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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PC Code: 014504
DP Barcode: 425211
June 9, 2015

MEMORANDUM

SUBJECT: Registration Review – Problem Formulation for the Ecological Risk Assessment and Drinking Water Exposure Assessment to be Conducted for Mancozeb

FROM: Justin Housenger, Biologist
Mohammed Ruhman, Senior Agronomist
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

06/11/15

06/11/15

THROUGH: Mah Shamim, PhD, Branch Chief
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

TO: Steven Snyderman, Chemical Review Manager
Tracy Perry, Team Leader
Kelly Sherman, Acting Branch Chief
Risk Management and Implementation Branch 3
Pesticide Re-Evaluation Division (7508P)

Please, find attached the Preliminary Problem Formulation for the Ecological Risk Assessment and Drinking Water Exposure Assessment for Registration Review to be conducted for Mancozeb

Table of Contents

1. Executive Summary

The Environmental Fate and Effects Division (EFED) has completed the problem formulation for the ecological risk, environmental fate, endangered species, and drinking water assessments to be conducted as part of the registration review of mancozeb. The problem formulation describes the methods planned to be used during the completion of drinking water and ecological risk assessments in support of registration review and provides an overview of the environmental fate, ecological effects, and potential risks associated with the use of mancozeb as well as uncertainties unique to risk assessment of mancozeb. This document also identifies additional studies that would be beneficial to the conduct of an ecological risk assessment to parent mancozeb and the primary degradation product, ethylenethiourea (hereafter referred to as ETU). Major environmental fate and ecological effects uncertainties and the associated data needs related to the assessment are stated hereunder:

Uncertainties and Data Gaps

Environmental Fate

In the current data base for mancozeb, a major uncertainty exists on the identification of the un-extracted residues (**UER**). These residues appear to form at high levels with very limited degradation. Additionally, problems exist in characterization of the residues since thin layer chromatography (TLC) prevents accurate identification/quantification. Reduction of these uncertainties is expected with submission of requested data. Hereunder is a list of requested studies:

Hydrolysis (OCSPP 835.2120): A new guideline hydrolysis study for a mancozeb active ingredient to which solubility is known (pre-determined by a guideline study) with concentration below this pre-determined solubility. In this study, the starting residues, just after dissolution should be characterized and tracked to the end of the study.

Aerobic soil metabolism (OCSPP 835.4100): A new guideline study for ETU (ETU as the test substance) in two soils from areas where the pesticide is used with varied pH, organic matter content and cation exchange capacity

Aerobic Aquatic metabolism (OCSPP 835.4300): A new guideline study for ETU in two water/sediment systems

Anaerobic Aquatic metabolism (OCSPP 835.4400): Two new guideline studies for mancozeb parent and ETU in two water/sediment systems. Note that it may be possible to obtain the data for ETU from the parent study.

In these studies, the registrant is requested to better characterize and if possible identify the un-extracted residues. This is because these residues were found to be more toxic than the parent compound in submitted sediment toxicity studies. Additionally, complete identification/ quantification of all degradates is expected along with tracking their formation and decline. Lastly, the following should be observed:

(1) The maximum single application rate for mancozeb ranges from 4.9 to 17.5 lbs a.i/A, therefore, the application rate to the aerobic soil and aquatic studies may be conducted with a concentration at or below the predetermined solubility (expected to be 13 ppm as reported). At this solubility, mancozeb as a parent is not expected to be present; therefore, the parent residue is what is applied to the soil/sediment and it should be analyzed before application and throughout the study duration. Due to the fact that there are transient species forming early, it is recommended that shorter intervals are chosen for the first week of the study;

(2) The objective of metabolism studies is to track the formation/decline of all transient species/degradates of mancozeb residues applied to the soil/sediment; and

(3) For all metabolism studies requested for mancozeb residues and ETU, the registrant should show efforts to extract and identify residues that may be left associated with soil or sediment following EFED un-extracted residues guidance[1].

ECM/ILV (OCSPP 835.6100): The registrant is requested to submit environmental chemistry method and associated independent laboratory validation (ECM/ILV) studies for determination of mancozeb and ETU in soil and mancozeb only in water.

Ecological Effects

The following uncertainties are identified for mancozeb:

Extent of Toxicity to Larval and Juvenile Honey bees

Currently, there are data available that characterize the acute contact and acute oral toxicity of mancozeb to adult honey bees. The extent to which mancozeb exerts toxic effects on honey bee larvae or juvenile honey bees is unknown. Further toxicity data that is recommended below is needed to characterize this uncertainty.

Extent of Toxicity of un-extracted residues to other sediment-dwelling invertebrates

As this assessment will show, the un-extracted residues of mancozeb form immediately after introduction in an aerobic aquatic system and steadily increase to approximately 28% of the applied radioactivity after 7 days, and from there to over 40% after 105 days. Sediment dwelling invertebrates are expected to be exposed to these residues as part or all of their life cycle is spent in contact with the sediment and pore water. Currently, there are two subchronic (10-day) sediment toxicity studies, one conducted with parent mancozeb and the other with the un-extracted residues of mancozeb. Both studies are conducted with the freshwater midge (*Chironomus tentans*). The data indicate enhanced toxicity by approximately an order of magnitude of the un-extracted residues as compared to parent mancozeb. It is an uncertainty as to the sensitivity of other sediment dwelling invertebrates such as the freshwater amphipod, *Hyalella azteca*, and the

[1] URL: http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/environmental_fate_tech_team/Unextracted_Residues_in_Lab_Studies.htm

estuarine/marine amphipod, *Leptocheirus plumulosus*. It is also an uncertainty the extent of toxicity that chronic exposures, beyond 10 days, of these un-extracted residues would have to sub-lethal measures of effects including reproductive endpoints.

Extent of toxicity and bioavailability of un-extracted residues to terrestrial organisms

As this assessment will show, the un-extracted residues of mancozeb form immediately after introduction into an aerobic soil system (up to 46% of the applied radioactivity) at Day 0 and increase steadily therefore to approximately 65% after 7 days. It is an uncertainty if similar formation rates are observed when mancozeb is sprayed on foliage. Additionally, it is an uncertainty the extent of the toxicity and bioavailability of these residues to terrestrial taxa, like birds, mammals, and terrestrial invertebrates. Although available ecotoxicity studies show that the major mancozeb degradate, ETU, is less toxic to terrestrial organisms as compared to parent mancozeb, maximum ETU residues in the soil reach approximately 13% after 1 day before steadily declining with time thereafter. Hereunder is a list of requested studies:

Avian Acute Oral Toxicity Test (OCSPP 850.2100). Currently there are no available acute oral toxicity studies for mancozeb that are suitable for quantitative risk assessment and are therefore recommended. Please see Section 11.2 for further details.

Avian Dietary Toxicity Test (OCSPP 850.2200). Two subacute dietary toxicity studies are recommended to characterize the dietary toxicity route of exposure to birds which will allow the estimation of acute dietary-based risk to birds feeding on mancozeb contaminated food items. Previously, no subacute dietary toxicity studies to birds have been submitted for mancozeb. Two studies are recommended, one with an upland game bird species (northern bobwhite quail) and one with a waterfowl species (mallard duck).

Seedling Emergence and Seedling Growth (OCSPP 850.4100): There is currently one available Tier I Seedling Emergence study available for mancozeb which is classified as acceptable. However, this study tested at an application rate of 0.02 lbs a.i/A. Mancozeb is associated with single application rates as high as 4.9 lbs a.i/A for food crops (pome fruits and cranberries) and 17.5 lbs a.i/A for non-food uses (turf). A new study is requested that tests mancozeb at the highest maximum single application rate in order to estimate risk to listed and non-listed species of terrestrial plants.

Vegetative Vigor (OSCPP 850.4150): There is currently one available Tier I Vegetative Vigor study available for mancozeb which is classified as acceptable. However, this study tested at an application rate of 0.02 lbs a.i/A. Mancozeb is associated with single application rates as high as 4.9 lbs a.i/A for food crops (pome fruits and cranberries) and 17.5 lbs a.i/A for non-food uses (turf). A new study is requested that tests mancozeb at the highest maximum single application rate in order to estimate risk to listed and non-listed species of terrestrial plants.

Non-Guideline Study (OECD TG 213) (Tier 1): Honey Bee Adult Acute Oral Toxicity. Honey bees can be exposed to pesticides through multiple pathways including contact with sprays and dusts and through ingestion of residues in food/water (*e.g.*, pollen/nectar and water used to maintain colony temperature). Worker bees foraging on flowers for pollen and nectar can be

repeatedly exposed to residues in pollen and nectar either through direct contamination of these matrices by foliar sprays. Residues can in turn be brought back to bee colonies where in-hive bees including young adult and developing brood (*i.e.*, eggs, larvae and pupae) may be exposed. EPA guidance on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended to facilitate screening for potential acute and chronic effects to individual adult and larval bees as part of a tiered approach.[2] Acceptable acute contact toxicity data are available for adult honey bee exposures to mancozeb; however, data are not available for oral toxicity to adults on an acute exposure basis. Certain classes of chemicals have indicated differential toxicity depending on the route of exposure. An acute oral toxicity test to adult honey bees would address this uncertainty. No protocol needs to be submitted to the Agency before the initiation of this study as guidance for its parameters is documented in OECD Test Guideline 213. Pending the results of this study, higher tiered (*e.g.* semi-field) studies as well as residue studies may be required.

Non-guideline Study (OECD TG 237) (Tier 1): Honey Bee Larvae Acute Oral Toxicity[3] As noted above, EPA guidance on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended to facilitate screening for potential acute and chronic effects to individual adult and larval bees. Acceptable acute contact toxicity data are available for adult honey bee exposures to mancozeb; however, data are not available for larval toxicity. Honey bee larvae have been sometimes shown to be more sensitive to chemicals than adults and therefore this study, along with a honey bee larval chronic toxicity, are recommended to address this uncertainty. No protocol needs to be submitted to the Agency before the initiation of this study as guidance for its parameters are well documented in OECD Test Guideline 237. Pending the results of this study, higher tiered (*e.g.* semi-field) studies as well as residue studies may be required.

Non-guideline Study (Tier 1): Honey Bee Larvae Chronic Oral Toxicity. As mentioned above, EPA guidance on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended to facilitate screening for potential acute and chronic effects to individual adult and larval bees. There are currently no data available to characterize the acute or chronic toxicity to honey bee larvae. EFED recommends that a protocol (following the OECD draft test guideline document, February 25, 2014)[4] be submitted for review and approval by the Agency prior to initiation of this study. Pending the results of this study, higher tiered (*e.g.* semi-field) studies as well as residue studies may be required.

Non-guideline Study: Honey Bee Adult Chronic Oral Toxicity (Tier 1). As discussed above, EPA guidance on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended to facilitate screening for potential acute and chronic effects to individual adult and larval bees. The 10-day toxicity study with young adult bees provides no-observed adverse effect level (NOAEL) and lowest-observed adverse effect level (LOAEL) for assessing chronic effects, including mortality as well as sub-lethal effects such as food consumption. Risk estimates based on these data will be considered along with other lines of evidence to determine whether

[2] Available online at: http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

[3] Depending on the design of the "Honey Bee – 21-day repeated dose chronic larval toxicity" study, a 72-hour LD_{50} value may be derived from this study. If that is possible, it would obviate the need for this study.

[4] http://www.oecd.org/chemicalsafety/testing/Draft_GD_honeybee_larval_tox_repeated_exposure_25_February_2014.pdf

higher-tier studies are needed at the whole colony level. EFED recommends that the registrant submit a protocol and consult with the Agency prior to study initiation.

Non-guideline Study: Field Trial of Residues in Pollen and Nectar (Tier 2): If the Tier 1 bee toxicity data and screening level risk assessment indicates potential risk to bees, refinement of exposure estimates for residues in pollen and nectar may be needed. . Specifically, the screening level exposure concentrations that are estimated in Tier 1 for pollen and nectar are intended to be conservative. Measurement of residues in pollen and nectar would allow for more accurate exposure analysis when applications are made at bloom. This chemical is of low toxicity to adults, but applications at bloom could contaminate pollen and nectar that adult foragers bring back to the colonies, resulting in potential exposures to the brood. If this study is considered necessary based on the results of the Tier 1 risk assessment, EFED recommends that the registrant submit a protocol and consult with the Agency prior to study initiation.

Non-guideline Study: Semi-Field Testing for Pollinators (Tunnel or Colony Feeding Studies) (Tier 2). Screening level and refined Tier 1 risk assessments with the honey bee larvae may indicate the need to progress to higher tier toxicity testing under semi-field conditions. In evaluating the effects of mancozeb on honey bees at the colony level, there are uncertainties relating effects to individual bees to that at the colony level. Semi-field testing data can be used to address these uncertainties with either a tunnel or colony feeding study experiment design. If this study is considered necessary based on the results of the Tier 1 risk assessment, EFED recommends that the registrant submit a protocol and consult with the Agency prior to study initiation.

850.3040: Field Testing for Pollinators (Tier 2 or 3): Screening level and refined Tier 1 risk assessments with the honey bee larvae may indicate the need to progress to higher tier toxicity testing under field conditions. In evaluating the effects of mancozeb on honey bees at the colony level, there are uncertainties relating effects to individual bees to that at the colony level. Field testing data can be used to address these uncertainties. If this study is considered necessary based on the results of the Tier 1 risk assessment, EFED recommends that the registrant submit a protocol and consult with the Agency prior to study initiation.

Aquatic Plant Toxicity Test using *Lemna* spp. (OCSPP 850.4400): There is currently no toxicity study available with a vascular aquatic plant conducted for mancozeb. Further analysis in this assessment (presented in Section 5) will show a rapid degradation of parent to the primary degradate ETU. Within 6 hours, parent mancozeb relative concentrations fall from approximately 80% to approximately 40% of the applied radioactivity while concentrations of ETU increase during this time. After 1 day, relative water column concentrations of parent in an aerobic aquatic system was determined to be 10%. Despite this rapid transformation, an available algal toxicity study conducted with the freshwater green algae (*Selenastrum capricornutum*) indicates a 96-hr EC_{50} of 47 µg a.i/L and a 96-hr NOAEL of 22 µg a.i/L. It is noted that this study was initiated with parent mancozeb. Previous risk assessments have identified peak surface water EECs up to 4 fold higher than this, suggesting parent mancozeb, despite its rapid degradation, has enough time to elicit a toxic effect to aquatic plants. Additionally, it is noted that the aforementioned study was a static system, and percent recoveries of the test substance ranged 65-80% of nominal at hour 0, 17-21% at hour 48, and 1.3 – 7.3% at test termination. Despite the clear degradation of the test substance in the lab, current labels permit mancozeb to be applied up to 15 times at intervals as

low as every 4 days. Therefore, even with a rapid transformation to degradates that will be shown in this assessment to be less toxic than parent, it is indicated in the available algal toxicity study that mancozeb can elicit toxic effects, at environmentally relevant concentrations that may be present at levels that would make up for its decomposition.

A study with the vascular aquatic plant *Lemna gibba* is recommended to address this uncertainty.

Algal Toxicity (Freshwater diatom) (OCSPP 850.4500): There is currently no algal toxicity study with a freshwater diatom submitted for mancozeb. As discussed above, a study with a freshwater green algae species indicated toxicity that would be above the level of concern when risk is estimated using peak surface water EECs. This study is being recommended to address the potential increased sensitivity of freshwater diatoms as compared to other algal species.

Algal Toxicity (Marine diatom) (OCSPP 850.4500): There is currently no algal toxicity study with a marine diatom submitted for mancozeb. As discussed above, a study with a freshwater green algae species indicated toxicity that would be above the level of concern when risk is estimated using peak surface water EECs. This study is being recommended to address the potential increased sensitivity of marine diatoms as compared to other algal species.

Cyanobacteria (*Anabaena flos-aquae*) toxicity (OCSPP 850.4550): There is currently no algal toxicity study with a cyanobacteria species submitted for mancozeb. As discussed above, a study with a freshwater green algae species indicated toxicity that would be above the level of concern when risk is estimated using peak surface water EECs. This study is being recommended to address the potential increased sensitivity of cyanobacteria as compared to other algal species.

2. Introduction

Mancozeb [CAS name: [[I ,2-ethanediylbis[carbamodithioato]](2-)] manganese mixture with [[I, 2-ethanediylbis[carbamodithioato]](2-)]zinc.; IUPAC name: Manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt; CAS number 8018-01-7 ; PC Code 014504; and molecular formula $C_4H_8MnN_2S_4Zn$], is an ethylene bis dithiocarbamate (EBDC) non-systemic fungicide with protective action on contact. The specific mode of action (MOA) is unknown and is classified by the code M3 (multi-site action) by the Fungicide Resistance Action Committee (FRAC[5]).

3. Use Characterization

3.1 Labelled Use

Based on a sample of twenty six section 3 and forty four 24(c) labels, mancozeb is formulated as either a dry flowable, flowable concentrate, wettable powder, or dust and applied as a liquid spray using ground, aircraft, or through irrigation systems (chemigation). In addition,

[5] Fungicide Resistance Action Committee: URL: http://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2015-finalC2AD7AA36764.pdf (accessed June, 2015)

mancozeb is used as dip treatment and to treat seed and seed pieces in many crops. **Table 1** contains a summary of section 3 labelled uses.

Table 1 Mancozeb use patterns

Crop Use Pattern	*Application Parameters* [1]				*Notes* [2]
	MSR	*MNA*	*MTR*	*MAI*	
Asparagus: Crowns dip treatment	**Refer to Text**				Pre-plant crowns dip treatment
Asparagus: Crop	**1.60**	**4**	**6.4**	**10**	A/G Foliar sprays; APW= Pre-plant & Post-harvest
Bananas & Plantains	**2.40**	**10**	**24.4**	**14**	A/G Foliar sprays & C
Brassica Veg.: Broccoli/ Cabbage	**1.6**	**6**	**9.6**	**7**	A/G Foliar sprays & C
Capri fig: Dip treatment	**Refer to Text**				In the Summer to prepare for pollination
Cereal Grains [3]	**1.63**	**3**	**4.9**	**7**	A/G Foliar sprays & C
Christmas tree plantations	**3.2**	**NS**	**NS**	**7**	A/G Foliar sprays & C; APW= Spring/early Summer
Conifers plantations/nurseries	**1.5**	**NS**	**NS**	**7**	A=Aerial/G=Ground Foliar Sprays
Corn (unspecified, field sweet/pop)	**1.22**	**15**	**18.3**	**4**	A/G Foliar sprays & C
Cranberry	**4.9**	**3**	**14.7**	**7**	A/G Foliar sprays & C
Cucurbit Vegetables [4]	**2.43**	**8**	**19.4**	**7**	A/G Foliar sprays & C
Fennel	**1.63**	**8**	**13.0**	**7**	A/G Foliar sprays & C
Forestry [5]	**3.2**	**NS**	**NS**	**7**	A/G Foliar sprays & C; APW= Spring/early Summer
Fruiting Vegetables [6]: Peppers W	**1.6**	**6**	**9.6**	**7**	
Peppers E	**2.4**	**8**	**19.2**	**7**	A/G Foliar sprays & C
Tomatoes W	**1.6**	**4**	**6.4**	**7**	A/G Foliar sprays & C; APW= Post-transplant at
Tomatoes E	**2.44**	**7**	**17.1**	**7**	seedling stage in addition to Foliar
Garlic & Onion: dried; Shallot	**2.44**	**10**	**24.4**	**7**	A/G Foliar sprays & C
Ginseng	**1.6**	**12**	**19.2**	**7**	A/G Foliar sprays & C
Grapes: West of the Rockies	**2.0**	**3**	**6.0**	**7**	A/G Foliar sprays & C; APW= Start when Shoots ½ to
East of the Rockies	**3.2**	**6**	**19.2**	**7**	1 ½ inch long. In CA don't apply after bloom
Lettuce: California	**1.6**	**4**	**6.4**	**7**	
All other States	**1.6**	**6**	**9.6**	**7**	A/G Foliar sprays & C
Nut Trees: Almonds	**4.8**	**3**	**14.4**	**7**	A/G Foliar sprays & C; APW: Delayed dormant
Walnuts	**1.82**	**10**	**18.2**	**7**	through petal fall
Ornamentals [7]: Cut F/Greenhouse	**NS**	**20**	**NS**	**3?**	G=Ground Foliar Sprays/C= Chemigation
All others	**1.6**	**20**	**32.0**	**7**	A/G Foliar sprays & C
Pome Fruits [8]	**4.88**	**4**	**19.5**	**7**	A/G Foliar sprays & C
Peanuts	**1.6**	**10**	**16.0**	**7**	A/G Foliar sprays & C
Potatoes: Crop	**1.63**	**7**	**11.4**	**5**	A/G Foliar sprays & C
Seed pieces	**Refer to Text**				Pre-plant crowns dip treatment
Seed Treatments: Many crops	**Refer to Text**				Pre-plant seed treatments
Sugar beet	**1.6**	**7**	**11.2**	**7**	A/G Foliar sprays & C
Tropical/Subtropical Fruits [9]	**2.0**	**14**	**28**	**7**	A/G Foliar sprays & C
Turf [10]: COM/IND/RREC	**17.5**	**4**	**70**	**10**	A/G Foliar sprays & C
Turf [11]: Golf course/Cold Season					
Golf course/Warm Season					
Turf: Sod Farms	**17.4**	**4**	**69.6**	**10**	A/G Foliar sprays & C

[1] **Application Parameters: MSR=** maximum single rate (lbs a.i./acre), ***MNA***= maximum number of applications, ***MTR***= maximum total rate (lbs a.i./acre/year), and ***MAI***= Minimum application intervals in days. **Note:** Any label that species application/crop cycle should be modified as it is assumed in this table to be per year;

[2] **Abbreviations for Notes: A**=Aerial/**G**=Ground Sprays/**C**=Chemigation; **APW**= Application Window

[3] **Cereal Grains:** Barley, Oats, Triticale, Wheat, Rye;

Crop Use Pattern	Application Parameters [1]				Notes [2]
	MSR	MNA	MTR	MAI	

[4] **Cucurbit Vegetables:** cucumber, cantaloupe, pumpkin, Momordica spp., Melons (honeydew, citron melon, casaba melon, Crenshaw melon, watermelon, Musk melon) and Winter/Summer Squash; Gourds (edible & Chinese wax);
[5] **Forestry:** Douglas fir forestry and shelterbelt;
[6] **Fruiting Vegetables:** Peppers and tomatoes: West/East of the Mississippi River;
[7] **Ornamentals**: shade trees, ground cover plants, herbaceous plants, non-flowering plants, woody shrubs and vines and **Ornamentals: Cut F/Greenhouse=** Ornamental cut flower/foliage in Greenhouse;
[8] **Pome Fruits:** Apples, Crabapples, Pears and Quince;
[9] **Tropical/Subtropical Fruits:** Papaya, Atemoya, Canistel, Cherimoya, Mamey, Mango, Papaya, Sapodilla, Sapota (white), Custard/Star/Sugar Apples; noting that the stated rates are for most of these tropical fruit trees. Some of these fruit trees have lower rate and/or a 14-day application intervals;
[10] **Turf: COM/IND/RREC**: commercial/industrial/recreational noting that turf in residential settings and athletic fields are excluded; and
[11] **Turf: Golf Courses**: It is noted that the RED document states that one less application for warm season grasses and No Arial or chemigation (only few labels abide by this requirements).

