab Project Number: AZ 205 340: SPA 05/94. Unpublished study prepared by Schering AG. 31 p.

43583101 Smith, S.; Meyer, B. (1994) Uptake of Residues of (Carbon 14)-Formetanate Residues in Soil by Rotational Crops Under Confined Conditions: Addendum 1 to Report: Lab Project Number: 503Y. Unpublished study prepared by AgrEvo USA Co. 95 p.

43610401 Wrede, A. (1995) Stability of Formetanate x HCl and Its Metabolite ZK 10714 During Deep Freeze Storage of 33 Months in Apples: Lab Project Number: PF-R 92061: R216: R/V41/94.3/16. Unpublished study prepared by Hoechst Schering AgrEvo GmbH. 75 p.

43610403 Wrede, A. (1995) Stability of Formetanate x HCl and Its Metabolite ZK 10714 During Deep Freeze Storage of 2 Years in Citrus Peel and Citrus Flesh: Lab Project Number: PF-R 92030: R218: R/V 40/94-PA 10 970.3/16. Unpublished study prepared by Hoechst Schering AgrEvo GmbH. 87 p.

44054800 AgrEvo USA Co. (1996) Submission of Environmental Fate Data in Support of Reregistration Data Call-In for Formetanate Hydrochloride. Transmittal of 1 Study.

44151201 Cole, M. (1996) Dissipation of Foliar Dislodgeable Residues of Formetanate Hydrochloride Following Application of Carzol SP to Apples and Citrus, USA, 1995: (Interim Report): Lab Project Number: U044/R742: Y-94R-03: 95519. Unpublished study prepared by AgrEvo USA Co. 121 p.

44948501 McAlinden, D. (1999) Rat 21-Day Dermal Toxicity Study Formetanate Hydrochloride: Lab Project Number: TOX 98178: C004820: TOX/99/197-87. Unpublished study prepared by Quintiles England Ltd. 384 p. {OPTS 870.3200}

45314201 Beyrouty, P. (2000) Rat Acute Oral Neurotoxicity Study: Formetanate Hydrochloride: Lab Project Number: 97553: TOX20009. Unpublished study prepared by ClinTrials BioResearch Ltd. 519 p. {OPPTS 870.6200}

45314202 Beyrouty, P. (2000) Rat 13-Week Dietary Neurotoxicity Study: Formetanate Hydrochloride: Lab Project Number: 97554: TOX20010. Unpublished study prepared by ClinTrials BioResearch Ltd. 526 p. {OPPTS 870.6200}

46618901 Barnett, J. (2005) Oral (Gavage) Acute Relative Sensitivity Study of Formetanate HCl in Neonatal and Adult Rats: Final Report. Project Number: WJI00007, WJI00005, WJI00006. Unpublished study prepared by Charles River Laboratories. 648 p.

E. Generic Data Call-In

Note that the complete generic Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

F. Product-Specific Data Call-In

Note that the complete product-specific Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

G. EPA's Batching of Formetanate HCl Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency has determined that batching is not needed for formetanate HCl due to the low number of products.

H. List of Registrants Sent Data Call-Ins

A list of registrants sent this data-call in will sent at a later date.

I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms

Pesticide Registration Forms (these forms are in PDF format and require the Acrobat reader)

Instructions

1. Print our and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer than printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below or the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information'.

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by email at williams.nicole@epa.gov

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf

8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit: www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

   c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

a. Registration Division Personnel Contact List

b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of

pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager Assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition. To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.