Dip Treatment

This application will be calculated (in lbs a.i/A), considered as an application at the planting date/depth and ***added*** to application(s) labeled for the crop, if any. Labelled dip treatment are for the following crops:

(1) **Asparagus: Crowns dip treatment (for crown rot):** In one of the labels, the treatment is described as follows: (a) Prepare the dipping suspension (1.0 Ib. a.i/100 gal of water) in a clean tank; (b) Pack pre-washed crowns loosely into a burlap bag and soak, with gentle agitation, in the fungicide solution for 5 minutes; and (c) Remove bag, drain well, and plant crowns as soon as possible. The maximum specified for preparing 100 gallons of the dipping suspension ranges from 0.814 to 1.0 pound of a.i. For future modeling, the registrant is requested to specify how many pounds of crowns that may be treated with the 100 gallons dipping suspension, how many pound of treated crowns needed to plant one acre and what to do with dipping suspension after treatment;

(2) **Capri fig: Dip treatment** (for molds and fusariurn): In one of the labels, the treatment is described as follows: (a) Prepare the dipping suspension (4.0 Ib. a.i/100 gal of water); (b) Prepare mamme figs by making a shallow cut through the eye and then hand dividing to avoid wasp injury; and (c) Submerge mamme figs in the fungicide suspension for a minimum of 15 minutes. The fungicide suspension should be stirred frequently to prevent settling out and fresh dipping solution should be used after treating 4 or 5 batches of figs. After treatment, figs should be drained prior to placement in trees. For future modeling, the registrant is requested to specify how many pounds of figs that may be treated with the 100 gallons dipping suspension, how many pound of treated figs needed for one acre and what to do with dipping suspension after treatment; and

(3) **Potato pieces: Dip treatment:** Pre-plant seed/seed pieces dip tank is prepared @ 0.08 lbs a.i/100 lbs of seeds/seed pieces. In future modeling the rate in lbs a.i/A will be calculated based on BEAD maximum seeding rate (lbs of seeds/seed pieces needed to plant one acre). Again, the registrant is requested to specify what to do with the dipping suspension after treatment.

Seed Treatment

This application will be calculated (in lbs a.i/A) using BEADs maximum seeding rate for each crop, considered as an application at the planting date/depth and ***added*** to application(s) labeled for the crop, if any. Labelled seed treatment are for the following crops (rate per 100 lbs of seeds): Barley (0.2100); Corn (0.2719); Cotton (0.3156); Flax (0.3602); Oats (0.3150); Peanuts (0.81), Rice (0.2094); Rye (0.1801); Safflower (0.1063); Sorghum (0.2271); Tomatoes (0.430); Triticale (0.1650); and Wheat (0.1625).

24(c) Labels

The LUIS report contains forty four 24(c) labels for local use in the following states: **CA** (Two for walnuts); **ID** (One for Carrot); **OR** (Two, carrot/vegetables, refer to **Table 2** below); **WA** (Three: One for Brassica vegetables, beet (un-specified)/carrots/ vegetables, refer to **Table 2**, below), Two for pears); and all others (36 labels) are for Tobacco including: **CT** (5); **GA** (1); **IN** (3); **KY** (2); **MA** (2); **MD** (2); **MO** (3); **NC** (3); **OH** (3); **PA** (3); **SC** (3); **TN** (2); **VA** (4), refer to Table 2 for the application parameters for crops covered by these 24 (c) labels.

Table 2 A summary of the application parameters for 24(c) labels (for abbreviation refer to the labelled use table, above)

	Application Parameters				
Crop Use Pattern	***MSR***	***MNA***	***MTR***	***MAI***	***Notes***
Beet (un-specified)	**1.5**	**8**	**12.0**	**7**	**A**=Aerial/**G**=Ground Foliar Sprays (OR & WA)
Brassica Vegetables	**1.5**	**12**	**18.0**	**7**	**A/G Foliar sprays & C=** Chemigation (WA)
Carrot	**1.5**	**12**	**18**	**7**	**A/G Foliar sprays & C** (OR & WA)
Swiss Chard, Coriander, Arugula "Roquette", Spinach, Parsley, Parsnip, Dill, Endive	**1.5**	**12**	**18**	**7**	**A/G** Foliar Sprays (OR & WA); Lettuce: only **A**
Crucifer (assumed= all Brassica Vegetables)	**1.5**	**6**	**9**	**7**	**A/G** Sprays (OR)
Leek and Onion	**1.5**	**12**	**18**	**7**	**A/G** Sprays (OR & WA); Leek: Only **A**
Tobacco	**2.0**	**NS**	**NS**	**5**	**G=** Pre-plant seed bed and Foliar

It is important to note that labelled uses summarized above are based on most, ***not all***, mancozeb labels. Additionally, application parameters are chosen from labels containing the highest rates and minimum application intervals. It is also noted that many labels do not contain necessary information for application. The registrants are requested to check the labelled summary Tables and information above and provide necessary addition(s)/correction(s). In addition, it is necessary to modify their labels accordingly. In future modeling and in the absence of the required information, EFED will use the ***most conservative*** parameters. Labels should contain the following information:

(1) Maximum single and yearly not crop cycle, application rate, maximum number of application and minimum application intervals;

(2) Timing of application or information that can be used for determining the application window; and

(3) Application procedure(s) for each crop.

3.2 Usage

From the mancozeb BEAD chemical profile (BCP) drafted by the Biological and Economic Analysis Division (01/22/2015) mancozeb use in terms of pounds a.i. applied in the U.S. has remained fairly constant during the 1998-2012 time frame with very slight decreases in years (2006-2009). Similar trends were found for total area treated. During the 1998-2012 time frame, approximately 6.4 million pounds a.i. were applied on average annually to treat 4.5 million acres at an overall average a.i. application rate of 1.4 lbs a.i. per acre. During the 2008-2012 time frame, approximately 6 million pounds a.i. were applied annually on average to treat 4 million acres at overall average a.i. application rate of 1.5 lbs a.i. per acre.

4. Conclusions from Previous Risk Assessments

Two main risk assessments were conducted for mancozeb and its main degradate ETU:

(1) Environmental Fate and Ecological Risk Assessment for Mancozeb, Section 3 Reregistration for Control of Fungal Diseases on Numerous Crops, a Forestry Use on Douglas Firs, Ornamental Plantings, and Turf (Phase 3 Response)," dated June, 2005 which was accompanied by the Environmental Fate and Ecological Risk Assessment for Ethylenethiourea (ETU) a Common Degradate of the Ethylenebisdithiocarbamate fungicides (EBDCs): Metiram, Mancozeb, and Maneb (Phase 3 Response)," dated June, 2005. The two documents were prepared by EFED for the Reregistration Eligibility Decision for Mancozeb (RED) (Document 738-R-04-012 dated September, 2005);

(2) Risks of Mancozeb and Maneb Uses to the Federally Listed California Red Legged Frog (*Rana aurora draytonii*) dated October, 2007.

This problem formulation updates aspects of these recent risk assessments, including the following:

- Changes in labelled use patterns following the RED required mitigation measures which included: use patterns that are ineligible for reregistration and changes in application rates, procedure and intervals for some crops;

- New crop registrations following issuance of the RED document in 2005 which included addition of new crops and changes in application intervals; and

- Modify the previous assignments for the stressor of concern following new submittals including:

- Fate studies with better characterization/quantification of mancozeb residues;
- New ecological toxicity studies for ETU, the major degradate of mancozeb; and
- New sediment toxicity studies on mancozeb and the un-extracted residues.

4.1 Ecological Risk Assessment

As stated previously, the Agency had completed two main ecological risk assessments on mancozeb in addition to several updates for new uses that serve as a basis for this problem formulation. It is important to note that the previous ecological risk assessments conservatively considered the stressor to be the "**mancozeb complex**' which was defined to include all of the mancozeb residues: ethylene thio-urea (ETU), ethylene urea (EU), Ethylene-bis-isothiocyanate sulfide (EBIS), Hydantoin (HYD) and the un-extracted residues (UER). Previous risk findings are summarized in **Table 3.**

Table 3. Summary of risk concerns identified for mancozeb in previous assessments*****

Birds	Mammals	Terr. Plants	Terr. Inverts	Fish	BCF	Aquatic Inverts	Aquatic Plants	Groundwater Contamination	Persistence	Degradates of Concern
Yes[1]	**Yes[1]**	**Uncertain[2]**	**NA[3]**	**Yes**	**No[4]**	**No**	**Yes**	**Yes[5]**	**Yes[6]**	**Mancozeb Complex**

***** "**Yes**" **=** at least one LOC has been exceeded in previous assessments; "**No**" = LOCs have not been exceeded in previous assessments; "**NA**" = RQs have not been calculated previously

[1] Chronic RQs exceeded LOC for certain uses

[2] Available studies are conducted at rates of 0.02 lbs a.i/A, several orders of magnitude below the current maximum use rates permitted.

[3] RQs were not previously calculated for terrestrial invertebrate

[4] Due to the very low K_{OW} of 22; noting that a fish bio-accumulation study was previously waived

[5] Based on ETU, the degradate of concern of mancozeb which is characterized by high solubility and low K_{OC} (288 L/kg)

6 Based on only mineralization of the "Mancozeb Complex" to CO_2.

4.1 Drinking Water Exposure Assessments

Ethylenethiourea (ETU) is the common degradate of all Ethylene-bis-dithiocarbamates (EBDCs) fungicides including mancozeb. ETU, a group B2 carcinogen, was established to be the drinking water stressor resulting from the use of all EBDCs. Several EFED drinking water assessments were generated covering original/additional new uses of all or any of the EBDCs for the estimated drinking water concentrations (EDWCs) of ETU for use in human risk assessments (DP Barcode: 290057 dated May 7, 2003; DP Barcode: D290057 dated August 26, 2004; DP Barcodes: 323141/3 dated August 11, 2006; DP Barcode: 397306 dated July 3, 2012; and DP Barcode: 420706 dated September 8, 2014).

For surface water, estimated drinking water concentrations (EDWCs) were calculated using the linked PRZM and EXAMS simulation models on the assumption of very rapid degradation of the parent EBDC pesticide to ETU on a mole per mole basis. Following the submission of a two-year targeted ETU monitoring study by the EBDC Task force, the chronic long term average EDWC was based on monitoring while the acute EDWC remained to be based on PRZM/EXAMS modeling. For ground water, a single acute/chronic EDWC was derived from community water system intake concentration of a targeted groundwater monitoring study conducted by the EBDC Task Force from 1999 to 2003. Targeted monitoring data were submitted under MRIDs 455703-01, 457083-01, 458364-01 and 461454-01. **Table 4** contains a summary of the current Tier II EDWCs of ETU which was used for human health drinking water risk assessment**.**

Table 4. Tier II EDWCs (in ppb of ETU) for human health drinking water risk assessment

Stressor	*Acute EDWC Surface Water (PRZM/EXAMS Modeling)*	*Chronic Surface Water EDWC (Monitoring detection limit) for Non-cancer/Cancer chronic*	*Acute and Chronic Ground Water EDWC (Monitoring)*
ETU	**25.2***	**0.1**	**0.21**

* This is the highest value in a range of EDWC values which are expected to be **between 0.1 ppb** (the detection limit) **and 25.2 ppb** (the highest peak value after adjustment by the then 0.87 national PCA).

Requested data, from this registration review for mancozeb and ETU will be considered for the determination of EDWCs for ETU resulting from mancozeb degradation. An updated drinking water assessment may be needed as part of the future Registration Review process. If a new drinking water assessment is needed, EFED will include recently revised percentage crop area (PCA) factors, revised drift factors as well as the use of current SWCC and PRZM-GW models to determine EDWCs in surface and ground waters, respectively. Use of monitoring data for the acute and chronic ground water EDWCs will be dependent on modeled PRZM-GW EDWCs. EFED will consider the use of PFAM model for mancozeb use on cranberries.

4.2 Clean Water Act Programs

Mancozeb and its major degradate ETU were not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act and no Total Maximum Daily Load (TMDL) criteria have been developed for the two chemicals (Refer to URL: http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885, accessed 03/08/2015).

A summary of fish/invertebrates acute/chronic aquatic benchmarks have been established only for ETU **(Table 5).** However, no acute non-vascular/vascular plants aquatic benchmarks or Office of Water aquatic life criteria (maximum & continuous concentrations) were established for either mancozeb or ETU (Refer to URL: http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm, accessed 03/08/2015).

Table 5 OPP Aquatic life benchmarks for fresh water (µg / L) for ETU

Fish		*Invertebrates*	
Acute [1]	*Chronic* [2]	*Acute* [3]	*Chronic* [4]
> 251,000	**37,320**	**134,500**	**2**

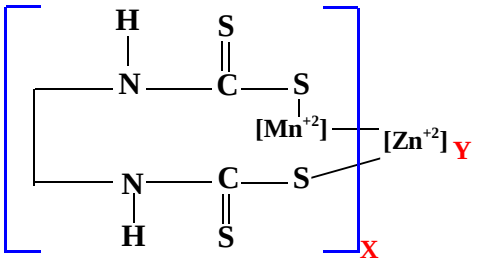
[1] Benchmark = Toxicity value x LOC. For acute fish, toxicity value is generally the lowest 96-hour LC50 in a standardized test (usually with rainbow trout, fathead minnow, or bluegill), and the LOC is 0.5.
[2] Benchmark = Toxicity value x LOC. For chronic fish, toxicity value is usually the lowest NOAEC from a life-cycle or early life stage test (usually with rainbow trout or fathead minnow), and the LOC is 1.
[3] Benchmark = Toxicity value x LOC. For acute invertebrate, toxicity value is usually the lowest 48- or 96-hour EC_{50} or LC_{50} in a standardized test (usually with midge, scud, or daphnids), and the LOC is 0.5.
[4] Benchmark = Toxicity value x LOC. For chronic invertebrates, toxicity value is usually the lowest NOAEC from a life-cycle test with invertebrates (usually with midge, scud, or daphnids), and the LOC is 1.

Any data submitted or otherwise located as part of the registration review process may be used to update aquatic life benchmarks, if applicable.

5. Environmental Fate and Transport

5.1 Mancozeb

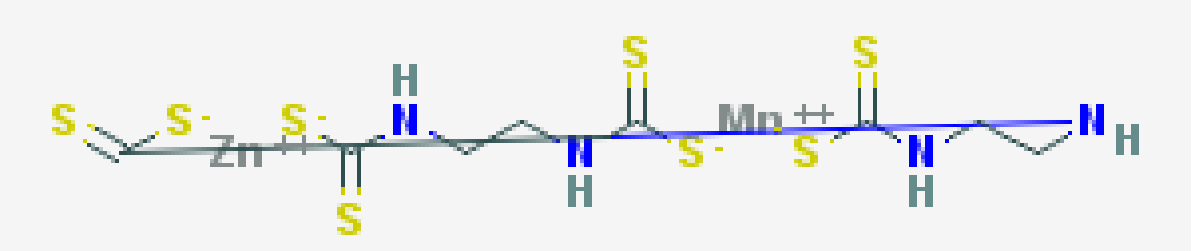
Mancozeb is a polymer coordination complex of zinc and manganese ethylene bis di-thio carbamate ions (referred to hereafter as EBDC ions) containing: **77.6% EBDC** as an **anion** in coordination with two **cations**: **20% Mn^{+2}** and **2.4% Zn^{+2}**. Hereunder is the monomer unit chemical structure, Formula and molecular weight



Mancozeb **X:Y= 10:1**

Formula: $(C_4H_6MnN_2S_4)x\ (Zn)y$; where x=1 and y=1/11= 0.090909;
Formula Weight= 265.3 x 1 + 65.4 x 0.0909**= 271.25 g $mole^{-1}$**;

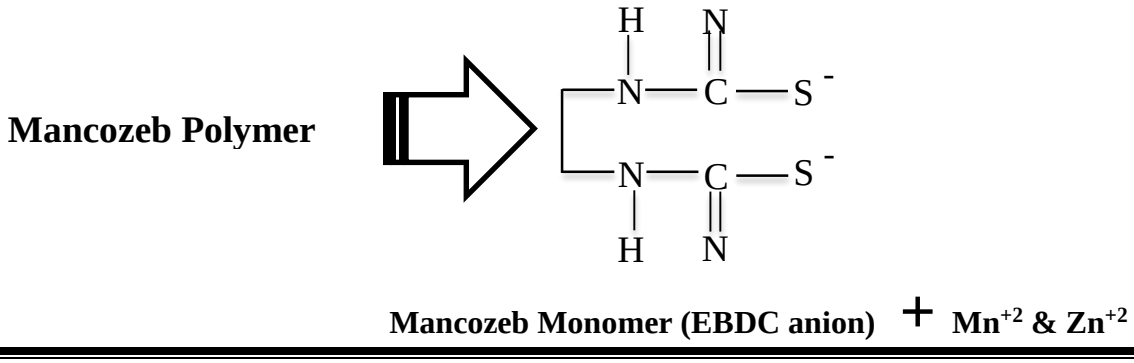
The 2-D structure for two monomer units, formula and molecular weight are as follows:



Formula: $C_8H_{12}MnN_4S_8Zn$; Formula Wt.: 541.05 g mole^{-1} (National Institute of Health Open Chemistry Database; URL: http://pubchem.ncbi.nlm.nih.gov/search/#collection=compounds&query_type=text&query=%22MANCOZEB%22 [1]

Mancozeb polymer has a unique water solubility property as it decomposes in water within hours at acid, neutral, and alkaline conditions. Complete decomposition of the polymer structure into monomeric units appears to be dependent on the concentration of the polymer. This solubility was reported, by the registrant, to be equal 0.6 ppm. However, this value was claimed later, by the registrant, to be 13 ppm. In other reports, the solubility of mancozeb was reported to be **6.2 ppm** @ pH 7.5 and 25 ^oC and **6.0 ppm**, respectively[6]. It appears that solubility is dependent on the source of the mancozeb and that the process of decomposition by water is probably related to breakage of the polymeric chains into monomeric units as shown in **Figure 1**. In this respect, the process of decomposition is probably associated with abiotic hydrolysis and therefore the whole process may be referred to as decomposition/hydrolysis. Additionally, it is important to note that parent studies should be conducted using mancozeb with a predetermined solubility.

Figure 1 Expected decomposition/hydrolysis process for mancozeb in water



The length of the polymer chains, of the mancozeb active ingredient, may be related to the particle size of the active ingredient which may be related to the manufacturing/formulation processes. Finer particle size is expected to contain shorter polymer chains causing more susceptibility to the process of decomposition into shorter or monomeric chains by solution/hydrolysis in water.

In the field, mancozeb is expected to be applied into moist plant foliage and reach, upon application and later due to wash-off, a moist soil system. In addition lesser quantities are expected to reach aquatic systems by drift (usually estimated to be 4-16% depending on type of application). Therefore, the process of decomposition/hydrolysis of mancozeb into its monomeric units is expected to occur in soil and water/sediment. The maximum single application rate of mancozeb ranges from 4.88 lbs. a.i/acre (in crops other than turf) to 17.5 lbs. a.i/acre (in turf). Upon application, the maximum expected concentrations of mancozeb in the soil system will probably be <2.4 to 8.6 ppm depending on how much of the applied reaches the soil. The concentration in aquatic systems is expected to be lower. In contrast, reported solubility of 0.6 to 13 ppm suggests

[6] Tomlin, C.D.S. (Ed.). *The Pesticide Manual - World Compendium*, 11th ed., British Crop Protection Council, Surrey, England 1997; and Wauchope R. D. *et al*. 1991. Rev Environmental Contamination Toxicology 123: 1-36.

that the decomposition/hydrolysis process is important and that its importance will probably depend on the nature of the polymer and the availability of moisture. In dry conditions the importance of this process is expected to be relatively lower than moist conditions.

Based on the fact that mancozeb, as a polymer, is expected to be short lived in the environment. It is necessary to obtain exposure data for mancozeb as well as the residues forming in soil and water/sediment systems following the decomposition/hydrolysis process.

(a) Physical Chemical Properties and Abiotic Transformation

Physical and chemical properties and abiotic transformation of mancozeb are included in **Table 6**.

Table 6 Physical/chemical properties and abiotic transformation of mancozeb

Property	*Value*	*Reference*
***n*-octanol-Water Coefficient (K_{OW})**	**21**; based on its reported log of **1.33**	**USDA [1]**
Vapor Pressure	***Registrant Data:*** <2.10 x 10^{-8} torr (MRID 457365-03) ***HSDB:*** 1.3 x10^{-10} torr @ 25 ºC	**HSDB [2]**
Henry's Law constant	<2.31 x 10^{-9} and 1.4 x 10^{-11} atm. m^3 $mole^{-1}$ @ 25 ºC, respectively & **USDA**= 1.52 x 10^{-11} **(Based on solubility of 13 ppm)**	**Calculated & USDA**
Hydrolysis half-life (t ½)	**0.8 to 1.4** days @ pHs 5,7 and 9 and 25 ºC ***Major Transformation Products:*** **ETU, EU, EBIS, HYD** and others (Identified/quantified by TLC) **[3]**	**000971-62** supplemented w/ **402582-01 (S) [4]**
Aqueous photolysis t ½	**Stable** (Based on data and UV/Visible spectra were absorption maxima occurring at 200 & 282 nm noting that the visible light ranges from 400 to 700 nm)	**001621-03 (A) [4]**
Soil photolysis t ½	**Stable** (Based on data and UV/Visible spectra)	**002639-07 (A) [4]**

[1] USDA Database: URL http://www.ars.usda.gov/SP2UserFiles/ad_hoc/12755100DatabaseFiles/PesticidePropertiesDatabase/IndividualPesticideFiles/MANCOZEB.TXT
[2] HSDB Database: URL: http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~DYF5Kf:1
[3] Transformation products identification was done using two TLC solvent systems with variable results and nearly 20% of the radioactivity was not identified. Refer to **Figure 2** for structures and chemical names of transformation products.
[4] A= Acceptable; S= Supplemental

Based on a hydrolysis study, parent (polymeric mancozeb) degraded with a half-life of 0.8 to 1.4 days in aqueous sterilized media in the dark in acid, neutral and alkaline conditions (**Table 6**). The results of the study suggest that abiotic hydrolysis caused degradation of the monomeric units of mancozeb polymeric units that is expected to form initially upon dissolving the polymer in water. Therefore, the fate of mancozeb polymer chains appears to be affected significantly by two processes. The ***first*** process is the breakdown of polymeric parent into monomeric units of EBDCs with the loss of the metal ions (**Figure 1**, above) upon dissolution in water. The ***second*** is abiotic hydrolysis of the monomeric units. The combined decomposition/ hydrolysis, results in the formation of the major transformation products observed in the hydrolysis study (EBIS, ETU, EU and HYD). Although the study gives certainty that mancozeb parent is highly affected by hydrolysis, there are many uncertainties in this study that prevents accurate conclusions on the hydrolysis profile for polymeric mancozeb and resultant residues. Uncertainties are because

transformation products were identified/ quantified by TLC alone (the appropriateness and adequacy of the TLC methodology is questionable), and 20% of the radioactivity was not identified. Therefore, the registrant is requested to submit a new hydrolysis study for a mancozeb active ingredient to which solubility is known (pre-determined by a guideline study) with starting concentration below this pre-determined solubility.

Furthermore, data in **Table 6** indicate that mancozeb is not expected to partition into the air from dry/wet soils or from water (low vapor pressure and Henry's Law constant). However, it could move with drift. For this reason, the California Department of Pesticide Regulation (CDPR) is recommending air monitoring for mancozeb and ETU (Refer to the 2014 CDPR recommendation document[7]). Most likely, air transport will be related to drifted parent especially in California dry conditions. The n-octanol-water partitioning coefficient suggests low bio-concentration potential for mancozeb in aquatic organisms like fish and data on UV/Visible absorption maxima for mancozeb suggest photolysis in water/on soil are not important in dissipation of mancozeb in the environment.

(b) Biotic Transformation

As stated previously, fate data will be presented for mancozeb and major constituents of mancozeb residues. A summary of this data is presented in **Table 7**.

Table 7 Summary of environmental fate properties of mancozeb and residues.

Property	*Value for Mancozeb Parent & Residues*	*MRID Reference [1]*
Aerobic soil t ½ @ 20 ºC (End of study (EOS)= 120 day)	**Mancozeb parent** **Observed in Hours** in Speyer 2.3: A sandy loam soil from Germany; pH= 6.5 and organic carbon "O.C" = 0.71%); **Observed in Hours** in Speyer 2.2: A loamy sand soil from Germany; pH= 5.7 and O.C= 2.17%; and **Observed in Hours** in Senozan: A silty loam soil from France; pH= 5.8 and O.C= 0.99% **Mancozeb residues (Range in the three soils)** ***Degradates:*** **EBIS:** Max 25-29% @ <1 d to nearly 1% at 14 d then declined to EOS; **ETU:** 14-25% @ 1 d then declined to 1-2% @ EOS; **EU:** 12-14% @ 1 d then sharply declined to nearly 1% @ EOS; Un-identified(**UN-ID** consisting of 8-12 degradates): 7-22% ***Un-extracted Residues (UER):*** Max 55-71% @ 7-28 d declined to 49-62% @ EOS ***Mineralization to CO_2:*** Max range 44-50% @ EOS	**457445-01 (S)**
Aerobic Aquatic t ½ @ 25 ºC EOS= 105 days	**Mancozeb Parent** **16 Hours** in a water/loamy sand sediment from the Rhine River, Switzerland (water: pH 8.0-8.2, total organic carbon 2.6 mg/L ; sediment: pH=6.9, O.C= 1.4% and CEC=2.8 meq/100g); and **16 Hours** in a water/loamy sand sediment from	**462043-01 (A)**

[7] URL: http://www.cdpr.ca.gov/docs/emon/pubs/tac/recomm/mancozeb_recomm_2014.pdf

Property	*Value for Mancozeb Parent & Residues*	*MRID Reference [1]*
	Ormalingen pond, Switzerland (water: pH 7.4, total organic carbon 1.1 mg/L; sediment: pH=6.7, O.C= 5.0% and CEC=7.1 meq/100g) **Mancozeb residues(Range in the two systems)** ***Degradates:*** **EBIS:** Max 9-13% @ <1 d to nearly 1% at 30 d then declined to no detection @ EOS; **ETU:** 42-52% @ <1-2 d then declined to <1% @ EOS; **EU:** 23-32% @ 30 d in the river system then sharply declined to nearly 1% @ EOS and was 32% @ 59 d then declined to only 23% in the pond system; Un-identified (**UN-ID** consisting of two degradates): 20-23% @ 7-14 d then declined to 3-5% @ EOS ***Un-extracted Residues (UER):*** Max 35-44% @ 30 d to EOS ***Mineralization to CO_2:*** Max 43% @ EOS in the river system and only 18% @ EOS in the pond system	
Anaerobic Aquatic t ½ @ 25 ºC	**Study suggests possible longer half-lives than the aerobic conditions; if no study is submitted, the mancozeb residues will be considered stable.**	**402582-03 (U)**
Study Classification: A= Acceptable; S= Supplemental and U= Un-acceptable		

Data in **Table 7** suggest that [^{14}C] mancozeb parent degraded within hours under aerobic soil conditions when applied at a nominal rate of 3.3 ppm. The study suggests the effect of the following processes on the polymeric chains of mancozeb:

- Decomposition/hydrolysis of the polymer chains of mancozeb, by water, into EBDC ions; and transformation of the EBDC ions into a residue containing several degradation products by hydrolysis/biotransformation;

- Formation of substantial amounts of un-identified/un-extracted residue (UER); and

- Mineralization of the mancozeb residues into CO_2.

The process of decomposition/hydrolysis appears to start in the step of preparing the stock solution of mancozeb polymer as indicated by two observations: reduction of mancozeb concentration from 96.7% in the stock solution to 92% at time zero and the rapid disappearance of mancozeb, as a parent, within hours of application to the soil. In fact, decomposition half-lives were much shorter than the hydrolysis half-lives determined in the hydrolysis study possibly due to the use of EDTA as part of the extraction system (EDTA affects parent solubility by removing the Mn and Zn associated with the EBDC ligand). Hydrolysis/biotransformation appear to cause transformation of the EBDC units into the mancozeb residues consisting of the following major transformation products: EBIS, ETU, EU and un-identified degradates. Partitioning of significant amounts of the mancozeb residues into the soil resulted in the formation of substantial amounts of an UER. Finally, mineralization of part of the mancozeb residues resulted in production of CO_2.

Observed decomposition/degradation in two aerobic water/sediment systems were similar to that observed in the soil systems. It appears that processes involved in these systems are similar to those suggested earlier for the aerobic soil systems. In the two systems, parent decomposes rapidly (within hours) with the formation of the mancozeb residues consisting of degradates EBIS, ETU, EU, Glycol urea (Hydantoin "HYD"), UER and CO_2.

(c) Mobility

Data for mobility was estimated from a supplemental adsorption/desorption study and a leaching study (**Table 8**). Calculations were based on radioactivity adsorbed to the soils used in these two studies. This is because mancozeb degraded very quickly forming the mancozeb residues. Therefore, calculated Koc values are for the total mancozeb residues. It is noted that there were problems with these two studies such as the use of formulated product rather than the active ingredient. No new adsorption/desorption studies are requested at this time. Average adsorption coefficient data suggest that the mancozeb residues as a whole are expected to be slightly mobile. It is however noted that this conclusion may be applied to the mancozeb residues and chemicals in these residues may vary in mobility.

Table 8 Summary of the transport properties for the mancozeb residues

Property	*Value for Mancozeb Parent & Residues*	*MRID Reference* [1]
Adsorption Coefficient (Koc) (Adsorption/desorption study)	**5,288 mL/g** for a Sandy soil from GA (O.M= 0.9%, pH= 5.7 and CEC= 4 meq/100g); **1,534 mL/g** for a Sandy loam soil from GA (O.M= 2.8%, pH= 5.9 and CEC= 6 meq/100g); **892 mL/g** for a Silt loam soil from PA (O.M= 3.5%, pH= 6.4 and CEC= 10 meq/100g); and **1,707 mL/g** for a Clay loam soil from MS (O.M= 2.5%, pH= 7.4 and CEC= 13 meq/100g)	**402229-01 (S)**
Adsorption Coefficient (Koc) (Leaching study)	**1,642 mL/g** for a Sandy loam soil; **1,000 mL/g** for a Silt loam soil; and **860 mL/g** for a Silt loam soil	**405883-02 (S)**
Average value	**1,846 mL/g**	
Range of values	**860- 5,288 mL/g**	
Study Classification: S= Supplemental		

(d) Field Dissipation

A dissipation half-life (DT_{50}) of 3 days was reported for a silty clay loam soil under Philippine field conditions using soil column receiving natural rainfall (a total of 12" in 21 days). CS_2-determined mancozeb remained on the top 2.5 and no leaching was observed under the conditions of the experiment. ETU and EU were the only degradation products whereas un-extractable residues were not characterized and accounted for 38-70% of the total residues (Calampang S. *et al*, 1993. International J. of Pest Management, 39 (2) 161-166).

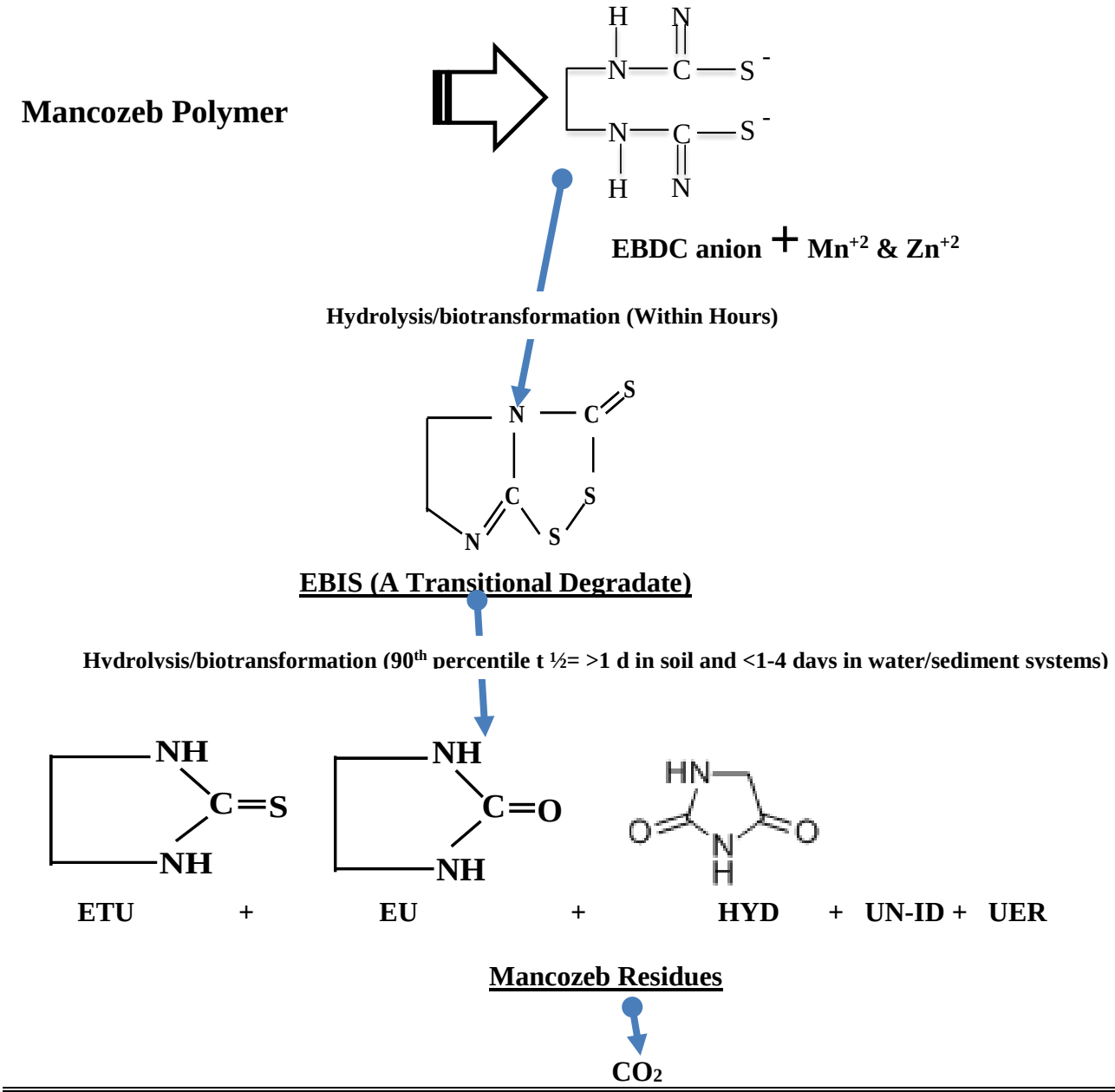
(e) Bioconcentration

Mancozeb is associated with very low K_{OW} value of 22. A fish bioaccumulation study was previously waived for mancozeb based on the expected low bioconcentration as indicated from the K_{OW} value.

(f) Transformation Products

Mancozeb polymer reaching soil (directly and by wash-off) and aquatic systems (by drift) is expected to decompose/hydrolyze/bio-transform rather quickly in the water present in these systems. Initial products are expected to include negatively charged monomeric EBDC units and positively charged Mn and Zn ions. Monomeric EBDC units are expected to be highly vulnerable to abiotic hydrolysis and biotransformation resulting in the formation of the intermediate transformation product EBIS. With time, EBIS appears to degrade rather quickly into ETU that appears to degrade into EU, HYD and other un-identified chemical species (UN-ID). In the presence of a solid phase such as soil/sediment and organic matter particles, substantial part of this residue is expected to partition into the soil phase and become un-extractable (UER). Data also show that part(s) of the mancozeb residues are expected to be mineralized into CO_2 (**Figure 2**).

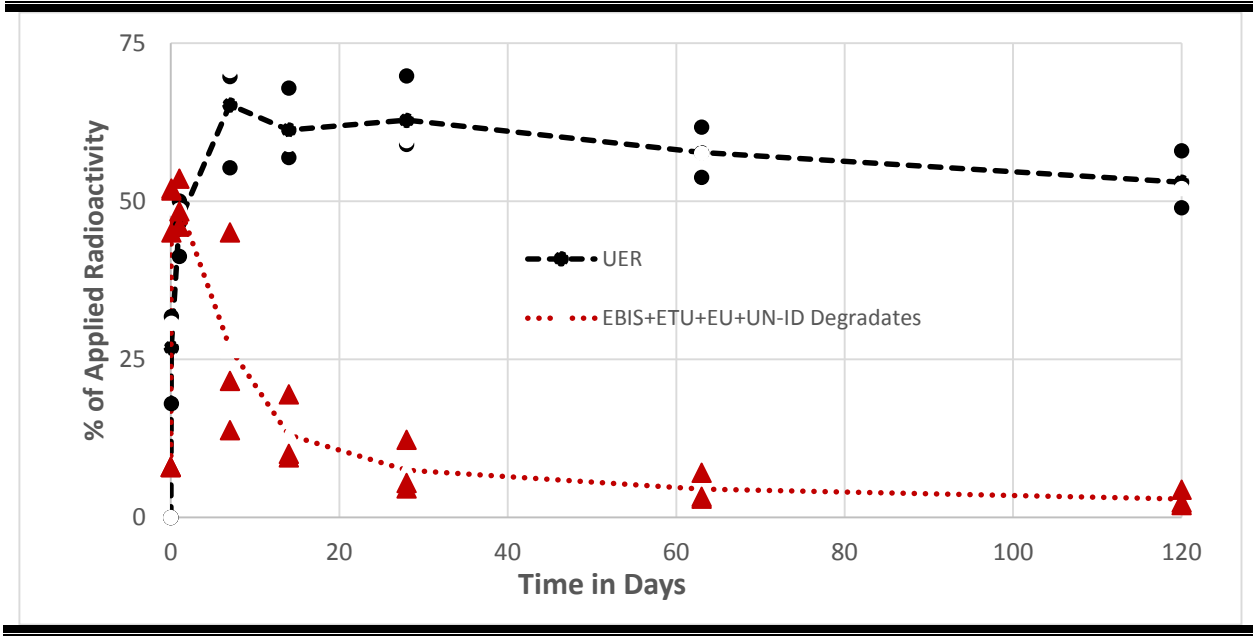
Figure 2 Transformation profile for mancozeb in soil and aquatic systems (refer to abbreviations below).



- **EBIS=** Ethylene bis isothiocyanate sulfide (5,6-Dihydro-3H-imidazol(2,1-C)-1,2,4-dithiazole-3-thione **;**
- **ETU=** Ethylene thio urea (2-Imidazolidinethione)**;** $CH_3H_6N_2S$; **CAS No.:**96-45-7; **Mol. Wt.**: 102.16 g mole^{-1}
- **EU=** Ethylene urea (2-Imidazolidinone); $CH_3H_6N_2O$; **CAS No.:**120-93-4; **Mol. Wt.**: 86.09 g mole^{-1}
- **HYD=** Hydantoin or Glycol urea (2.4-(3H,5H)-Imidazoledione)**;** $CH_3H_4N_2O_2$; **CAS No.:**461-72-3; **Mol. Wt.**: 100 g mole^{-1}
- **UN-ID=** un-identified degradates;
- **UER=** Un-extracted/Unidentified Residue

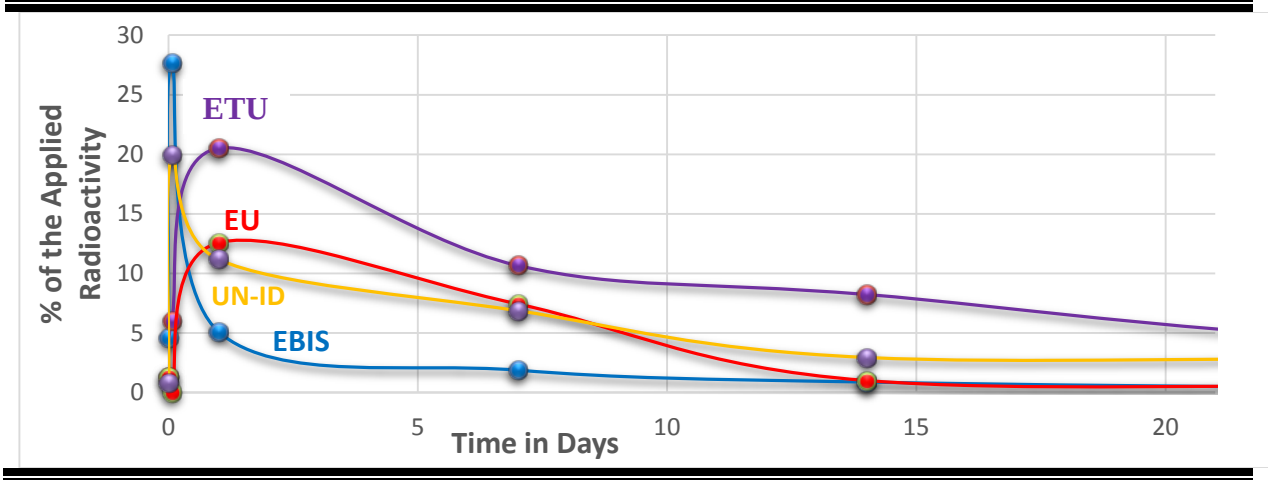
Figure 3 contains a summary of the observed total degradates and the UER in the aerobic soil system.

Figure 3 Observed degradates and UER in three soil systems (in percent of the applied radioactivity as parent equivalent with dotted line representing the average)



In the aerobic soil system, a suite of degradates (EBIS, ETU, EU and unidentified degradates) forms and reaches maximum of nearly 50% of the applied rather quickly (within one day). Following this maximum and within four weeks, a sharp decline of this suite follows to reach levels of <5% of the applied parent. The sharp decline of the degradate suite appears to coincide with the formation of persistent un-identified/un-extracted residues (UER). The UER reaches a maximum of nearly 65% of the applied within one week and stays nearly stable to the end of the study (**Figure 3**). **Figure 4** shows the formation/degradation profile of the various constituents of the observed degradate suite.

Figure 4 Formation and decline of the major degradates of mancozeb in aerobic soils (The figure represents averages from three soils and is truncated at 21 days as all degradates were below 5% of the applied radioactivity after 21 days)



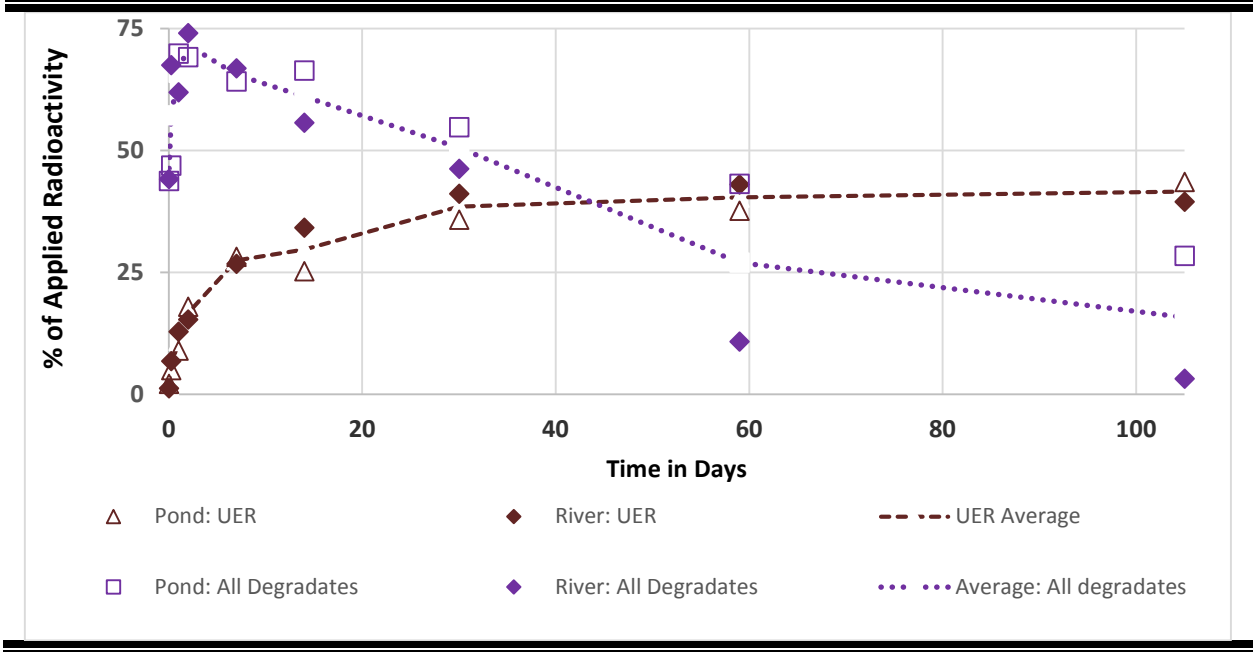
Data in **Figure 4** suggest the following:

(a) EBIS is a transitional degradate that forms immediately following application to the soil with a 90th percentile half-life (from maximum formation) of 0.6 days (range 0.3-0.6 days). Similarly, the UN-ID degradates form at the same time with a 90th percentile half-life (from maximum formation) of 8 days (range 1-8 days). This suggests that these un-identified degradates forms from parent mancozeb immediately upon application; and

(a) ETU and EU degradates reach their maximum within one day (just after the sharp decline of EBIS) suggesting their formation from EBIS. Although the maximums for these two degradates occur nearly at the same time, their level of formation were different (ETU maximums range from 15-25% of the applied while EU maximums range from 12-14% of the applied). The 90th percentile half-life (from maximum formation) was 19 days (range 4.4-18.2 days) for ETU and was 2.7 days (range 1.7-2.7 days) for EU.

Figure 5 contains a summary of the observed total degradates and the UER in two aerobic water/sediment soil systems.

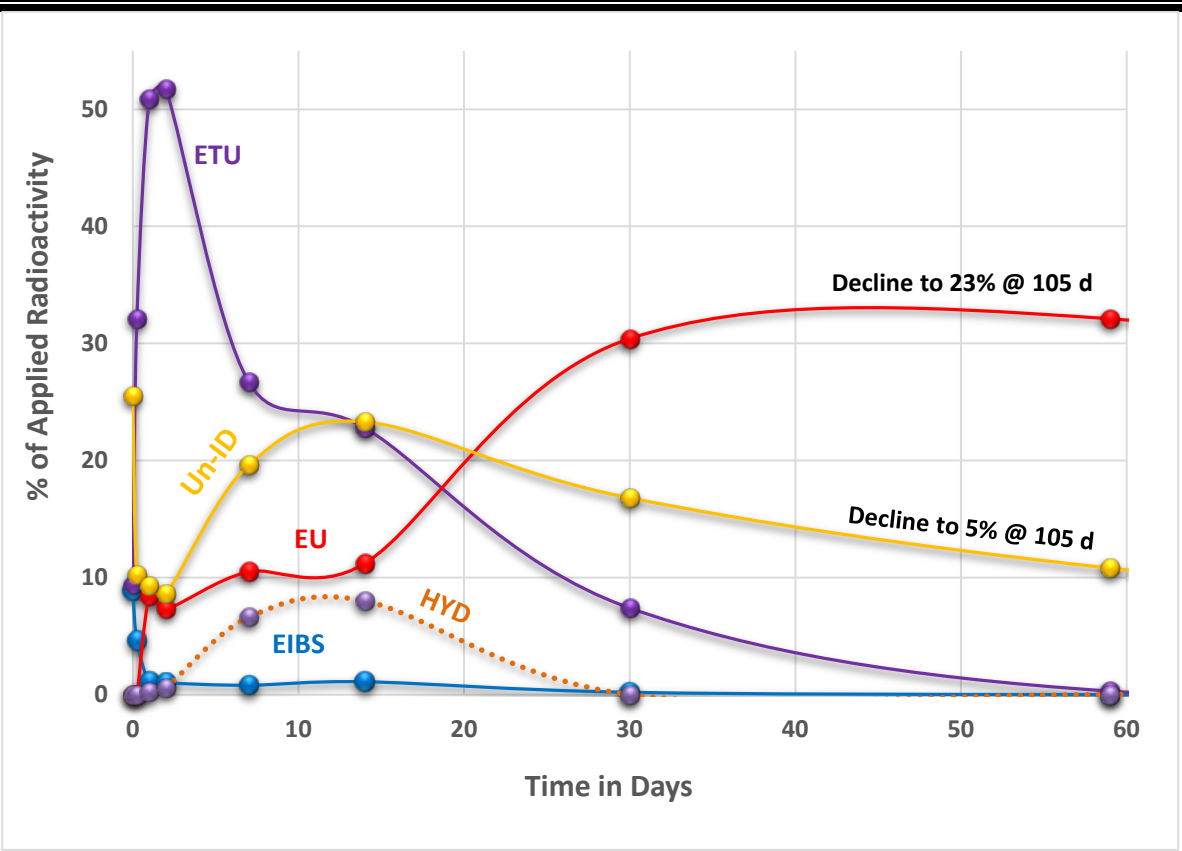
Figure 5 Observed degradates and UER in two aerobic water/sediment systems



In the aerobic water/sediment systems, a suite of degradates (EBIS, ETU, EU, HYD and unidentified degradates) forms and reaches maximum of nearly 75% of the applied rather quickly (within two days). Following this maximum, a gradual decline of this suite continues to reach levels of 28% of the applied parent in the pond system and 3% in the river system. The gradual decline of the degradate suite appears to coincide with the formation of relatively persistent un-identified/un-extracted residues (UER). The UER reaches a maximum of nearly 40% of the applied within one month and stays nearly stable to the end of the study (**Figure 5**). It is noted that formation levels of the UER with time were the same in both pond and river system.

Figure 6 shows the formation/degradation profile of the various constituents of the observed degradate suite in the water/sediment systems.

Figure 6 Formation and decline of the major degradates of mancozeb in aerobic water/sediment systems (The figure represents averages for river/pond)



Data in **Figure 6** suggest the following:

(b) EBIS is a transitional degradate that forms immediately following application to the water/sediment systems with a 90th percentile half-life (from maximum formation) of 8 days (0.3 days in the river system and 4 days in the pond system);

(c) UN-ID degradates form immediately at levels of nearly 10% and increase gradually within two weeks to 23% then decline slowly to 5% at 105 days. The 90th percentile half-life (from maximum formation) was 70 days (55 days in the river system and 41 days in the pond system).This suggests that these degradates forms from parent mancozeb immediately upon application as well as from residues later;

(d) ETU reached the maximum within one to two day (just after the sharp decline of EBIS) suggesting its formation from EBIS. The half-life (from maximum formation) was 5 days (SFO= Single 1st order) in the river system and 9 days (SFO) in the pond system. It is important to note that much longer single 1st order half-lives for ETU were estimated from metiram studies (7 days in a river system and 264 days in a pond system);

(e) EU appears to increase gradually but slowly (within one month) into a plateau (30-32%) and very slowly declines to 23% by the end of the 105-day study. The 90th percentile half-life (from maximum formation) was 229 days (range 9 days in the river system and 117 days in the pond system);

(f) HYD reached the maximum of 12% in the river system and 14% in the pond system in a 7-14 day period then declined to non-detection.

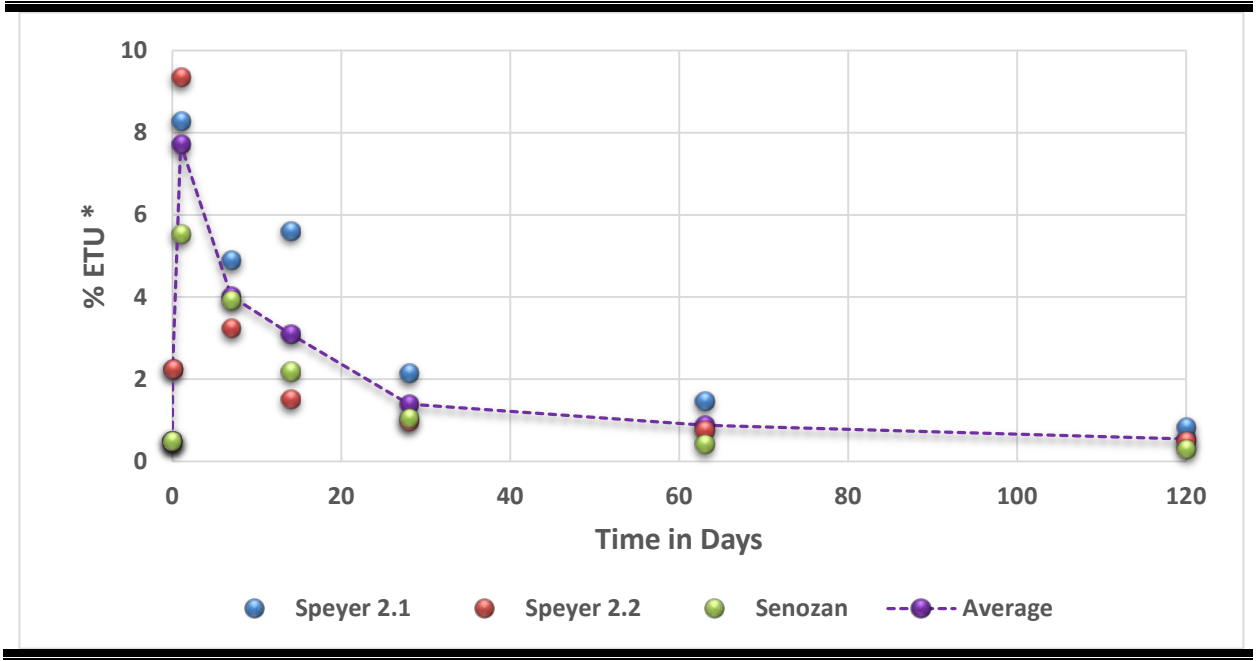
5.2 The Major Mancozeb Degradate: Ethylenethiourea (ETU)

ETU is a common metabolite/degradate of the EBDC fungicides (EBDCs) including mancozeb. As a mancozeb degradate, ETU can be anticipated to be found wherever this fungicide is used. In an agricultural setting, ETU is introduced into the environment in three ways following application of mancozeb fungicide. ***First***, ETU may be added with the applied formulation as it may form in these formulations as a result of particle size reduction (i.e. colloidal milling) and/or due to unfavorable storage. In EBDCs, up to 13% of the active ingredient was found to be converted to ETU. ***Second***, ETU is produced from hydrolytic/biotic degradation of parent mancozeb following its application to soils and/or after reaching water bodies by drift. ***Third***, ETU may be produced from further hydrolysis/biotransformation of transient species in pore water/water bodies and possibly from soil/sediment bound residue of mancozeb. Rapid hydrolysis/biotransformation of mancozeb parent and/or residues are expected to be the major processes that control ETU production in soils and water bodies. In addition, slow biotic degradation of un-extracted (UER) mancozeb residues may also contribute to the production of ETU in the long term. It is noted that the slow production of ETU from mancozeb UER is uncertain as the identity of these residues is unknown.

As stated above, ETU is produced mainly from decomposition/hydrolytic/biotic degradation of parent mancozeb. Laboratory data on hydrolysis of mancozeb suggest that hydrolysis may be one of the major processes in ETU production. However, data presented are uncertain as identification of transient species and degradates were largely dependent on the TLC methods which was affected by poor separation of degradates and the occurrence of degradation caused by the solvent systems employed. Therefore, a new hydrolysis study is requested for mancozeb in which all degradation products, including ETU are tracked.

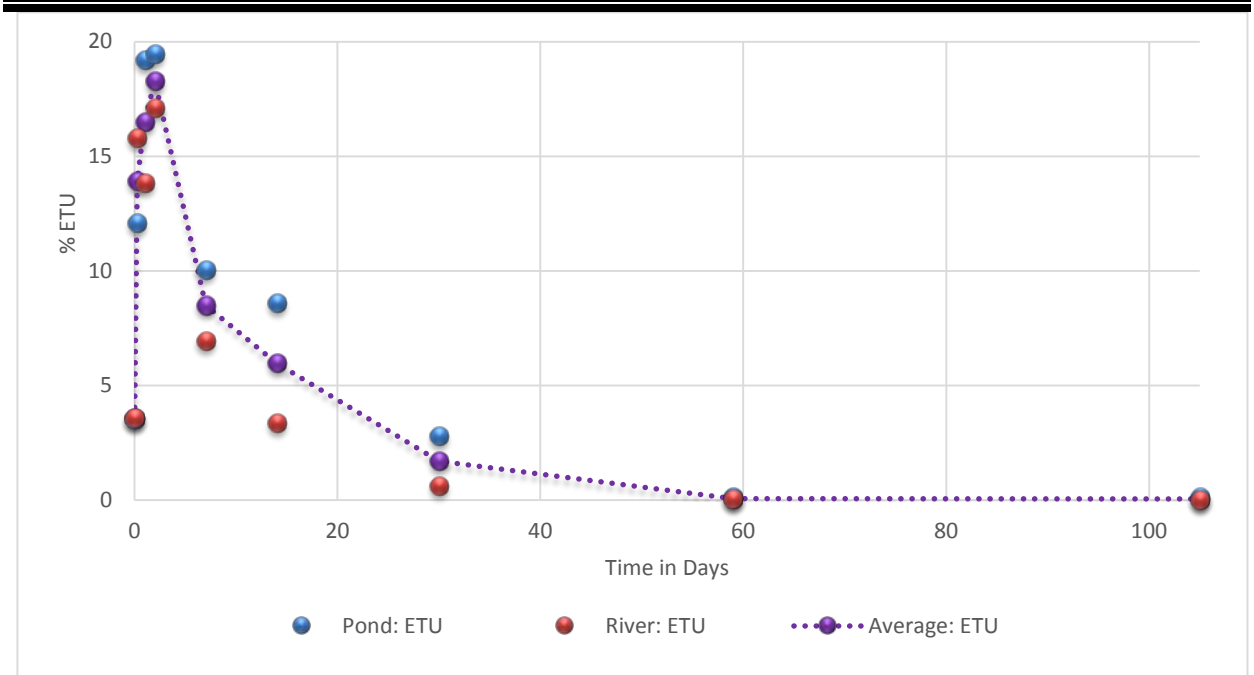
In the aerobic soil system, hydrolytic/biotic degradation of parent mancozeb appears to produce ETU. The maximum observed in three soils ranges from 6-9% (15-29% of parent equivalent) (**Figure 7**)

Figure 7 Formation and decline of ETU in a mancozeb aerobic soil study (three soils)



Similarly ETU was observed to be produced in the aerobic aquatic systems from hydrolytic/biotic degradation of parent mancozeb. In these systems, maximums observed ranged from 17-20% (45-52% of parent equivalent) (**Figure 8**)

Figure 8 Formation and decline of ETU in a mancozeb aerobic aquatic study (two systems)

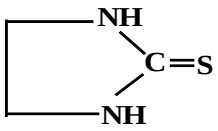


Finally, ETU may also be introduced to the environment from its extensive use as accelerator in synthetic rubber production and as vulcanizing agent in some poly-ethers production. Environmental contamination from these industrial uses are not within the FIFRA statutory framework and to will not be covered by the future risk assessment.

(a) Physical/Chemical and Abiotic Transformation

The chemical structure, physical/chemical characteristics and abiotic transformation of ETU are summarized in **Table 9**.

Table 9 Chemical structure, physical/chemical characteristics and abiotic transformation of ETU

Property	*Value*	*Reference*
Identity/Structure	 CAS Number (Name): 96-45-7 (2-Imidazolidinethione)	
Molecular Weight (Formula)	102.2 g mole^{-1} ($C_3H_6N_2S$)	
n-octanol-Water Coefficient (K_{OW})	0.2	**MRID 406510-01 (A)**[1]
Vapor Pressure	5.01x10^{-3} torr	**Neely WB & Blau GE**[2]
Henry's Law constant	3.4X10^{-7} atm. m^3 mole^{-1}	**Meylan WM & Howard PH**[3]
Water Solubility	**20,000 ppm** @ 20 °C and 90,000 ppm @ 60 °C	
Hydrolysis half-life (t ½)	**Stable** @ 25 °C and pH 5, 7, and 9	**MRID 404661-03 (A)**[1]
Aqueous photolysis t ½	**Stable** in pH 7 buffered water (Ross and Crosby [3] reported that the Maximum ETU absorbance lies at 240 nm)	**MRID 404661-02 (A)**[1]
Soil photolysis t ½	**Stable** (Based on Data and UV/Visible spectra)	**MRID 404661-01(A)**[1]

[1] **Study Classification: A= Acceptable; S= Supplemental**
[2] **Neely WB and Blau GE** 1985. Environmental Exposure from Chemicals. Boca Raton, FL: CRC Press pp. 31
[3] **Meylan WM & Howard PH** 1991. Environ Toxicol Chem 10: 1283-93 (Fragment constant estimation method)

Data in **Table 9** indicate that ETU is a low molecular-weight chemical that is highly soluble in water. The high vapor pressure of ETU suggests partitioning into the air can be an important route of its dissipation in the environment, especially from dry surfaces. The relatively low Henry's Law constant suggests possible low volatilization of ETU into the air from wet soil and water. ETU has a low K_{ow} value suggesting that it will not be significantly bio-concentrated by aquatic organisms such as fish. Abiotic process such as hydrolysis and photolysis are not expected to be important in dissipation of ETU in the environment.

(b) Biotic Transformation

Fate data for ETU is extracted from parent studies and/or ETU studies where ETU is the test substance. A summary of this data are presented in **Table 10**.

Table 10 Summary of environmental fate properties of ETU

Property	*Value*	*MRID Reference* [1]
Aerobic soil t ½ (Parent Study: @ 20 ºC and End of study (EOS)= 120 day); ETU study @ 25 ºC and End of study (EOS)= 7 day)	**From Parent Study:** **18.2 days** in Speyer 2.3: A sandy loam soil from Germany; pH= 6.5 and organic carbon "O.C" = 0.71%); **4.4 days** in Speyer 2.2: A loamy sand soil from Germany; pH= 5.7 and O.C= 2.17%; **10.7 days** in Senozan: A silty loam soil from France; pH= 5.8 and O.C= 0.99% **Note: ETU:** Max 14-25% @ 1 d then declined to 1-2% @ EOS **From ETU Study:** **1.6 days** in Collamer silt loam soil from Wayne Co., NY; pH= 6.1, organic matter= 3.6% and CEC= 13 meq/100g; and **1.4 days** in Oakville sand soil from Wayne Co., NY; pH= 6.8, organic matter= 2.1% and CEC= 6 meq/100g; **Note: t ½= 3.2 days** was observed in Collamer silt loam soil when soil moisture was reduced from 70 to 40% of the soil water holding capacity ***Major Degradates:*** **EU** was only tracked with Max of 3-3.4% @ <1-2 days and then declined to <0.2-0.3% @ EOS ***Un-extracted Residues (UER); Mineralization to CO_2 and Mass Balance:*** Not determined	**Parent Study: 457445-01 (S);** **ETU Study: 452251-01 (S) & 451464-01 (S)**
Aerobic Aquatic t½ @ 25 ºC	**From Parent Study:** **5 days** in a water/loamy sand sediment from the Rhine River, Switzerland (water: pH 8.0-8.2, total organic carbon 2.6 mg/L ; sediment: pH=6.9, O.C= 1.4% and CEC=2.8 meq/100g); and **9 days** in a water/loamy sand sediment from Ormalingen pond, Switzerland (water: pH 7.4, total organic carbon 1.1 mg/L; sediment: pH=6.7, O.C= 5.0% and CEC=7.1 meq/100g) **Note: ETU Max** 42-52% @ <1-2 d then declined to <1% @ EOS **From ETU Study:** No Acceptable study	**Parent Study: 462043-01 (A)**
Anaerobic Aquatic t½ @ 25 ºC	**Studies suggest longer half-lives than the aerobic conditions; if no study is submitted, ETU will be considered stable**	**001633-35 000888-20& 402582-03 (U)**

Study Classification: A= Acceptable; S= Supplemental and U= Un-acceptable

Data in **Table 10** suggest the following:

(1) ETU degraded under aerobic soil conditions with a 90th percentile t½ of 12 days (n=5). Only EU degradate was tracked and observed at levels ranging from 3-3.4% of the applied

radioactivity. The study demonstrated vulnerability of ETU to biodegradation in the soil system;

(2) ETU degraded under aerobic water sediment systems with a 90th percentile half-life of 13 days; and

(3) Observed half-lives of ETU in the soil system is much shorter than those observed in the water/sediment systems.

Due to deficiencies in submitted anaerobic aquatic studies, ETU will be considered stable unless a new study is submitted that indicates otherwise. In requested studies, ETU and degradates should be tracked with the latest available analytical procedures. In addition, extraction method should prove to be appropriate as per EFED un-extracted residues guidance[8].

(c) Mobility

Data for mobility were estimated from a supplemental adsorption/desorption study (**Table 11**). It is noted that there were problems with this study such as the possibility of occurrence of degradation of ETU before conducting the experiment. The study was classified as supplemental following registrant submittal of data suggesting that the applied test substance included significant quantities of ETU.

Table 11 Summary of the transport properties for ETU

Property	*Value for Mancozeb Parent & Residues*	*MRID Reference [1]*
Adsorption Coefficient (Koc) (Adsorption/desorption study)	**150 mL/g** for a Sandy soil from GA (O.M= 0.9%, pH= 5.7 and CEC= 4 meq/100g); **57 mL/g** for a Sandy loam soil from GA (O.M= 2.8%, pH= 5.9 and CEC= 6 meq/100g); **42 mL/g** for a Silt loam soil from PA (O.M= 3.5%, pH= 6.4 and CEC= 10 meq/100g); and **34 mL/g** for a Clay loam soil from MS (O.M= 2.5%, pH= 7.4 and CEC= 13 meq/100g)	**002588-96 And 000971-58 (S)**
Average value	**71 mL/g**	
Range of values	**34- 150 mL/g**	
Study Classification: S= Supplemental		

Based on data presented in **Table 11**, ETU is expected to be highly mobile in most soils (Average K_{oc}= 71 mL/g).

(d) Field Dissipation

Dissipation half-lives (DT_{50}s) of 1 to 6 days and <7 days were observed in fine sand and silt loam field soils (Supplemental studies: Accession Nos. 255229 and 000889-23).

[8] URL: http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/environmental_fate_tech_team/Unextracted_Residues_in_Lab_Studies.htm

(e) Bioconcentration

ETU is associated with very low K_{OW} values of 2. Fish bioaccumulation study was previously waived for ETU based on the expected low bioconcentration as indicated from $K_{OW.}$

(f) Transformation Products

ETU is a result of abiotic/biotic degradation of mancozeb/mancozeb residues reaching soil directly and by wash-off and reaching aquatic systems by drift. ETU itself is not expected to be affected by hydrolysis/direct photolysis in soils or aquatic systems. In contrast, ETU is expected to be highly affected by aerobic biodegradation in soils and to a lesser extent in biologically active aquatic media. Many degradation products were thought to be forming as a result of ETU degradation such as **EU** (2-Imidazolidone; CAS No. 107-15-3); **HYD** or Glycolylurea (2,4-(3H,5H)-Imidazoledione; CAS No. 461-72-3); **IMID** (2-Imidazoline; CAS No. 504-75-6); **GLY** (Glycine= Amino acetic acid; CAS No. 56-40-6); **J.B** (Jaffe's Base=1-(4,5-Dihydro-1H-imidazol-2-yl)-imidazolidin-2-thion; CAS No. 484-92-4); **EDA** (Ethylenediamine) and CO_2. However, only **EU** and **HYD** were confirmed since the results of the TLC method are considered not reliable due to problems stated earlier. The degradation products of ETU will be corrected based on the results of requested new studies.

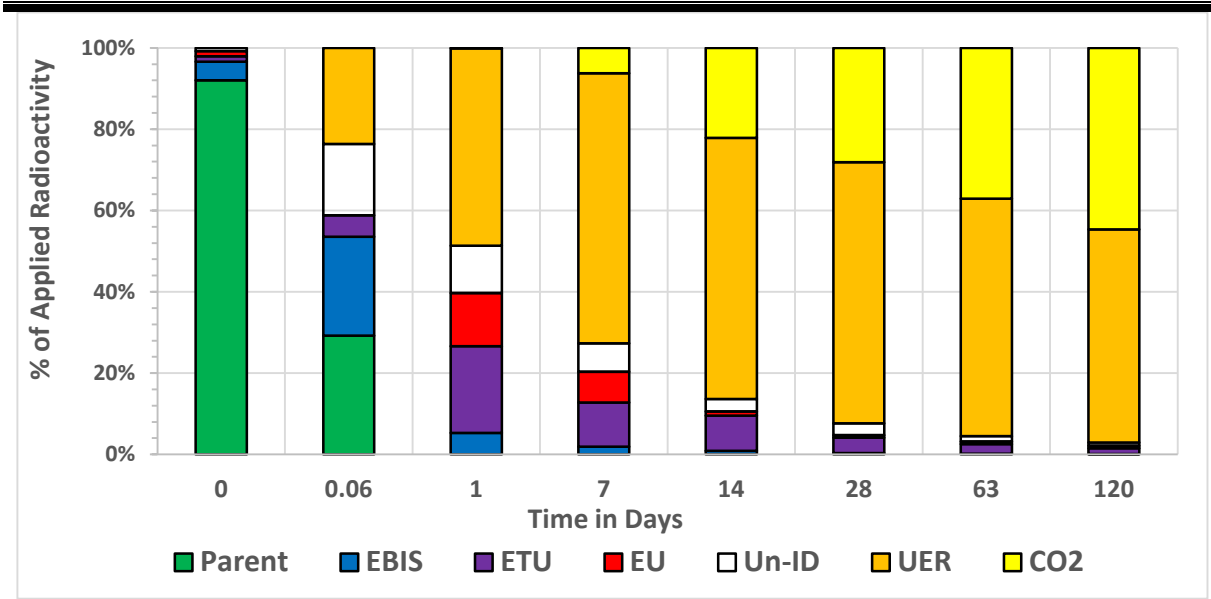
5.3 Determination of the Stressor of Concern for Ecological Risk Assessment

Chemical species intensity and timing of exposure and toxicity are used to determine the stressor of concern for the future ecological risk assessment.

Exposure

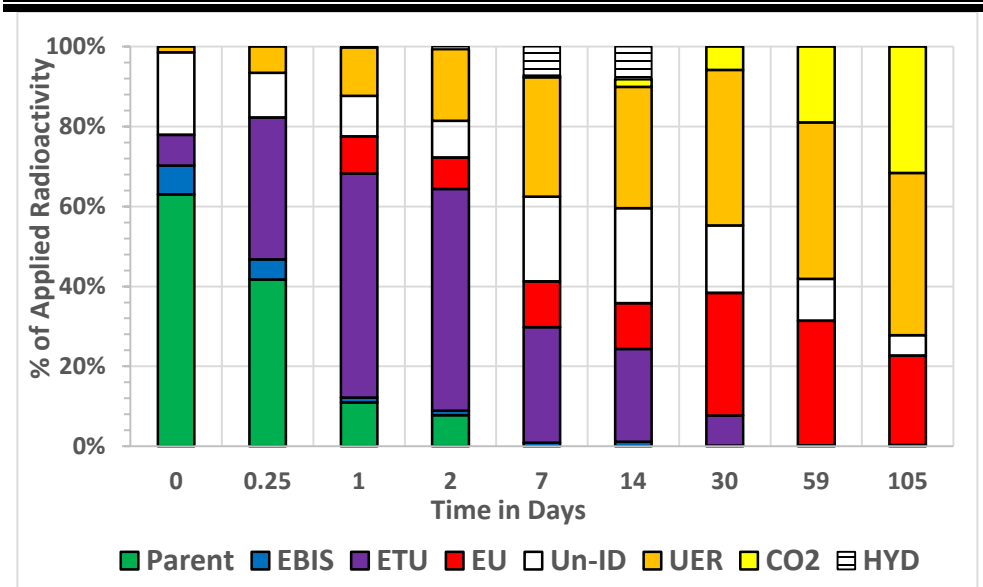
In the soil system, mancozeb reaching the soil indirectly upon application and later from wash-off is expected to degrade into multi chemical species or the mancozeb residues. The timeline for the change in the chemical species in of the mancozeb residues in the soil is summarized in **Figure 9**.

Figure 9 Expected relative changes in the chemical constituents of the mancozeb residues with time in the aerobic soil system (average of three soils).



Data in **Figure 9** suggest that chemical species that may reach aquatic systems by run-off from the soil include significant amounts of the UER and lesser amounts of ETU, EU and UN-ID degradates. In contrast, mancozeb reaching aquatic systems, by drift, is expected to also degrade into the mancozeb residues producing similar chemical species with different concentrations and at a different time-line as shown in **Figure 10**.

Figure 10 Expected relative changes in the chemical constituents of the mancozeb residues with time in aerobic aquatic systems (Average of two systems).



Data in **Figure 10** suggest that the constituents of the mancozeb residues will be dominated by un-degraded parent, EBIS and ETU at the short term and EU and the UER at the long term.

Therefore, aquatic exposure will be associated with un-degraded parent from drift alone, EBIS, ETU and EU at the short term and the UER and EU at the long term. Based on expected aquatic exposure, a mancozeb residues consisting from parent, ETU and EU are important at the short term and a mancozeb residues containing UER and EU at the long term.

Toxicity

The toxicity of the major degradates EBIS, ETU, EU and UER is considered hereafter to decide on which of these degradates may be included in the stressor.

As noted above, there is a relatively robust data set available to characterize the acute and chronic toxicity of ETU to aquatic taxa. These data are further discussed in Section 7 of this assessment. A comparatively smaller dataset exists for EU and only for acute exposure. These data are summarized in **Table 12** below alongside the endpoints derived from parent mancozeb studies. For the transient degradate EBIS, there is no registrant submitted data available, and therefore the structural activity relationship (SAR) tool ECOSAR (v 1.1) was employed to estimate the toxicity to taxa where no data are available. The results below indicate that for taxa for which registrant submitted studies are available for as well as ECOSAR estimates for where there are gaps in the dataset for EU, that ETU and EU are generally at least one order of magnitude less toxic than parent mancozeb and usually two or more orders of magnitude less toxic. As shown in **Table 12**, the transient degradate EBIS is estimated to elicit toxicity similar to that of parent mancozeb and for some taxa is estimated to be more toxic than parent mancozeb.

Table 12. Summary of registrant submitted and ECOSAR estimates of the various degradation product of mancozeb

Taxa → Stressor (data source)	**FW Fish LC_{50}**	**FW Invert LC_{50}**	**FW fish NOAEC**	**FW invert NOAEC**	**E/M fish LC_{50}**	**E/M invert LC_{50}**	**E/M Fish NOAEC**	**FW Green Algae**
Parent Mancozeb (registrant submitted data)	0.91	1.04	0.001	0.02	1.6	0.009		0.047
ETU (registrant submitted data)	>502	26.9		Study in review	>895	7.8		23
EU (registrant submitted data)	>122	985						119
EU (Substituted ureas ECOSAR class)	2735	8624	5.57	204	94.2	1351	4.07	156
EU (Amides ECOSAR class)	7183	855	22.7	272	17.6	1428		21.6
EBIS (Thiocarbamate, di (substitute ECOSAR class)	0.18	0.62	0.015[1]	0.041**				0.10

*May not be soluble at this level to elicit estimated effect
**Estimated using an acute to chronic ratio

As shown in **Figure 10** above, upon entering the water column, mancozeb shows a rapid transformation within 6 hours to ETU, at which point the relative concentration of parent remaining is approximately 40%. This decomposition continues where by after 1 day, total parent mancozeb is less than 10% while ETU and EU residues make up a combined 70%. The toxicity

of the un-extracted residues, that along with EU, comprise the majority of residues in the water/sediment system after 30 days, is characterized only to freshwater sediment-dwelling organisms (see **Section 6** for more details). While their toxicity to other taxa represent an uncertainty, the extent to which the un-extracted residues would be bioavailable to water column organisms is expected to be low. More likely, these pelagic organisms would be exposed to relatively stable concentrations of EU which registrant submitted studies show to be less toxic than mancozeb on an acute basis and ECOSAR estimates show to be less toxic than mancozeb on a chronic exposure basis

What follows is a summarization of the ecological stressor of concern for each taxa:

Ecological stressor of concern (aquatic organisms):

- The total residues of un-degraded **mancozeb parent plus EBIS** for acute exposure: the source of mancozeb parent and EBIS is expected to be from drifted parent alone as mancozeb reaching the soil system and resultant transient species (*i.e.*, EBIS) and degradates ETU and EU forming in the soil are not expected to reach aquatic systems by run-off because they are short lived. Additionally, it is noted that *at most* (per **Figure 10**), EU is 27X less acutely toxic than parent (based on freshwater invertebrate data), and at Day 1, EU is present at about 6X that of parent, so its contribution to overall toxicity would be very limited.

- For chronic exposure**: UER** that forms following degradation of drifted parent and that carried by run-off from the **UER** forming in the soil system.

Ecological stressor of concern (terrestrial foliar residues for birds and mammals):

- **Parent mancozeb residues on various food items for both acute and chronic risk** noting that this will be conservative because the possible occurrence of degradation by moisture will reduce exposure due to the production of the less toxic degradates ETU and EU. It is also noted that this degradation applies to parent mancozeb behavior on soil. It is an uncertainty as to whether mancozeb follows a similar dissipation pattern on foliage and therefore it is assumed that, without data to suggest otherwise, these residues would be available for ingestion by avian and mammalian species.

Ecological stressor of concern (terrestrial foliar residues for honey bees):

- The discussion above relating to **parent mancozeb residues on various food items for both and chronic risk** also apply to honey bees via direct contact spray toxicity. As mancozeb does not exhibit systemic properties, its residues would not be expected to be present in pollen and nectar.

In contrast, the drinking water stressor is ETU, the major degradate of mancozeb forming in aquatic systems from drifted parent and ETU that forms in the soil and transported to these systems by run-off.

6. Receptors

As described in the Agency's Overview Document (U.S EPA, 2004), the most sensitive endpoint for each taxonomic group will be used to calculate risk quotients (RQs). Assessment endpoints include direct toxic effects on the survival, reproduction, and growth of terrestrial and aquatic life as well as indirect effects such as reduction in prey base and/or modification of habitat. Acute and chronic toxicity data from studies submitted by pesticide registrants along with the available open literature are used to evaluate the potential direct effects of mancozeb to the aquatic and terrestrial receptors identified in this section. This includes toxicity data on the technical grade active ingredient, degradates, and when available, formulated products. The open literature studies are identified through EPA's ECOTOX database (http://cfpub.epa.gov/ecotox/), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife.

6.1 Effects to Aquatic Organisms

A summary of the available eco-toxicity information and the incident information for mancozeb is provided below. **Table 13** provides a summary of the taxonomic groups and the surrogate species tested to help understand potential acute and chronic ecological effects of mancozeb. In addition, the table provides a preliminary overview of the potential acute toxicity of mancozeb by providing the acute toxicity classifications.

There are several acute toxicity studies available to characterize the toxicity of mancozeb to freshwater fish. Acute LC_{50} endpoints range from 0.91 to 9.3 mg a.i/L, which classifies mancozeb as highly toxic to freshwater fish on an acute exposure basis. Clinical signs of toxicity that were observed in studies included loss of equilibrium, bulging eyes, and resting on the bottom of the tank. These effects generally occurred at concentrations where at least one mortality was observed. Chronic early life stage and chronic full life cycle toxicity tests are available for freshwater fish. The chronic NOAEC values determined for the ELS study and full life cycle study were within a factor of 2 (2.19 and 1.35 µg a.i/L, respectively). It is noted that parent mancozeb will not be associated with long persisting residues in the water column as indicated in the previous discussion (Section 5.3). While the NOAEC was based off of survival effects for the ELS study, the number of eggs per female per day was the most sensitive endpoint for the fish full life cycle. There were no clinical signs of toxicity observed in either study.

Available data indicate that mancozeb is moderately toxic to estuarine/marine fish on an acute exposure basis with an LC_{50} of 1.6 mg a.i/L. There were no reported clinical signs of toxicity during the course of the study. Despite the study being classified as supplemental, there was evidence of test substance stability issues during the course of the study with percent recoveries ranging from 43 – 50%.

There is currently one chronic early life stage with the estuarine/marine fish species, Sheepshead minnow (MRID 48627702), that is currently in review.

Acute and chronic toxicity studies are available to characterize effects on freshwater invertebrates. On an acute exposure basis, mancozeb is classified as moderately toxic with an EC_{50} of 1.04 mg a.i/L. A chronic life cycle study conducted with formulated (77.1% a.i) mancozeb indicated a NOAEC of 18 µg a.i/L based on significant ($p<0.05$) effects on mortality and reproduction (total number of live young).

Available data for characterization the acute toxicity of mancozeb to estuarine/marine invertebrates indicate the chemical is very highly toxic on an acute exposure basis with a LC_{50} value of 9.49 µg a.i/L. Despite being classified as supplemental, the study review indicates that the control appeared to be contaminated with test substance. Correspondence that was attached to the review of the study dated in May, 1989, indicated that the issue of control contamination had been discussed between the Rohm and Haas Company and EPA. At that time, EPA stated that because no control mortality occurred, no further testing would be needed. An examination of the analytical data indicates that mancozeb was detected in the control samples at 2.31 µg a.i/L at test initiation, 1.05 µg a.i/L at 48 hours, and no detected at 96 hours (test termination). Given that no control mortality occurred, and no other notable deviations from guideline recommendations were present, this study is considered suitable for risk assessment purposes.

There is one chronic life cycle toxicity study available for estuarine/marine invertebrates (mysid shrimp) that is currently in review (MRID 48627701).

There is one study available to characterize the toxicity of mancozeb to aquatic non-vascular plants, specifically to freshwater green algae. No studies are available for vascular aquatic plants or for freshwater and estuarine/marine diatoms and cyanobacteria.

Table 13. Summary of the Most Sensitive Endpoints from Aquatic Toxicity Studies for Mancozeb

Taxonomic Group	Study Type – Test Material	Surrogate Species	Toxicity Value (all units in terms of measured active ingredient)[2]	Acute Toxicity Classification	Source (Classification)
Freshwater fish[1]	Acute - TGAI	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50}: 0.91 mg/L (0.77 – 1.1; N/A)	Highly toxic	45934701 (Supplemental)
	Acute - formulation	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50}: 1.1 mg/L (0.90 – 1.43, N/A)	Moderately toxic	40467501 (Supplemental)
	Chronic (Early life stage) - TGAI	Fathead minnow (*Pimephales promelas*)	28-day NOAEC: 2.19 µg/L; LOAEC (survival): 4.56 µg/L	--	43230701 (Acceptable)
	Chronic (Full life cycle) - TGAI	Fathead minnow (*Pimephales promelas*)	215-day NOAEC 1.35 µg a.i/L; LOAEC (number of eggs, number of eggs/female/day)	--	49030601 (Acceptable)
Freshwater invertebrates	Acute - TGAI	Water flea (*Daphnia magna*)	48-hr EC_{50}: 1.04 mg a.i/L (0.87 – 1.32; N/A)	Moderately toxic	40467503 (Supplemental)

Taxonomic Group	Study Type – Test Material	Surrogate Species	Toxicity Value (all units in terms of measured active ingredient)[2]	Acute Toxicity Classification	Source (Classification)
	Chronic - formulation		21-d NOAEC: 18 µg a.i/L; LOAEC (mortality and total number of young): 81 µg a.i/L	--	46023702 (Supplemental)
Estuarine/marine fish	Acute - TGAI	Sheepshead minnow (*Cyprinodon variegatus*)	96-hr LC_{50}: 1.6 mg a.i/L(N/A; N/A)	Moderately toxic	41844901 (Acceptable)
	Chronic - TGAI		Study in review (48627702)		
Estuarine/marine invertebrates	Acute – formulation	Mysid shrimp (*Americamysis bahia*)	96-hr LC_{50}: 9.49 µg/L (8.26 – 11.4; N/A)	Very highly toxic	41822902 (Supplemental)
	Acute - TGAI	Eastern oyster (*Crassostrea virginica*	96-hr EC_{50}: 1.60 mg a.i/L (1.40 – 1.80; N/A)	Moderately toxic	40885102 (Acceptable)
	Chronic - TGAI	Mysid shrimp	Study in review (MRID 48627701)		
Sediment-Dwelling Invertebrates	Subchronic Spiked sediment system - TGAI	Freshwater midge (*Chironomus dilutus*)	<u>Sediment:</u> NOAEC/LOAEC (mortality and dry weight): 8.17/15.7 mg TRR/kg dw <u>Pore water:</u> NOAEC/LOAEC (mortality): 1.92/5.25 mg TRR/L	--	47410101 (Acceptable)
	Subchronic Spiked sediment system – Non-extractable residues		<u>Sediment:</u> NOAEC/LOAEC (mortality): 0.912/19.3 mg TRR/kg dw <u>Pore water:</u> NOAEC: 0.083 mg TRR/kg LOAEC (mortality): 0.18 mg TRR/L	--	47410102 (Acceptable)
Aquatic plants and algae	Non-vascular[2] - TGAI	Freshwater Green Algae (*Selenastrum capricornutum)*	96-hour EC_{50} (cell density): 47 µg/L (42 – 51; N/A) 96-hr NOAEC: 22 µg/L	--	43664701 (Acceptable)

[1] Freshwater fish may be surrogates for aquatic-phase amphibians.
[2] (95% confidence intervals; slope) if available
[3]Endpoints expressed in terms of mean measured active ingredient

Additionally, there are 9 studies available to characterize the acute and chronic toxicity of the primary degradate of mancozeb, ETU, to aquatic organisms (**Table 14**). As alluded to earlier, acute toxicity studies with freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and aquatic plants indicate that ETU is generally less toxic than parent mancozeb by at least an order of magnitude, depending on the taxa.

Table 14. Summary of Endpoints from Aquatic Toxicity Studies for the Mancozeb Degradate ETU

Taxonomic Group (study type)	Surrogate Species[2]	Toxicity Value[1]	Acute Toxicity Classification	Source (Classification)
Freshwater fish[2] (acute toxicity)	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50}: >502 mg/L (N/A; N/A)	Practically non-toxic	45910401 (Acceptable)
	Bluegill sunfish (*Lepomis macrochirus*)	96-hr LC_{50}: >988 mg a.i/L	Practically non-toxic	47441202 (Acceptable)
Freshwater invertebrates (acute toxicity)	Water flea (*Daphnia magna*)	48-hr EC_{50}: 26.9 mg a.i/L (19.6 – 38.5; 1.92)	Slightly toxic	45910402 (Acceptable)
Freshwater invertebrates (chronic toxicity)		Study in review		
Estuarine/marine fish (acute toxicity	Sheepshead minnow (*Cyprinodon variegatus*)	96-hr LC_{50}: >895 mg a.i/L (N/A; N/A)	Practically non-toxic	47441201 (Acceptable)
Estuarine/marine invertebrates (acute toxicity)	Mysid shrimp (*Americamysis bahia*)	96-hr LC_{50}: 7.8 mg a.i/L (5.1 – 10.9; N/A)	Moderately toxic	47441204 (Acceptable)
Estuarine/marine invertebrates (acute toxicity)	Eastern oyster (*Crassostrea virginica*)	96-hr >110 mg a.i/L (N/A; N/A)	Practically non-toxic	47474301 (Acceptable)
Aquatic plants	Freshwater green algae (*Pseudokirchneriella subcapitata*)	72-hr EC_{50} (cell density): 23.0 mg a.i/L (N/A; N/A) 72-hr NOAEC: 5.0 mg a.i/L	--	45910403 (Acceptable)
	Duckweed (*Lemna gibba*)	7-d EC_{50}: >960 mg a.i/L 7-d NOAEC: 230 mg a.i/L 7-d LOAEC (frond density and growth rate): 480 mg a.i/L	--	47441203

[1]Concentrations expressed in terms of mean measured active ingredient.
[2]Freshwater fish may be surrogates for aquatic-phase amphibians.

There are 3 studies available to characterize the acute toxicity to the degradate of ETU (itself a degradate of mancozeb) ethylene urea (EU) to freshwater fish, invertebrates, and green algae (**Table 15**). The available acute toxicity study for freshwater fish, while not testing as high as the study with ETU, indicates that EU is practically non-toxic to fish on an acute exposure basis. For freshwater invertebrates and freshwater green algae, available data indicate that EU is at least one order of magnitude less toxic as compared to ETU and at least 2 orders of magnitude less toxic than parent mancozeb.

Table 15. Summary of Endpoints from Aquatic Toxicity Studies for the ETU Degradate Ethylene Urea (EU)

Taxonomic Group (study type)	Surrogate Species[1]	Toxicity Value[1]	Acute Toxicity Classification	Source (Classification)
Freshwater fish[2] (acute toxicity)	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50}: >122 mg/L (N/A; N/A)	Practically non-toxic	46462902 (Acceptable)
Freshwater invertebrates (acute toxicity)	Water flea (*Daphnia magna*)	48-hr EC_{50}: >985 mg/L	Practically non-toxic	46462903 (Acceptable)
Aquatic plants	Freshwater green algae (*Pseudokirchneriella subcapitata*)	96-hr EC_{50}: >119 mg/L 96-hr NOAEC: 119 mg/L	--	46462904 (Acceptable)

[1] Concentrations expressed in terms of mean measured active ingredient.
[2] Freshwater fish may be surrogates for aquatic-phase amphibians.

6.2 Effects to Terrestrial Organisms

Available data are inadequate to fully characterize the acute oral and sub-acute dietary risk of mancozeb to avian species. Three studies are currently available, and despite being classified as supplemental, have deficiencies that limit their utility in a quantitative risk assessment.

In a study conducted with the Japanese quail (*Coturnix japonica*, MRID 00080717), the study was initially planned as an avian dietary test, but changed to a multiple dose oral study. The age, gender, and source of the test animals was not provided, four animals per treatment level (as opposed to 10) were used, and regurgitation occurred at certain test concentrations during the course of the study. Therefore, it is uncertain as to what level of test substance the test birds actually received. Similarly, in a multiple-dose oral toxicity study conducted with the mallard duck (MRID 00080716), test bird age, gender, and source were also unspecified. Additionally, differing numbers of animals were used depending on the concentration (all below the guideline-recommended 10 animals per treatment group), as well as regurgitation occurring at the two highest treatment levels. This study was classified as supplemental but has limited utility on quantitative risk assessment given the uncertainty of the doses that test birds received at the two highest treatment groups. Finally, mancozeb was tested with multiple acute oral doses to sparrow (*Passer* sp.), starlings (*Sturnus vulgaris*), and pheasants (*Phaisanus* sp.) (MRID 00036094). The starlings and sparrows were wild caught and the pheasants were obtained from an unknown commercial rearer. No age or gender information was given and there was a reduced number of birds per treatment level than the guideline–recommended number. These deficiencies, despite a study classification of supplemental limit its use in quantitative risk assessment.

There are no subacute dietary toxicity studies available for mancozeb.

A chronic avian reproduction study conducted with the mallard duck (MRID 41948401) indicated several effects at the highest treatment concentration (1000 ppm) including reduced egg production, early and late embryo viability, hatchability, and 14-day hatching weight. Similarly, in the bobwhite quail study (MRID 44238001), 14-day hatching weight was also significantly reduced at the highest treatment concentration (1000 ppm) although this was the only adverse

effect observed during the study. There were no clinical signs of toxicity observed at any treatment level in both studies.

An acute oral toxicity study with mancozeb on the Norway rat (*Rattus norvegicus*) (MRID 00142522) indicated that mancozeb is practically non-toxic to mammals on an acute exposure basis with an LD_{50} of >5000 mg a.i/kg-bw. In a 2-generation reproduction study, (MRID 41365201), significant ($p<0.05$) decreases in parental body weight were observed at the highest treatment level (1200 ppm) along with increased relative thyroid weights and increased incidence of thyroid follicular cell hyperplasia.

Tier I seedling emergence and vegetative vigor studies are available for mancozeb (MRID 47486102 and 47486101, respectively). Both studies tested a single application rate of 0.02 lbs a.i/A. In the seedling emergence study, there were no effects that were observed to be greater than a 25% reduction from that of the negative control. For ryegrass, the most sensitive monocot, there was a 19% reduction in dry weight and therefore a definitive NOAEC could not be established. There were no significant reduction for dicots. In the vegetative vigor study, definitive EC_{25} and NOAEC values could not be determined due to a lack of toxicity. It is noted that the maximum single application rate of mancozeb ranges from 4.88 lbs. a.i/acre (in crops other than turf) to 17.5 lbs. a.i/acre (in turf), which range from 2 – 4 orders of magnitude larger, respectively, than the rates assessed in the available studies.

In an acute contact toxicity study that assessed multiple chemicals, bees of unknown age and source were exposed to mancozeb via a bell-jar vacuum duster. The doses at which bees were exposed is not available from the DER, nor was there any further information about the husbandry conditions, experimental test design, and raw data. The 96-hr LD_{50} was determined as 179 µg a.i/bee. The utility of this study in quantitative risk assessment is limited however given that the test substance was not applied to the thorax of the honey bee as in guideline recommended acute contact toxicity studies. Furthermore, critical information about the test organism and experimental conditions are missing from the study review. Acute oral toxicity data, as well as studies to characterize the toxic effect to honey bee larvae are not available.

In an acute contact and reproductive study (MRID 45577201) with the predatory mite (*Typhlodromus pyri*), primary leaves of common beans were used as the treatment substrate. Mites were then exposed to 6 treatment concentrations plus a negative control and after 14 days, the residue concentration to cause lethality to 50% of the population (LR_{50}) was determined. Additionally, NOAEC and LOAEC values were determined for the mean number of eggs hatched per female. The LR_{50} (mortality) and NOAEC (reproduction) determined in this study were 0.1 lb a.i/A and <0.02 lb a.i/A, respectively.

In a subchronic toxicity test conducted with the earthworm (*Eisenia fetida*), test organisms were exposed to varying concentrations of TGAI mancozeb for 28-days. There were no effects on mortality or body weight. The number of surviving offspring per adult was significantly ($p<0.05$) reduced at the two highest treatment concentrations.

Table 16. Summary of the Most Sensitive Endpoints from Terrestrial Toxicity Studies for Mancozeb

Taxonomic Group	Study Type	Surrogate Species	Toxicity Value (all units in terms of measured active ingredient)[2,3]	Acute Toxicity Classification	Source (Classification)
Birds[1]	Acute Oral	No data adequate for quantitative risk assessment			
	Sub-acute dietary	No data previously submitted			
	Chronic	Mallard duck quail (*Anas platyrhynchos*)	NOAEC = 125 ppm (14-day old hatchling weight, egg production, hatchability, embryo viability) LOAEC = 1000 ppm	--	41948401 (Acceptable)
Mammals	Acute Oral	Norway rat (*Rattus norvegicus*)	14-day LD_{50} >5000 mg/kg bw (N/A; N/A)	Practically non-toxic	00142522 (Acceptable)
	Chronic (2-generation reproduction)	Norway rat (*Rattus norvegicus*)	NOAEC (parental body weight) = 120 ppm LOAEC = 1200 ppm	--	41365201 (Acceptable)
Insects	Acute contact - TGAI	Honey bee (*Apis mellifera*)	96-hr LD_{50}: 179 µg a.i/bee	Practically non-toxic	00018842 (Acceptable)
Terrestrial plants	Seedling Emergence (Tier I)	Monocot – Ryegrass	EC_{25} > 0.02 lbs a.i/A NOAEC (dry weight) = <0.02 lbs a.i/A	--	47486102 (Acceptable)
		Dicot – None	EC_{25} : >0.02 lbs a.i/A NOAEC = 0.02 lbs a.i/A		
	Vegetative Vigor (Tier I)	Monocot - None	EC_{25} >0.02 lbs a.i/A NOAEC = 0.02 lbs a.i/A		47486101 (Acceptable)
		Dicot - None	EC_{25} >0.02 lbs a.i/A NOAEC = 0.02 lbs a.i/A		

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.
[2] Concentrations expressed in terms of active ingredient.
[3] An N/A under endpoint means that there was not a most sensitive species tested.

Additionally, there are six studies available to characterize the toxicity of ETU to terrestrial organisms. In two acute oral studies with the zebra finch and bobwhite quail (MRID 48437501 and 4834001, respectively), ETU was not associated with any mortalities during the course of the study. In two subacute dietary toxicity studies with the bobwhite quail and mallard duck (MRIDs 48417801 and 48417802, respectively), ETU did not cause mortality in all treatment concentrations. In the bobwhite quail study, there was a reduction in mean body weight change in the three highest treatment concentrations as we all as a significant ($p<0.05$) reduction in mean body weight in the two highest treatment concentrations. In the study with the mallard duck, there was a significant ($p<0.05$) decrease in mean body weight that was determined at all treatment concentrations.

There are two chronic avian reproduction studies conducted with ETU on the bobwhite quail (MRID 48819701) and mallard duck (MRID 48819702) that are currently in review.

Table 17. Summary of Endpoints from Terrestrial Toxicity Studies for the ETU

Taxonomic Group (study type)	Study Type	Surrogate Species	Toxicity Value (all units in terms of measured active ingredient)2	Acute Toxicity Classification	Source (Classification)
Birds[1]	Acute oral toxicity	Bobwhite quail (*Colinus virginianus)*	14-d LD_{50} >2250 mg/kg-bw (N/A; N/A)	Practically non-toxic	48343001 (Acceptable)
		Zebra finch (*Taeniopygia guttata)*	14-d LD_{50} >2250 mg/kg-bw (N/A; N/A)	Practically non-toxic	48437501 (Acceptable)
	Subacute dietary toxicity	Bobwhite quail (*Colinus virginianus)*	8-d LC_{50} > 5620 mg/kg-bw (N/A; N/A)	Practically non- toxic	48417801 (Acceptable)
		Mallard duck (*Anas platyrhynchos*)	8-d LD_{50} > 5620 mg/kg-bw (N/A; N/A)	Practically non- toxic	48417802 (Acceptable)
	Chronic avian reproduction	Bobwhite quail (*Colinus virginianus*	Study in review (MRID 48819701)		
		Mallard duck (*Anas platyrhynchos*)	Study in review (MRID 48817702)		

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.
[2]Range of numbers within parentheses refers to the 95% confidence limit of the point estimate value; followed by probit slope estimate if available

6.3 Ecological Incidents

The ecological incident information system (EIIS) is an EFED-maintained database that houses ecological incidents that have been reported to the Agency. When available, EIIS includes date and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. EIIS incidents are categorized according to the certainty that the incident resulted from pesticide exposure. The OPP-maintained Incident Database System (IDS) and the Aggregate Incident Database provide incident counts at the chemical and product level but do not provide the narrative information contained in EIIS. The Avian Incident Monitoring System (AIMS) is a database administered by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. Many of the incidents listed in this database are also in the EIIS. Searches of the incident databases were conducted in February, 2014.

A search of the IDS, AIMS, and Aggregate Incident Database returned no reported wildlife incidents involving mancozeb.

A search EIIS returned six incidents ranging in dates from 1970 to 2002. A summarization of the incidents with information regarding the date, location, taxa of organisms involved, certainty that

mancozeb was responsible for the incident, and other information is tabulated below (**Table 18**). Three incidents involved freshwater fish with the other half involving terrestrial plant damage. In all but two instances, the likelihood of mancozeb being responsible for the incident was reported as unlikely or possible. These two "possible" incidents are without any confirmatory chemical residue analysis. In the remaining two incidents classified as "probable," there was a chemical residue analysis conducted that confirmed the presence of mancozeb.

There were no reported wildlife incidents in any of the aforementioned databases for ETU.

Table 18. Summary of reported wildlife incident for mancozeb in EIIS.

Incident number	Year	Taxa Affected	Location	Certainty	Legality	Other narrative information
B0000-233	1970	Freshwater fish	Washington	Unlikely	Misuse (accidental)	- Large fish kill reported near Chewelah, WA - Resulted from an aerial application of flowable sulfur, Dithane M-45 (Mancozeb), and thiodan - Witnesses reported seeing the aircraft continue its spraying even when it was over the river - No residue analysis for mancozeb but residues of endosulfan found in fish sample suggest mancozeb was not the cause.
I000799-008	1992	Freshwater fish	North Carolina	Unlikely	Undetermined	- Small pond has fish kill reported after airblast sprayer used to treat apple orchard drifted - Orchard had been treated with Thiodan, fenarimol, and mancozeb - Water and soil samples were taken but not fish tissues -Analysis indicated that soil detects were present for mancozeb but it is unlikely that it is responsible for the observed fish kill due to endosulfan (thiodan) having restrictions around water and its presence in the water and soil samples
I008745-004	1995	Freshwater fish	Prince Edward Island (Canada)	Probable	Misuse (accidental)	- Rohm and Haas company reported the incident where spray tank filled with Dithane DF (mancozeb) fungicide overturned with as much as 36 kg entering a nearby stream - 30,000 – 35,000 fish found dead in nearby salmon hatchery - No analyses were made of the

Incident number	Year	Taxa Affected	Location	Certainty	Legality	Other narrative information
						fish or water but the fish were reported dead the morning after the contaminated water reached a salmon hatchery
I014406-002	1996	Terrestrial plants	Washington	Possible	Undetermined	- This incident was reported in the 1996 Annual Report of Pesticide Incident Reporting and Tracking Review Panel by the Washington State Department of Health. - It was alleged that an onion field was damaged by an aerial application of diazinon, metalaxyl, mancozeb, and chlorothalonil.
I013884-013	1998	Terrestrial plants	Washington	Probable	Registered use	- This incident is from the 1999 Annual Report from the Washington State Department of Health and Pesticide Incident Reporting and Tracking Review Panel. - Person complained of spray drifting over her neighbor's fence and onto her fruit and vegetable garden. - Chemical analysis of sample shows a trace of the applied pesticide
I014597-034	2002	Terrestrial plants	Oregon	Possible	Registered use	- Mancozeb and fludioxonil applied as a seed treatment to potatoes - Report states that 240 acres were treated and 100 acres were damaged, having miscellaneous symptoms - No chemical analysis was conducted to confirm

7. Exposure Pathways of Concern

The environmental fate properties and use patterns of mancozeb indicate that direct spray, spray drift, and runoff (mainly in events accompanied by erosion), represent potential transport mechanisms of mancozeb residues to aquatic and terrestrial organisms. Leaching to groundwater is an important pathway for ETU, the drinking water degradate of concern, and however, atmospheric deposition are not important pathways for this chemical.

Other Exposure Pathways to Terrestrial Species

Drinking Water Exposure

The Screening Imbibition Program (SIP v.l.0), Released June 15, 2010) was used to calculate an upper bound estimate of exposure using mancozeb's solubility (6.2 mg/L), the most sensitive chronic avian toxicity endpoint (northern bobwhite quail NOAEC of 125 ppm) and the most sensitive acute and chronic mammalian toxicity endpoints (Norway rat LD_{50} of >5000 mg a.i/kg-bw and Norway rat NOAEL 120 ppm, respectively). Acute exposure for birds was not estimated due to the uncertainties in the available acute toxicity studies (multiple oral doses as opposed to single oral doses, regurgitation, small number of test birds per treatment level). Drinking water exposure alone was not determined to be a potential pathway of concern for chronic avian exposure and acute and chronic mammalian exposure. Due to insufficient data for birds for acute exposure, risk could not be precluded.

Although drinking water exposure alone does not appear to be of concern (with the exception to acute exposure to birds), when aggregated with other exposure pathways (dietary food sources, dermal, inhalation), drinking water may contribute to a total exposure that has a potential for effects on non-target animals. Because there is a high degree of conservatism in the SIP 1.0 exposure estimate, there is a limited expectation that use scenarios not triggering a SIP 2.0 concern would contribute significantly to aggregate risks from water plus diet when a refined water exposure model is incorporated in the actual quantitative risk assessment. Detailed information about SIP v.l.0 as well as the tool can be found on the EPA's website at http://www.epa.gov/pesticides/science/models/pg.htm#terrestrial.

Inhalation Exposure

The Screening Tool for Inhalation Risk (STIR v.l.0, November 19, 2010) was used to calculate an upper bound estimate of exposure using mancozeb's vapor pressure ($1.32x10^{-10}$ torr) and molecular weight (265 g/mol) for vapor phase exposure as well as the maximum application rate and method of application for spray drift. STIR incorporates results from several toxicity studies including acute oral and inhalation rat toxicity endpoints obtained from the "six pack," of core studies for technical and formulated products (rat oral LD_{50} = >5000 mg a.i/kg-bw and inhalation LC_{50} = >5.14 mg/L). Acute inhalation exposure to birds cannot be estimated due to aforementioned uncertainties with the available avian acute oral toxicity studies. Based on the results of the STIR model, inhalation exposure alone was not determined to be a potential pathway of concern for mammalian species on an acute basis.

Inhalation exposure via spray drift and/or vapor-phase of mancozeb alone does not appear to be of concern (although the conclusions for birds is an uncertainty). The analysis of the inhalation route in STIR does not consider that aggregation with other exposure pathways such as dietary, dermal, or drinking water may contribute to a total exposure that has a potential for effects to non-target animals. However, the Agency does consider the relative importance of other routes of exposure may be potentially significant contributors to wildlife risk (US EPA, 2004). Detailed information about STIR v.l.0, as well as the tool, can be found on the EPA's website at: http://www.epa.gov/pesticides/science/models/pg.htm#terrestrial

Dermal exposure

Potential exists for mancozeb dermal exposure to terrestrial wildlife. At the present time, the Agency does not have a method to quantify levels of dermal exposure from chemical applications, but is actively working on a screening tool to account for this route of exposure.

Exposure resulting from bioaccumulation

Mancozeb is associated with a K_{OW} value of 22 (log K_{OW}= 1.3). Based on its low potential for bio-concentration in aquatic organisms such as fish, a fish bioaccumulation study was previously waived.

8. Analysis Plan

8.1 Stressors of Concern

i. Ecological Risk Assessment

Please see the section entitled "Determination of Mancozeb Residues of Ecological Concern" in **Section 5.3** of this problem formulation for a detailed rationale for identifying the stressor of concern for the registration review ecological risk assessment.

ii. Drinking Water

The stressor of concern for drinking water is Ethylenethiourea (ETU, a group B2 carcinogen), the common degradate of all Ethylene-bis-dithiocarbamates (EBDCs) fungicides including mancozeb.

8.2 Measures of Exposure

EFED will use the most current accepted models to evaluate potential exposures to aquatic and terrestrial organisms as described at http://www.epa.gov/pesticides/science/models_db.htm**.** Aquatic Exposure EECs will be estimated for the total toxic residues of **parent plus EBIS**, the stressor for the water column of the aquatic system. Additionally, sediment only EECs for the **UER** will be estimated, by modeling, using its observed maximum concentration in the soil system as an application rate and the observed half-lives to represent degradation. PFAM will be used to estimate relevant surface water concentrations for the use on cranberries.

The Agency is aware of ETU monitoring conducted by the EBDCs Task Force and will consider this data and any other available federal and state agencies data in the future registration review risk assessment.

8.3 Measures of Effect

Toxicity data presented in **Section 3** of this problem formulation will be used to calculate risk quotients. Any additional information submitted by the registrant or found in the open literature prior to conduct of the risk assessment will also be considered. The open literature studies are

identified using EPA's ECOTOXicology database (ECOTOX), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of both sources of data can also provide insight into the direct and indirect effects of pesticides on biotic communities from loss of species that are sensitive to the chemicals and from changes in structure and functional characteristics of the affected communities.

9. Endangered Species Assessments

Consistent with EPA's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to federally listed threatened and endangered (listed) species from registered uses of pesticides in accordance with the Joint Interim Approaches developed to implement the recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA. EPA will address concerns specific to mancozeb in connection with the development of its final registration review decision for mancozeb.

In November 2013, EPA, the U.S. Fish and Wildlife Service, National Marine Fisheries (the Services), and USDA released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.*

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological problem formulation supporting the Preliminary Work Plan for mancozeb does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the planned risk assessment for the registration review of mancozeb will describe the level of ESA analysis completed for this particular registration review case. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses of mancozeb as part of completing this registration review.

10. Endocrine Disruptor Screening Program

Mancozeb was not included in the first group of 67 chemicals issued an order to conduct Tier 1 EDSP testing. For additional information the EDSP program, visit http://www.epa.gov/endo/.

11. Preliminary Identification of Data Gaps

11.1 Environmental Fate

Due to the complex nature of polymeric mancozeb and the state of science when some of the studies were conducted, difficulties were observed in these studies include:

(1) Parent degradation in the preparation steps of parent for the experiments. For example, in one mancozeb aerobic soil study, the starting purity of the parent was 87% decreased to 59.2% when measured at time zero. High quantities of the degradate ETU at this time were related to degradation before initiation of the study;

(2) High percentage of the un-identified radioactivity remained un-extracted in the soil/sediment. For example, in an aerobic soil study the level of un-extracted un-identified residue reached maximums of 80% of the applied;

(3) Methods used for extraction have had degradation effects on polymeric parent and possibly monomeric segments of the parent. For example, extraction in one study appeared to cause some degree of conversion of parent into ETU even in the presence of chemicals that is believed to minimize such effects;

(4) Solvents including water appeared to cause hydrolytic decomposition of the polymeric parent into un-identified residue (possibly monomeric species); and

(5) Particle size reduction and presence of metal ions (that may replace zinc ion in the structure) are thought to increase hydrolytic decomposition and degradation rate.

The Agency understands difficulties that relates to the nature of the chemical and therefore request only studies that are expected to produce data with less uncertainties giving the advances in science since these studies were conducted. **Tables 19** and **20** identify environmental fate studies by MRID for mancozeb and its main degradate ETU, respectively, along with their study classifications. The tables also show where additional data are needed to support the future risk assessment.

Table 19. Submitted environmental fate data for mancozeb

OCSPP Guideline	*Data Requirement*	*Submitted Studies (MRID)*	*Study Classification*	*Are data needed to conduct risk assessment?*
835.2120	Hydrolysis	**000971-62** Supplemented by **402582-01**	Supplemental	**Yes** for Mancozeb a.i
835.2240	Aqueous photolysis	**001621-03**	Acceptable	No

OCSPP Guideline	*Data Requirement*	*Submitted Studies (MRID)*	*Study Classification*	*Are data needed to conduct risk assessment?*
835.2410	Soil photolysis	**002639-07**	Acceptable	No
835.4100	Aerobic soil metabolism	**457445-01**	Supplemental	No
835.4200	Anaerobic soil metabolism	No acceptable study		No
835.4300	Aerobic aquatic metabolism	**462043-01**	Acceptable	No
835.4400	Anaerobic aquatic metabolism	No acceptable study		**Yes** for Mancozeb a.i
835.1230 835.1240	Adsorption/ desorption and leaching	**402229-01** **And 405883-02**	Supplemental	No
835.1410	Volatility – laboratory	Waived based on low vapor pressure and inhalation toxicity		No
835.6100	Terrestrial field dissipation	**409236-01** **With 445241-01**	Published Article	No
835.8100	Volatility - field	Not required		No
850.1730	Fish bio-concentration	Waived because mancozeb K_{ow} 22		No
850.6100	Environmental chemistry method in soil/validation (ECM/ILV)	None submitted		YES
850.6100	Environmental chemistry method in water/validation (ECM/ILV)	None submitted		YES

Table 20. Submitted environmental fate data for mancozeb major degradate ETU

OCSPP Guideline	*Data Requirement*	*Submitted Studies (MRID)*	*Study Classification*	*Are data needed to conduct risk assessment?*
835.2120	Hydrolysis	**404661-03**	Supplemental	No
835.2240	Aqueous photolysis	**404661-02**	Acceptable	No
835.2410	Soil photolysis	**404661-01**	Acceptable	No
835.4100	Aerobic soil metabolism	**452251-01 &** **451464-01**	Supplemental	**Yes** for ETU as test substance
835.4200	Anaerobic soil metabolism	No acceptable study		No
835.4300	Aerobic aquatic metabolism	No acceptable study		**Yes** for ETU as test substance
835.4400	Anaerobic aquatic metabolism	No acceptable study		**Yes** for ETU as test substance
835.1230 835.1240	Adsorption/ desorption and leaching	**002588-96** **And 000971-58**	Supplemental	No
835.1410	Volatility – laboratory	No acceptable study		No at this time
835.6100	Terrestrial field dissipation	**002552-29** **And 000889-23**	Supplemental	No
850.1730	Fish bio-concentration	Waived because mancozeb K_{ow} 2		No
850.6100	Analytical method in soil (ECM/ILV)	None submitted		**Yes**
	Analytical method in water (ECM/ILV)	ECM: **448804-01*** ILV: **451514-01**	Acceptable	No

*****URL: http://www2.epa.gov/sites/production/files/2014-12/documents/448804-01-w.pdf

11.2 Effects

Tables 21 - 25 identify ecological effects studies by MRID that offer data for each guideline requirement for parent mancozeb and the degradation products in the aquatic media and terrestrial environment, respectively, as well as study classifications and whether or not further data are needed in order to support risk assessment.

Currently there are no available acute oral toxicity studies for mancozeb that are suitable for quantitative risk assessment. Three acute studies for birds have been previously submitted. In a study conducted with the Japanese quail (*Corturnix japonica*) the study was initially planned as an avian subacute dietary test, but changed to a multiple dose oral study, a design that does not fulfill the 40CFR Part 158 standard for an acute oral study. Additionally, the age, gender, and source of the test animals was not provided, four animals per treatment level (as opposed to the guideline-recommended ten) were used, and regurgitation occurred at multiple test concentrations during the course of the study. Therefore, it is uncertain as to what level of test substance the test birds actually received at these doses where observations of regurgitation occurred. Similarly, in a multiple-dose oral toxicity study (as opposed to the guideline-recommended single dose) conducted with the mallard duck (*Anas platyrhynchos*), test bird age, gender, and source were unspecified as well as differing numbers of animals were used per treatment group (all below the guideline-recommended ten animals per treatment group), and regurgitation occurring at the two highest treatment levels. Finally, mancozeb was tested with similar multiple acute oral dose regimens to sparrows (*Passer domesticus*), starlings (*Sturnus vulgaris*), and pheasants (*Phasianus colchicus*). The starlings and sparrows were wild caught and the pheasants were obtained from an undisclosed commercial rearer. No age or gender information was given and there was a reduced number of birds per treatment level than the guideline–recommended number. These collective deficiencies, despite study classifications of supplemental limit their use in quantitative risk assessment. Two studies (one with the mallard duck or bobwhite quail and one with a passerine species) are recommend to characterize the acute oral toxicity to birds which will allow the estimation of acute dose-base risk to birds feeding on mancozeb contaminated food items. Given that mortalities were observed in the available studies, and considering the high and frequent applications permitted by labels, it is determined that this data will have an overall added value n the risk assessment.

Current records indicate the submission of an acute oral toxicity study with a passerine species (canary, *Serinus canaria*, MRID 48515401). A preliminary review of this study indicates that there was regurgitation observed at four of the five treatment groups. The observation of regurgitation occurred in a dose-dependent manner with no observation at the lowest treatment group (259 mg a.i/kg-bw) and 60, 80, 100, and 100% of the birds at the 432, 720, 1200, and 2000 mg a.i/kg-bw, respectively. While there were 2 mortalities observed at the highest treatment group, and one mortality in each of the 432, 720, and 1200 mg a.i/kg-bw treatment groups, it is an uncertainty as to what dose the birds regurgitated actually received in these groups where regurgitation was observed. EFED guidance ("Guidance for use when regurgitation is observed in avian acute toxicity studies with passerine species," April 2012[9]) recommends to proceed to conducting a dietary study to examine if changing the route of exposure would make the achievement of an acute estimate of toxicity potentially more feasible.

[9] Available online at: http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/terrestrial_biology_tech_team/tbtt_regurg_acute_passerine.htm

Table 21. Submitted Aquatic Ecological Effects Data for Mancozeb

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed to conduct risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.1010	Freshwater invertebrate acute toxicity	40467502	Invalid	No	--
		40467503	Acceptable		
		46656601	Invalid		
850.1025 850.1035 850.1045 850.1055	Saltwater invertebrate acute toxicity	41822901	Supplemental	No	--
		41822902	Supplemental		
		40586801	Supplemental		
		40885102	Acceptable		
		40586803	Supplemental		
		40885101	Acceptable		
850.1075	Freshwater fish acute toxicity	45935701	Supplemental	No	--
		45934702	Supplemental		
		40467501	Supplemental		
		00080719	Supplemental		
		00085459	Invalid		
		00097101	Supplemental		
		00091747	Acceptable		
850.1075	Saltwater fish acute toxicity	41844902	Invalid	No	--
		41844901	Acceptable		
		40586802	Supplemental		
		40586804	Supplemental		
850.1300	Freshwater invertebrate life cycle	46023702	Supplemental	No	--
850.1350	Saltwater invertebrates life cycle	48627701	Study in review	N/A	--
850.1400	Freshwater fish early-life stage	43230701	Acceptable	No	--
		46023701	Invalid		
	Saltwater fish early-life stage	48627702	Study in review	N/A	--
850.1500	Fish life cycle-saltwater fish	49030601	Acceptable	No	--

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed to conduct risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.1735	Whole sediment Acute Toxicity Invertebrates, Freshwater[10]	47410101	Acceptable	No	--
850.1735	Whole sediment Acute Toxicity Invertebrates, Freshwater (with un-extracted residues)	47410102	Acceptable		
850.4400	Aquatic plant Toxicity Test using Lemna spp.	No data available		**Yes**	--
850.4500	Algal toxicity	43664701	Acceptable	**Yes**	--
		40845001	Invalid		

Table 22. Aquatic Ecological Effects Data for ETU

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?
850.1010	Freshwater invertebrate acute toxicity	45910402	Acceptable	No
850.1025	Saltwater invertebrate acute toxicity	47474301	Acceptable	N/A
850.1035	Saltwater invertebrate acute toxicity	47441204	Acceptable	N/A
850.1075	Freshwater fish acute toxicity	45910401	Acceptable	No
		47441202	Acceptable	N/A
	Saltwater fish acute toxicity	47441201	Acceptable	N/A
850.1300	Freshwater invertebrate life cycle	46462901	In review	
850.4400	Aquatic plant toxicity test using Lemna spp.	47441203	Acceptable	N/A
850.4500	Algal toxicity	45910403	Supplemental	No

Table 23. Aquatic Ecological Effects Data for EU

[10] Also known as "Whole Sediment: Subchronic Freshwater Invertebrates," as per EFED Guidance Document Entitled "Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates." April 2014.

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?
850.1075	Freshwater invertebrate acute toxicity	46462902	Acceptable	No
850.1010	Freshwater invertebrate acute toxicity	46462903	Acceptable	No
850.4500	Algal toxicity	46462904	Acceptable	No

Table 24. Submitted Terrestrial Ecological Effects Data for Mancozeb

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.2100	Avian oral toxicity	00036094	Supplemental	**Yes**	--
		00080716	Supplemental		
		00080717	Supplemental		
850.2200	Avian dietary toxicity	No data available		**Yes**	--
850.2300	Avian reproduction	44159501	Acceptable	No	--
		41948401	Acceptable		
		41566702	Invalid		
		44238001	Acceptable		
850.3020	Honey bee acute contact toxicity	00018842	Acceptable	No	--
850.3030	Honey Bee toxicity of residues on foliage	No data available		No	--
850.6200	Earthworm Subchronic Toxicity	46023704	Supplemental	No	--
Non-Guideline Study (Tier 1)	Honey bee adult acute oral toxicity	No data available		**Yes***	
Non-guideline Study (Tier 1)	Honey bee adult chronic oral toxicity			**Yes***	
Non-Guideline Study (Tier 1)	Honey bee larvae chronic oral toxicity			**Yes***	
Non-guideline Study (Tier 2)	Field trial of residues in pollen and nectar			**Yes***	

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.3040 (Tier 2 or 3)	Field Testing for Pollinators			**Yes***	
Non-guideline	Semi-field study with the Honey bee			**Yes***	--
Non-guideline	Predatory mite – Acute contact and reproductive test	45577201	Supplemental	No	--
850.4100/4150	Seedling Emergence	47486101	Acceptable	**Yes**	Studies need to apply mancozeb at the maximum single application rates
850.4150	Vegetative Vigor	47486102	Acceptable		

Table 25. Terrestrial Ecological Effects Data for ETU

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?
850.2100	Avian oral toxicity	47769701	Acceptable	No
		48437501	Acceptable	No
850.2100	Avian dietary toxicity	48417801	Acceptable	No
		48417802	Acceptable	No
850.2300	Avian reproduction	48819701	Acceptable	No
		48819702	Acceptable	No

* These studies may be required based on results of Tier 1 bee studies and risk assessment.

Data Justification Tables for Non-Codified Exposure and Effects Studies with Bees

Study Title: Honey bee Adult Acute Oral Toxicity
Rationale for Requiring the Data
Terrestrial invertebrates are likely to be impacted if exposed to pesticides in various use settings. With eusocial bees, pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to the hive. Therefore, potential acute effects to adult honey bees and other insect pollinators from oral exposure to some pesticides could exist. Currently available toxicity studies do not address possible effects of oral exposure on adult terrestrial insect survival. Because of the potential for pollen and nectar to be contaminated with pesticide residues, and subsequently brought back to the hive, it is important to determine the acute oral toxicity of this compound to adult honey bees and other insect pollinators.

The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees using the honey bee as a surrogate test species. The guidances discusses Tier I laboratory-based acute oral toxicity studies of individual adult bees as a critical component of the screening-level risk assessment process for examining potential adverse effects from specific routes of exposure. The guidance can be found at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Additional guidance on the honey bee oral toxicity test design can be found in OECD Test Guideline 213 (http://www.oecd-ilibrary.org/docserver/download/9721301e.pdf?expires=1423074617&id=id&accname=guest&checksum=2F0764FCB4DCF01D32382952A2E995C3)

Practical Utility of the Data

How will the data be used?

The Tier 1 acute oral toxicity data on adult honey bees serve as a foundation for the screening-level assessment of potential risk non-target organisms such as federally listed threatened or endangered and non-listed terrestrial invertebrate insects, including pollinators, from acute oral exposures to pesticides. The data will be used to reduce uncertainties associated with the risk assessment for terrestrial invertebrates and will improve EPA's understanding of the potential direct and indirect effects on a broad range of taxa. This study will also provide information with which to compare whether oral toxicity estimates differ from contact toxicity estimates obtained from other Tier 1 studies. If acute oral effects data for adult honey bees are not available, risks to terrestrial insects from acute oral exposure will be assumed.

How could the data impact the Agency's future decision-making?

The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect listed threatened or endangered species and/or modify their designated critical habitat. Without these data, EPA may need to presume risk, which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in use restrictions.

Study Title: Honey bee Larvae Acute Oral Toxicity

Rationale for Requiring the Data

Terrestrial invertebrates are likely to be impacted if exposed to pesticides in various use settings. With eusocial bees, pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to the hive where developing larvae and pupae may be exposed. Therefore, potential adverse effects to developing bees could result from exposure to pesticide residues. Available toxicity studies do not address possible effects on brood (larvae and pupae) survival/development. Because of the potential for pollen and nectar to be contaminated with pesticide residues, and subsequently brought back to the hive, it is important to determine the acute toxicity of this compound to bee brood.

The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees using the honey bee as a surrogate test species. The guidances discusses Tier I laboratory-based acute toxicity studies of individual honey bee larvae as a critical component of the screening-level risk assessment process for examining potential risks from specific routes of exposure. The guidance be found at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Additional guidance on larval honey bee toxicity test design can be found in OECD Test Guideline 237 (http://www.oecd-ilibrary.org/docserver/download/9713171e.pdf?expires=1422485600&id=id&accname=guest&checksum=D8E07C2B1DF77BF096C3B29F55BF86A7). In some cases, information pertaining to acute toxicity to honey bee larvae may be obtained with the chronic honey bee larval test thereby negating the need for separate acute and chronic larval toxicity tests.

Practical Utility of the Data
How will the data be used? The Tier 1 acute toxicity data on honey bee larvae serve as a foundation for the screening-level assessment of potential risk to non-target organisms including federally listed threatened or endangered and non-listed terrestrial invertebrates, including pollinators, and/or modify their designated critical habitat from acute exposures to pesticides. The data will be used to reduce uncertainties associated with the risk assessment for terrestrial invertebrates and will improve EPA's understanding of the potential effects on terrestrial species and whether there is a differential sensitivity of larval bees relative to adult bees. If acute effects data for larvae are not available, risks to terrestrial insects from acute exposure will be assumed. **How could the data impact the Agency's future decision-making?** The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect listed threatened or endangered species and/or modify their designated critical habitat. Without these data, EPA may need to presume risk which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in use restrictions.

Study Title: Honey Bee Adult Chronic Oral Toxicity
Rationale for Requiring the Data
Terrestrial invertebrates are likely to be impacted if exposed to pesticides in various use settings. With eusocial bees, pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to the hive. Therefore, potential chronic effects to adult honey bees and other pollinators from oral exposure to some pesticides could exist. Currently available toxicity studies do not address possible lethal and sublethal effects of chronic oral exposure on adult terrestrial invertebrates and will assist in determining whether the sensitivity of adult bees differs from that of earlier life stages. Because of the potential for pollen and nectar to be contaminated with pesticide residues, and subsequently brought back to the hive, it is important to determine the chronic oral toxicity of this compound to adult honey bees and other pollinators. The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees using the honey bee as a surrogate test species. The guidances discusses Tier I laboratory-based chronic oral toxicity studies of individual adult honey bees as a critical component of the screening-level risk assessment process for examining potential risks from specific routes of exposure. The guidance can be found at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Although study design elements for the chronic 10-day oral toxicity test with honey bees are similar to the OECD TG 213 acute oral toxicity test (http://www.oecd-ilibrary.org/docserver/download/9721301e.pdf?expires=1422484908&id=id&accname=guest&checksum=C38495D2A570AC2216CFB1F223D24AA7), EPA requires that the proposed protocol for this study be submitted for review and approval by EPA prior to initiating the test.
Practical Utility of the Data
How will the data be used? The Tier 1 chronic toxicity data on adult bees serve as a foundation for the screening-level assessment of potential risk to non-target organisms including federally listed threatened or endangered species and non-listed terrestrial invertebrates, including pollinators, from chronic oral exposures to pesticides. The data will be used to reduce uncertainties associated with the risk assessment for terrestrial invertebrates and will improve EPA's understanding of the potential direct and indirect lethal and sublethal effects on a broad range of terrestrial species, particularly insect pollinators and to determine whether adult toxicity differs

substantially from other life stages evaluated in other Tier 1 tests. If chronic oral effects data for adults are not available, risks to terrestrial insects from chronic exposure will be assumed.

How could the data impact the Agency's future decision-making?
The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect listed threatened or endangered species and/or their designated critical habitat. Without these data, EPA may need to presume risk which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in use restrictions.

Study Title: Honey Bee Larvae Chronic Oral Toxicity

Rationale for Requiring the Data

Terrestrial invertebrates are likely to be impacted if exposed to pesticides in various use settings. For eusocial bees, pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to the hive where larvae and pupae may be exposed. Therefore, potential effects to developing bees could result from chronic exposure to pesticide residues. Available toxicity studies do not address possible chronic effects on brood (larvae and pupae) survival. Because of the potential for pollen and nectar to be contaminated with pesticide residues, and subsequently brought back to the hive, it is important to determine chronic larval/pupal toxicity and whether adult emergence is adversely affected. This study will provide information on whether honey bee larvae differ in sensitivity from adult bees following chronic exposure.

The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees using the honey bee as a surrogate test species. The guidances discusses Tier I laboratory-based chronic toxicity studies of individual honey bee larvae as a critical component of the screening-level risk assessment process for examining potential risks from specific routes of exposure. The guidance can be found at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Additional information on larval honey bee toxicity repeat exposure test design can be found in the OECD draft guidance (http://www.oecd.org/env/ehs/testing/Draft_GD_honeybees_rep_exp_for_2nd_CR_25_November_2013.pdf). Although study design elements for the chronic 21-day toxicity test with honey bee larvae have been drafted, EPA requires that the proposed protocol for this study be submitted for review and approval by EPA prior to initiating the test.

Practical Utility of the Data

How will the data be used?
The Tier 1 chronic toxicity data on bee larvae serve as a foundation for the screening-level assessment of potential risk to non-target organisms including federally listed threatened or endangered and non-listed terrestrial invertebrates, including insect pollinators, from chronic exposures to pesticides. These data will be used to reduce uncertainties associated with the risk assessment for terrestrial invertebrates and will improve EPA's understanding of the potential direct and indirect lethal and sublethal effects on a broad range of terrestrial species, particularly insect pollinators. These data will also assist in determining whether early life stages of the bee differ in their sensitivity to pesticides relative to adults. If chronic effects data for larvae are not available, risks to terrestrial insects from chronic exposure will be assumed.

How could the data impact the Agency's future decision-making?
The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect listed threatened or endangered species and/or modify their designated critical habitat. Without these data, EPA may need to presume risk which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in use restrictions.

Study Title: Semi-field Testing for Pollinators (tunnel or colony feeding studies)
Rationale for Requiring the Data
Tier II studies are conditional on the outcome of the screening-level assessment where acute and/or chronic risk levels of concern have been exceeded for terrestrial invertebrates. Terrestrial invertebrates are likely to be impacted if exposed to pesticides in various use settings. For eusocial bees, pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to the hive and may adversely affect developing brood (egg, larvae, and pupae) and adult bees. Screening-level (Tier 1) studies of individual bees do not address possible effects and/or exposure to pesticide residues at the colony-level. Because of the potential for pollen and nectar to be contaminated with pesticide residues, and subsequently brought back to the hive, it is important to determine whether bee colonies may be negatively affected under relatively controlled exposure conditions of a semi-field study. In addition to providing effects data, these studies can provide data on pesticide residues in pollen/nectar of treated plants. The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees usin the honey bee as a surrogate test species. This guidance describes the tiered testing process and can be foun at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Additional information o honey bee colony studies under semi-field conditions can be found in the OECD Guidance 7 (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282007%2922&dc clanguage=en). Due to the complexities of this study, EPA requires that the proposed protocol for this stud be submitted for review EPA prior to initiating the test.
Practical Utility of the Data
How will the data be used? Tier II colony-level data will be used to assess potential risk to non-target organisms including listed and non-listed terrestrial social invertebrate species and to determine whether effects observed in the screening-level (Tier I) laboratory-based studies of individual bees are evident in colony-level studies under semi-field conditions. The Tier II semi-field test of whole colonies is a relatively controlled study, *i.e.*, bees are confined to a specific area, that is designed to represent potential field-level exposure and account for hive dynamics, which are not achievable from other pollinator studies. This study will be used to determine whether adverse effects to insect pollinators at the whole colony level, may result for the use of pesticides and will help to refine risk estimates derived in the screening-level risk assessment for beneficial terrestrial invertebrates. Measured residues in pollen/nectar can also be used to refine risk estimates derived from model-based or default values in the screening-level assessment. **How could the data impact the Agency's future decision-making?** The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect federally listed threatened or endangered species or their designated critical habitat. Without these data, EPA may need to presume risk which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in significant use restrictions.

Study Title: Field Testing for Pollinators
Rationale for Requiring the Data
Tier III studies are conditional on the outcome of the screening-level assessment (Tier 1) where acute and/or chronic risk levels of concern have been exceeded for terrestrial invertebrates and where Tier II studies either under semi-field tunnel conditions and/or feeding studies have indicated potential adverse effects at the colony level. Available toxicity studies from lower-tier studies do not address possible effects and/or exposure to pesticide residues at the colony-level under actual pesticide use conditions and where specific uncertainties regarding the likelihood of exposure and/or effects remain. Full-field studies also provide an opportunity to measure residues in pollen and nectar as well as various matrices (beebread, honey, wax) within the colony to obtain a more realistic understanding of exposure. The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees usin the honey bee as a surrogate. This guidance describes the tiered testing process and can be found a http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Additional information o honey bee colony studies under full-field conditions can be found in the OCSPP 850.304 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0018). Useful guidance is als available through OCSPP 850.2500 (Field Testing of Terrestrial Wildlife http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series850.htm) Although design element for the full-field colony-level study are available through the 850.3040 and 850.2500, EPA requires that th proposed protocol for this study be submitted for review and approval by EPA prior to initiating the test; th protocol should attempt to address specific uncertainties identified in lower-tier studies.
Practical Utility of the Data
How will the data be used? Tier III colony-level data will be used to further characterize potential risk to non-target organisms including listed and non-listed terrestrial social invertebrate species and to refine screening-level risk estimates that were based on individual bee responses. The semi-field test is a controlled study that is designed to represent potential field-level exposure under relatively controlled conditions and account for hive dynamics, which are not achievable from lower-tier pollinator studies. This study will be used to determine whether adverse effects to insect pollinators at the whole colony level, may result for the use of pesticides and will help to refine the screening-level risk estimates for beneficial terrestrial invertebrates. This study will also be used to determine whether more refined (Tier 3) studies are needed to characterize risk. **How could the data impact the Agency's future decision-making?** The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect federally listed threatened or endangered species or their designated critical habitat. Without these data, EPA may need to presume risk which will limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in significant use restrictions.

Study Title: Residues in Pollen and Nectar

Rationale for Requiring the Data

Terrestrial invertebrates are likely to be impacted if exposed to pesticides residues in various use settings. Pesticide residues may be transferred to pollen and/or nectar of treated plants and subsequently brought back to hive all life stages may be exposed. For some pesticides, the quantification of pollinator-relevant residues in treated flowering plants is needed, since pollinators will be exposed to residues from either current or prior season applications (due to the potential for residues to accumulate in plants and trees). Residues in edible/transportable-to-hive parts of treated trees and plants, including (where appropriate), but not limited to, guttation water, sap/resins, whole plant tissue (*e.g.*, leaves, stems), as well as blooming, pollen-shedding, and nectar producing parts (*i.e.*, flowers and, if present, extra-floral nectaries) of plants may inform the potential for risk. Studies should be designed to provide residue data for crops and application methods of concern.

The Office of Pesticide Programs has made available a guidance regarding ecological testing for bees using the honey bee as a surrogate. This can be found at: http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance. Since residue studies are intended to provide exposure data in multiple matrices and under specific application conditions, EPA requires that the protocol is submitted for review and approval by EPA prior to initiation of the study.

Practical Utility of the Data

How will the data be used?

Measured residue data will be used to refine conservative estimates of pesticide exposure and reduce uncertainties associated with the Tier I exposure assessment by providing direct measurements of pesticide concentrations resulting from actual use settings. Measured residues may provide a more realistic understanding of exposure through contact or ingestion with which to calculate risk quotients for individual bees as well as to characterize exposure to the colony. If measured residue data are not available, risk estimates for terrestrial insects will be based on model generated or default values used to support the screening-level assessment.

How could the data impact the Agency's future decision-making?

The data will inform the determination required under FIFRA or the ESA as to whether continued registration of a pesticide is likely to result in unreasonable adverse effects to non-target species or is likely to adversely affect federally listed threatened or endangered species or their designated critical habitat. Without these data, EPA will have to rely on conservative estimates of exposure which may limit the flexibility of pesticide products to comply with FIFRA and the ESA, and could result in use restrictions.

12. References

Food and Agriculture Organization of the United Nations. 2000. FAO PESTICIDE DISPOSAL SERIES 8. Assessing Soil Contamination: A Reference Manual. Appendix 2. Parameters of pesticides that influence processes in the soil. Editorial Group, FAO Information Division: Rome, 2000. http://www.fao.org/DOCREP/003/X2570E/X2570E00.htm.

USEPA. 2004. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. United States Environmental Protection Agency (USEPA). Environmental Fate and Effects Division. Office of Pesticide Programs. Available at http://www.epa.gov/espp/consultation/ecorisk-overview.pdf (accessed 02/19/2014).

USEPA. 2006. Standard Soil Mobility Classification Guidance. Memorandum from Donald Brady dated April 21, 2006.

USEPA. 2010. Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in Problem Formulations for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments. Memorandum from Donald Brady dated January 25, 2010 (http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_reporting_fate.htm).

Appendix A. Mancozeb Fate and Ecological Effects Bibliography

PC Code 014504 Mancozeb Fate/Chemistry Bibliography

161-1 Hydrolysis

MRID	Citation Reference
64926	Rohm and Haas Company (1970) Degradation of Dithane M-45 in Sterile Water Systems: RAR Memorandum No. 593. (Unpublished study received Aug 2, 1972 under 1F1050; CDL:091882-B)
88918	Haines, L.D. (1973) The Hydrolytic Decomposition of Dithane M-45 at Room Temperature: TR 3923-73-25. (Unpublished study, including letter dated Dec 7, 1973 from W.R. Lyman to V.H. Unger, received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-D)
88919	Cruickshank, P.A.; Jarrow, H.C. (1973) Ethylenethiourea degradation. Journal of Agricultural and Food Chemistry 21(3):333-335. (Also in unpublished submission received Dec 9, 1981 under 707- 78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 070525-E)
88921	Graham, W.H.; Bornak, W.E. (1972) Greenhouse Studies with C^14I- Ethylene Thiourea on Potatoes and Tomatoes and Photodecomposition in Water: Laboratory 23 Research Report No. 23-52. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-G)
88922	Ross, R.D.; Crosby, D.G. (1973) Photolysis of ethylenethiourea. Journal of Agricultural and Food Chemistry 21(3):335-337. (Also in unpublished submission received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-H)
97111	Rohm and Haas Company (1970) Degradation of Dithane M-45 in Sterile Water Systems: RAR Memorandum No. 593. (Unpublished study received Aug 1, 1971 under 1F1050; CDL:091880-I)
97155	Schindler, F.J.; Clark, R.H. (1967) Decomposition of Soluble and Insoluble Ethylenebisdithiocarbamates in Aqueous Systems: Lab- oratory 57 Research Report #57-18. (Unpublished study received Jan 3, 1974 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:120481-B)
97159	Rohm and Haas Company (1970) Degradation of Dithane M-45 in Sterile Water Systems: RAR Memorandum No. 593. (Unpublished study received Jan 3, 1974 under 707-78; CDL:120481-G)
00097162	Haines, L.D. (1973) The Hydrolytic Decomposition of Dithane M-45 at Room Temperature: Technical Report No. 3923-73-25. (Unpublished study received Jan 3, 1974 under 707-78; submitted by Rohm and Haas Co., Philadelphia, Pa.; CDL:120481-K)
154985	Korotkova, O. (1976) Razlozhenie fungitsidov--proizvodnykh ditio- karbaminovoy kisloty (obzor literatury) [Decomposition of such fungicides as derivatives of

	dithiocarbamic **acid (literature re- view)]. Khim. Sel'sk. Khoz. 12(11):869-874, 1974. Abstracted in Pest. Abs. 76-0215.**
40258201	Haines, L. (1975) Supplement to the Hydrolytic Decomposition of Dithane M-45 at Room Temperature: Lab Project ID: TR 3923-73-25. Unpublished study prepared by Rohm and Haas Co. 6 p.
40258202	Haines, L. (1973) The Hydrolytic Decomposition of Dithane M-45 at Room Temperature: Lab Project ID: 3923-73-25. Unpublished study prepared by Bristol Dev. Ag. Chem. Research. 35 p.
40381930	Haines, L. (1985) Stability of WP EBDC Spray Slurries and Rate of Ethylenethiourea Formation: Rept. No. 31L-85-11. Unpublished study prepared by Rohm and Haas Co. 60 p.
40466103	Carpenter, M. (1987) Hydrolysis as a Function of pH AT 25 ?degree| C OF ?Carbon 14|-Ethylenethiourea: ABC Final Report No. 36287. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 543 p.

161-2 Photodegradation-water

MRID	Citation Reference
147111	Yeh, S. (1985) Water Photolysis Study of Mancozeb: Technical Report No. 31L-85-13. Unpublished study prepared by Rohm and Haas Co. and Biospherics, Inc. 178 p.
154985	Korotkova, O. (1976) Razlozhenie fungitsidov--proizvodnykh ditio- karbaminovoy kisloty (obzor literatury) [Decomposition of such fungicides as derivatives of dithiocarbamic acid (literature review)]. Khim. Sel'sk. Khoz. 12(11):869-874, 1974. Abstracted in Pest. Abs. 76-0215
00162103	Yeh, S. (1985) Water Photolysis Study of Mancozeb: Technical Report No. 31L-85-13. Unpublished study prepared by Rohm and Haas Co. and Biospherics, Inc. 232 p.
40466102	Carpenter, M.; Fennessey, M. (1987) Determination of the Photolysis Rate of ?Carbon 14|-Ethylenethiourea in pH 7 Aqueous Solution: ABC Re-amended Final Report No. 36288. Unpublished study pre- pared by Analytical Bio-Chemistry Labs., Inc. 658 p.
88921	Graham, W.H.; Bornak, W.E. (1972) Greenhouse Studies with C^14I- Ethylene Thiourea on Potatoes and Tomatoes and Photodecomposition in Water: Laboratory 23 Research Report No. 23-52. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-G)

161-3 Photodegradation-soil

MRID	Citation Reference

147112	Randazzo, D. (1985) Soil Photolysis Study of Mancozeb: Technical Report No. 31L-85-14. Unpublished study prepared by Rohm and Haas Co. 31 p.
162104	Randazzo, D. (1985) Soil Photolysis Study on Mancozeb: TR 31L-85- 24. Unpublished study prepared by Rohm and Haas Co. 165 p.
40466101	Carpenter, M. (1987) Determination of the Photolysis Rate of Ethylenethiourea (ETU) on the Surface of Soil: ABC Final Report No. 36289. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 504 p.

162-1 Aerobic soil metabolism

MRID	Citation Reference
88929	Fisher, J.D. (1969?) Dissipation Studies of Dithane M-45 and Ethylene Thiourea in Soil and Their Effects on Microbial Activity: Laboratory 11--Research Report No. 11-223. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070527-C)
162105	Randazzo, D. (1986) Aerobic and Anaerobic Soil Metabolism of Mancozeb: Technical Report No. 310-86-23. Unpublished study prepared by Rohm and Haas Co. 467 p.
40838701	Schweitzer, M. (1988) Response to the U.S. EPA Review of the Mancozeb Aerobic Soil Metabolism Study: Technical Report No. 34C-88-53. Unpublished study prepared by Rohm and Haas Co. 18 p.
45145201	Wright, M. (2000) Aerobic Soil Metabolism of (carbon-14) Mancozeb in Soil: Lab Project Number: XBL 99041: RPT00605. Unpublished study prepared by XenoBiotic Laboratories, Inc. 157 p.
45744501	Volkel, W. (2001) Degradation Rate of (Carbon 14)-Mancozeb in Three Soils Incubated Under Aerobic Conditions: Lab Project Number: 773346: TR34-01-03. Unpublished study prepared by RCC Ltd. 32 p.
87575	Rohm and Haas Company (1967) Persistence of Dithane M-45 Residues in Soil. (Unpublished study, including letter dated Jun 21, 1967 from W.E. Bornak to E.M. Swisher, received Dec 9, 1981 under 707-78; CDL:070521-A)
93257	Rohm & Haas Company (1965) Interim Report: First Year Study of the Persistence of Rohm & Haas Pesticides in Soil under Normal Use Conditions. (Unpublished study received Nov 2, 1965 under 6F0476; CDL:090532-D)

162-2 Anaerobic soil metabolism

MRID	Citation Reference
162105	Randazzo, D. (1986) Aerobic and Anaerobic Soil Metabolism of Mancozeb: Technical Report No. 310-86-23. Unpublished study prepared by Rohm and Haas Co. 467 p.

41177101	Olson, G.; Kesterson, A.; Lawrence, L. (1989) Anaerobic Metabolism of ?Carbon 14|Mancozeb in Silt Loam Soil: Report No. 1198: Project No. 272. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 65 p.

162-3 Anaerobic aquatic metabolism

MRID	Citation Reference
88820	Swan, L.H. (1978) Degradation of Dithane M-45 (Mancozeb) and Ethylenethiourea under Anaerobic Aquatic Conditions: TR 34F- 78-6. Includes method 1853-1 dated Jul 19, 1973. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070528-A)
88916	Rohm and Haas Company (1970) Degradation of Dithane M-45 in Sterile Water Systems: RAR Memorandum No. 593. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070525-B)
40258203	Swan, L. (1978) Supplement to the Degradation of Dithane M-45 and ETU under Anaerobic Aquatic Conditions: Lab Project ID: TR 34F-78-06. Prepared by Rohm and Haas Co. 5 p.
45945101	Muller-Kallert, H. (1994) (Carbon 14)-Mancozeb: Degradation and Metabolism in Aquatic Systems: Lab Project Number: RCC PROJECT 317970: 317970. Unpublished study prepared by RCC Umweltchemie Ag. 156 p.

162-4 Aerobic aquatic metabolism

MRID	Citation Reference
45945101	Muller-Kallert, H. (1994) (Carbon 14)-Mancozeb: Degradation and Metabolism in Aquatic Systems: Lab Project Number: RCC PROJECT 317970: 317970. Unpublished study prepared by RCC Umweltchemie Ag. 156 p.
46204301	Volkel, W. (1995) (14C)-Mancozeb: Degradation and Metabolism in Aquatic Systems. Project Number: 361462. Unpublished study prepared by RCC Umweltchemie Ag. 156 p.
88920	Rohm and Haas Company (19??) Degradation of C^14I Ethylene Thiourea in Water: TR 23-71-22. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070525-F)
45744501	Volkel, W. (2001) Degradation Rate of [14C]-MANCOZEB in Three Soils Incubated Under Aerobic Conditions. Unpublished Study Performed by RCC Ltd., Itingen, Switzerland; Sponsored and Submitted by Rohm and Haas Company, Spring House, PA. RCC Study No. 773346, Report No. TR34-01-03. Experiment initiated August 29, 2000 and Completed January 26, 2001 (p.8). Final Report Issued January 31, 2001.

163-1 Leach/adsorption/desorption

MRID	Citation Reference
65531	Adler, I.L. (1971) A Study of the Leaching of C^14I-Dithane M-45 and/or Metabolites in Soil: Laboratory 23 Research Report 23-31. (Unpublished study received Apr 26, 1974 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:224658-A)
88821	Rohm and Haas Company (19??) Soil Adsorption Studies with C^14I Ethylene Thiourea: Tech. Rept. #23-71-19. (Unpublished study received Dec 9, 1981 under 707-78; CDL:070528-C)
88822	Rohm and Haas Company (19??) Soil Adsorption Studies with C^14I Dithane M-45: Tech. Rept. #23-71-20. (Unpublished study re- ceived Dec 9, 1981 under 707-78; CDL:070528-D)
88925	Adler, I.L. (1972) Decomposition of Ethylene Thiourea Residues under Field Conditions: TR 23-72-31. (Unpublished study, including letter dated Sep 26, 1972 from I.L. Adler to W.R. Lyman, received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070525-L)
97154 OR 77154	Satterthwaite, S.T. (19??) Laboratory Soil Runoff Study with ^14IC Dithane M-45: Laboratory 11 Metabolism Group Memorandum Report No. 29. (Unpublished study received Jan 3, 1974 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:120481-A)
97157	Rohm and Haas Company (19??) Soil Adsorption Studies with C^14I Dithane M-45: Laboratory 23 Technical Report No. 23-71-20. (Un- published study received Jan 3, 1974 under 707-78; CDL:120481-E)
97158	Rohm and Haas Company (19??) Soil Adsorption Studies with C^14I Ethylene Thiourea: Laboratory 23 Technical Report No. 23-71-19. (Unpublished study received Jan 3, 1974 under 707-78; CDL: 120481-F)
146370	Rohm And Haas Co. (19??) Soil Adsorption Studies With (carbon-14) Dithane M-45: Report No. 23-71-20. Unpublished study. 10 p.
40222901	Yeh, S. (1986) Batch Soil Adsorption/Desorption of Mancozeb: Biospherics No. 86E204AD; Technical Report No. 310-86-62. Unpublished study prepared by Biospherics, Inc. 143 p.
40222902	Yeh, S. (1986) Batch Soil Adsorption/Desorption of Ethylenethio- urea (ETU): [Mancozeb Supplement]: Biospherics No. 86E205AD; Technical Report No. 310-86-63. Unpublished study prepared by Biospherics, Inc. 100 p.
40588302 40588301	Schweitzer, M. (1988) Leaching Characteristics of Soil Incorporated Mancozeb following Aerobic Aging: Technical Report: 34C-88-26. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 547 p.-

164-1 Terrestrial field dissipation

MRID	Citation Reference

71625 Nixon, W.B. (1981) Tank Mix Soil Dissipation Studies: Ridomil^(R)I/ Bravo^(R)I; Ridomil^(R)I/Difolatan^(R)I; Ridomil^(R)I/Dithane M- 45^(R)I: Report No. EIR-81003. (Unpublished study received Apr 15, 1981 under 100-607; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070010-A)

71627 Ciba-Geigy Corporation (1980) ?Tank Mix Soil Dissipation Studies with Various Chemicals|: AG-A 4801 I, II A. (Compilation; unpublished study, including AG-A 4801 I, II, III, 2nd Report A, 4802 I, II, III, 4802 I, II, III, Second Report B..., received Apr 15, 1981 under 100-607; CDL:070010-E)

87576 Rohm & Haas Company (1977) A Summary of the Results of Analysis of Soil and Water Samples for Residues Due to Dithane M-45: TR 34F- 77-03. (Compilation; unpublished study received Dec 9, 1981 under 707-78; CDL:070521-B; 070522)

140829 Rohm and Haas Company (1977) ?Dithane M-45 Residues in Soil|. (Compilation; unpublished study received Dec 9, 1981 under 707- 78; CDL:070523-A; 070524)

148126 Bornak, W. (1967) Persistence of Dithane M-45 Residues in Soil: Report No. 526. Unpublished study prepared by Rohm and Haas Co. 14 p.

40923601 Schweitzer, M.; Zogorski, W. (1988) Mancozeb Terrestrial Field Dissipation: Technical Report No. 34C-88-54. Unpublished study prepared by Rohm and Haas Co., in cooperation with Pan-Agricultural Associates and Environ-Bio-Tech, Ltd. 630 p.

44524101 Esterly, D. (1998) Recalculation of the ETU Soil Half-Life in California Soil Dissipation Studies of Mancozeb Supplement No. 1 to MRID 40923601: Lab Project Number: MTF-98-02. Unpublished study prepared by E.I. du Pont de Nemours and Co. 43 p.

44996201 Babbit, B.; Kleiner, A.; Lennon, G. (1999) Dissipation of Soil Residues of **Dimethomorph:** Lab Project Number: RES 99-073. 02: RES 99-081: RES 97-012. Unpublished study prepared by American Cyanamid Co. 593 p.

97156 Fisher, J.D. (1969) Dissipation Studies of Dithane M-45 and Ethylene Thiourea in Soil and Their Effects on Microbial Activity: Laboratory 11--Research Report No. 11-223. (Unpublished study received Jan 3, 1974 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:120481-D)

164-2 Aquatic field dissipation

MRID	Citation Reference
87576	Rohm & Haas Company (1977) A Summary of the Results of Analysis of Soil and Water Samples for Residues Due to Dithane M-45: TR 34F- 77-03. (Compilation; unpublished study received Dec 9, 1981 under 707-78; CDL:070521-B; 070522)
140829	Rohm and Haas Company (1977) ?Dithane M-45 Residues in Soil|. (Compilation; unpublished study received Dec 9, 1981 under 707- 78; CDL:070523-A; 070524)

165-1 Confined rotational crop

MRID	Citation Reference

44621901	Robinson, R.; Hanauer, R. (1998) (Carbon 14)-RH-3866: Confined Rotational Crop Study: Lab Project Number: RPT00399: XBL96026: 34P-96-27A. Unpublished study prepared by XenoBiotic Labs., Inc., Centre Analytical Labs., Inc. and American Agricultural Services, Inc. 600 p.

165-2 Field rotational crop

MRID	Citation Reference
45709501	Winkler, V.; Chisholm, K. (2002) Rotational Crop Plant Back Interval (PBI) Restrictions for Moncut Fungicide Use on Potatoes: Lab Project Number: R-3052: VW030602: E642.03-87. Unpublished study prepared by Gowan Co. 21 p. {OPPTS 860.1900}

166-2 Ground water-small retrospective

MRID	Citation Reference
45708301 or 46145401 (2003)	Bedosky, S. (2002) EBDC/ETU Task Force National Drinking Water Monitoring Survey: Lab Project Number: ETU-0201: 6942: ETU-2000-01. Unpublished study prepared by LFR Levine-Fricke. 353 p.

Non-Guideline Studies

MRID	Citation Reference
4334	Rohm & Haas Company (1964) Interim Report: First Year Study of the Persistence of Rohm & Haas Pesticides in Soil under Normal Use Conditions. (Unpublished study received Jan 28, 1966 under 6F0472; CDL:090524-AB)
88928	Doneche, B.; Sequin, G. (1976) Degradation of Mancozebe (Coordination Product of Zinc Ion with Manganese Ethylene-bis-dithiocar- bamate: MBL-1756. Translation of: La degradation du mancozebe (produit de coordination de l'ion zinc avec l'ethylene-bis-di- thiocarbamate de manganese). Academie des Sciences. Comptes Rendus Hebdomadaires des Seances 280(May 21):2265-2268. (Unpublished study received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070527-B)
88927	Adler, I.L. (1973) Ethylenethiourea Levels in Dithane M-45 Spray Slurries and Spray Deposits: TR 23-73-20. (Unpublished study, including letter dated Jun 28, 1973 from I.L. Adler to W.R. Lyman, received Dec 9, 1981 under 707-78; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:070527-A)
129284	Haines, L.; Burnett, T.; Wilson, D. (1982) The Octanol/Water Partition Coefficients of Dithane M-45, M-22, Z078 and Ethylenethiourea: Technical Report No. 31F-82-26.

(Unpublished study received May 13, 1983 under 707-78; submitted by Rohm & Haas Co., Philadelphia, PA; CDL:071597-B)

41841901 Weeks, J. (1990) Simulation of the Environmental Fate of Mancozeb and Its Degradation Product ETU Under Conditions of Use in California: Lab Project Number: JO-91-78. Unpublished study prepared by Labat-Anderson, Inc. 179 p.

44418601 Carbone, J.; Hurt, S. (1997) Geneec Modeling of Surface Water Concentrations of Mancozeb and ETU and Preliminary Drinking Water Risk Assessment: Lab Project Number: 97R-1100. Unpublished study prepared by Rohm and Haas Co. 30 p.

46145401 Bedosky, S. (2003) EBDC/ETU Task Force National Drinking Water Monitoring Survey:Final Report. Project Number: ETU/2000/01, ETU/0301, 004/06942/04. Unpublished study prepared by Levine-Fricke, Inc., Enviro-Test Laboratories (ETL), and Morse Laboratories. 572 p.

47434901 Diepenhorst, P. (1996) Validation of the Analytical Method DLA-206.5 Penncozeb 80 WP, Determination of Active Ingredient. Project Number: ATO/DL/96/010, ATO/DL/96/008. Unpublished study prepared by Elf Atochem Agri B.V. 38 p.

ETU Studies PC Code 600016: MRID No. (DER file reference)

Hydrolysis

404661-03 Carpenter, M. (1987) Hydrolysis as a Function of pH AT 25? Degrees C OF ?Carbon 14|-Ethylenethiourea: ABC Final Report No. 36287. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 543 p.

Photolysis in Water

404661-02 (2082324)
Carpenter, M.; Fennessey, M. (1987) Determination of the Photolysis Rate of ?Carbon 14|-Ethylenethiourea in pH 7 Aqueous Solution: ABC Re-amended Final Report No. 36288. Unpublished study pre- pared by Analytical Bio-Chemistry Labs., Inc. 658 p.

Photolysis on Soil

404661-01 (2082324)
Carpenter, M. (1987) Determination of the Photolysis Rate of Ethylenethiourea (ETU) on the Surface of Soil: ABC Final Report No. 36289. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 504 p.

Aerobic Soil Metabolism

452251-01
Wright, M. (2000) Aerobic Soil Metabolism Degradation Rate Determination for Ethylenethiourea (ETU) on Soil: Lab Project Number: XBL 99045: RPT00643: AR98197. Unpublished study prepared by Xenobiotic Labs., Inc. 160 p.

4515464-01
Wright, M. (2000) Aerobic Soil Metabolism Degradation for Ethylemethiourea (ETU) on Soil: Report of Degradation Rate Determination for ETU on New York Silt Loam Soil at 70% and 40% Normal Moisture Holding Capacity and 25 (degrees) C: Lab Project Number: XBL 99045: RPT00598: KP-98-39. Unpublished study prepared by XenoBiotic Laboratories. 123 p.01-Jun-2000

Volatility- Laboratory

42301501
Obrist, J. (1992) Laboratory Volatility Studies on ?carbon 14|-ETU: Final Report: Lab Project Number: HLA 6101-109. Unpublished study prepared by Hazleton Laboratories America, Inc. 24 p. 04-May-1992

ECMs and ILVs

448804-01
Bruns, G.; Tauber, R.; Gottschalk, R. (1999) Validation of the Method of Analysis for Ethylenethiourea (ETU) in Water by LC/MS/MS: Lab Project Number: ETU01ETL: ETL99RH01.PRO: 99RHC42.REP. Unpublished study prepared by Enviro-Test Laboratories. 146 p.

451514-01
Connolly, P. (2000) Independent Laboratory Analytical Method: Method for the Analysis of Ethylenethiourea (ETU) in Water by LC/MS/MS (MS 178.00) Revision 2: Lab Project Number: 002-342: 00P-002-342: MS 178.00. Unpublished study prepared by Centre Analytical Laboratories, Inc. 88 p. {OPPTS 850.7100}

Monitoring Data

45570301
Bedosky, S. (2001) EBDC/ETU Task Force National Drinking Water Monitoring Survey: Lab Project Number: ETU-2000-01: ETU-0101: 6942. Unpublished study prepared by LFR Levine Fricke. 394 p. 21-Dec-2001

45708301
Bedosky, S. (2002) EBDC/ETU Task Force National Drinking Water Monitoring Survey: Lab Project Number: ETU-0201: 6942: ETU-2000-01. Unpublished study prepared by LFR Levine-Fricke. 353 p. 28-Jun- 2002

45836401
Bedosky, S. (2002) EBDC/ETU Task Force National Drinking Water Monitoring Study: Interim Report: Lab Project Number: ETU-2000-01: ETU- 0202: 6942. Unpublished study prepared by LFR Levine-Fricke, Enviro-Test Laboratories, and Morse Laboratories 366 p. 13-Jan-
2003

46145401
Bedosky, S. (2003) EBDC/ETU Task Force National Drinking Water Monitoring Survey:Final Report. Project Number: ETU/2000/01, ETU/0301, 004/06942/04. Unpublished study prepared by Levine-Fricke, Inc., Enviro-Test Laboratories (ETL), and Morse Laboratories. 572 p.
05-Dec- 2003

46319901
Ollinger, J. (2004) EBDC/ETU Task Force Response to U.S. EPA's Draft Science Chapter for the Environmental Fate and Ecological Risk Assessment for Ethylenethiourea (ETU) Dated June 2, 2004. Project Number: EBDC/FQPA/2004/01. 38 p. 15-Jul- 2004

46480002
Ollinger, J. (2005) EBDC/ETU Task Force Response to U.S. EPA's Draft Science Chapter for the Environmental Fate and Ecological Risk Assessment for Ethylenethiourea (ETU) Dated October 20, 2004. Project Number: EBDC/FQPA/2005/01. Unpublished study prepared by EBDC/ETU Task Force. 24 p. 23-Feb- 2005

054401 Mancozeb Eco Effects Bibliography

850.2100 71-1 Avian Single Dose Oral Toxicity

36094 three species treated – 3 products	Robinson, D.; Shillam, K.W.G. (1966) Toxicity of Dithane S.35, Di- thane M.45 and Stam F.34 to Wild Birds: Report No. 1694/66/222. (Unpublished study received Jun 11, 1970 under 0F0932; prepared by Huntingdon Research Centre, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091587-U)
80717	Harper, K.H.; Palmer, A.K. (1965) Toxicity of Dithane M-45 to the Japanese Quail (~Conturnix japonica~): 1152/65/69. (Unpublished study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090519-C)
48515401	Hubbard, P.; Beavers, J. (2011) Mancozeb (Dithane M45): An Acute Oral Toxicity Study with the Canary (Serinus canaria). Project Number: 422/103, 2010/5. Unpublished study prepared by Wildlife International, Ltd. 63 p.

850.2200 71-2 Avian Dietary Toxicity

80716	Harper, K.H.; Palmer, A.K. (1964) Toxicity of Dithane M 45 to the Mallard Duck: 1000/64/215:2. (Unpublished study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL: 090519-B)
80717	Harper, K.H.; Palmer, A.K. (1965) Toxicity of Dithane M-45 to the Japanese Quail (~Conturnix japonica~): 1152/65/69. (Unpublished study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090519-C)
98649 or 129287	Harper, K.H.; Palmer, A.K. (1965) Toxicity of Dithane M.45 to the Japanese Quail (?~Coturnix japonica~?): 1152/65/69. (Unpublished study received Sep 8, 1965 under 707-78; prepared by Huntington Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:131575-A)

850.2300 71-4 Avian Reproduction

41566701	Hakin, B; Norman, A. (1990) The Effect of Dietary Inclusion of Mancozeb on Reproduction in the Mallard Duck: Lab Project Number: HRC 59/89384: R&H 88RC-0096. Unpublished study prepared by Huntingdon Research Centre, Ltd. 195 p.
41566702	Hakin, B. ; Norman, A. ; Chanter, D. (1990) The Effect of Dietary Inclusion of Mancozeb on Reproduction in the Bobwhite Quail: Lab Project Number: HRC 60/89385: R&H 88RC-0102. Unpublished study prepared by Huntingdon Research Centre, Ltd. 333 p.
41936801	Milligan, D. (1991) The Effect of Dietary Inclusion of Mancozeb on Reproduction in the Mallard: Total Production Results by Pen: Lab Project Number: 88RC-096A. Unpublished study prepared by Huntingdon Research Centre Ltd. 11 p.
41948401	Beavers, J.B., G. Marselas, G.J. Smith and M.J. Jaber (1991) Mancozeb: A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos). Prepared by

Wildlife International Ltd., Easton, MD. Laboratory **Project No. 129-144**. Submitted by Rohm and Haas Company, Spring House, PA.

41936802 Milligan, D. (1991) The Effect of Dietary Inclusion of Mancozeb in the Bobwhite Quail: Total Production Results by Pens: Lab Project Number: 88RC-102A. Unpublished study prepared by Huntingdon Research Centre, Ltd. 17 p.

42957501 Cameron, D. (1993) The Effect of Dietary Inclusion of Mancozeb on Reproduction in the Bobwhite Quail: Lab Project Number: 60/89385: 88RC-102B. Unpublished study prepared by Huntingdon Research Centre Ltd. 10 p.

43473401 Beavers, J.; Marselas, G.; Smith, G.; et al. (1994) Mancozeb: A One-generation Reproduction Study with the Mallard (Anas platyrhynchos): **Supplement II:** Lab Project Number: 89RC-0152C**: 129-144.** Unpublished study prepared by Wildlife International Ltd. 12 p.

44159501 Mitchell, L.; Haberlein, D.; Beavers, J. et al. (1996) Mancozeb (Dithane): A Reproduction Study with the Northern Bobwhite (Colinus virginianus): Amended: Lab Project Number: 422-101. Unpublished study prepared by Wildlife International Ltd. 219 p.

44238001 Pelfrene, A. (1997) Mancozeb: Reproduction in the Bobwhite Quail: Reissued Report: Lab Project Number: PWT 99/920944: PWT 99. Unpublished study prepared by Huntingdon Life Sciences Ltd. 383 p.

850.1075 72-1 Acute Toxicity to Freshwater Fish

80718 Harper, K.H.; Ball, I.R.; O'Neill, K.J. (1965) The Acute Toxicity of a Fungicide, Dithane M-45, to the Rainbow Trout,~Salmo~ ?~gairdnerii~Richardson, a Cold Water Fish: **1233/65/150**. (Un- published study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090519-D)

80719 Harper, K.H.; Ball, I.R. (1965) The Acute Toxicity of a Fungicide, Dithane M-45, to the Goldfish, ~Carassius auratus~: 1305/65/22. (Unpublished study received Nov 9, 1965 under 6F0467; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090519-E)

85459 Harper, K.H.; Ball, I.R. (1965) The Acute Toxicity of a Fungicide, Dithane M-45, to the Catfish,~Ictalurus nebulosus~: 1377/65/ 295. (Unpublished study received Nov 9, 1965 under 6F0467; pre- pared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090519-F)

97100 Harper, K.H.; Ball, I.R. (1965) The Acute Toxicity of a Fungicide, Dithane M-45, to the Catfish~Ictalurus nebulosus~?: 1377/65/295. (Unpublished study received Jan 10, 1969 under 707-93; prepared by Huntingdon Research Centre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:004348-F)

97101 Harper, K.H.; Ball, I.R. (1965) The Acute Toxicity of a Fungicide, Dithane M-45, to the Rainbow Trout~Salmo gairdnerii~Richardson, a Cold Water Fish: **1233/65/150**. (Unpublished study received Jan 10, 1969 under 707-93; prepared by Huntingdon Research Cen- tre, England, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:004348-G)

97147 McCann, J.A. (1967) ?Ditahane M-45: Bluegill (?~Lepomis macrochirus): Test Nos. 58 & 55. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:108279-A)

97173 McCann, J.A.; Pitcher, F. (1973) ?Dithane M-45: Bluegill (?~Lepomis macrochirus)|: Test No. 544. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:128295-A)

40118501 US EPA (1980) Biological Report of Analysis of Dithane-45; 96-hour LC50 (Bluegill): Static Jar Test 2444. Unpublished study prepared by Terrestrial and Aquatic Biology Laboratory. 5 p.

118502 US EPA (1980) Biological Report of Analysis of Dithane-45; 96-hour LC50 (Rainbow Trout): Static Jar Test 2447. Unpublished study prepared by Terrestrial and Aquatic Biology Laboratory. 5 p.

40467501 Bowman, J. (1987) Acute Toxicity of Dithane Flowable (F45) to Rainbow Trout (Salmo gairdneri): Final Report: ABC Laboratory Project ID #36281: Rohm and Haas Report No. 87RC-0056. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 17 p.

43917215 Toy, R. (1991) CME 151/Mancozeb 90/600 g/kg WP (SYS50586): Acute Toxicity to Salmo Gairdneri and Daphnia magna: Lab Project Number: SBGR.90.159: 4467. Unpublished study prepared by Shell Research Ltd. 37 p.

43917216 mixture Toy, R.; Gray, A. (1991) Dimethomorph: CME 151/Mancozeb 90/600 g/kg WP (SYS50579): Acute Toxicity to Oncorhynchus mykiss and Daphnia magna: Lab Project Number: SBGR.90.250: 4901. Unpublished study prepared by Shell Research Ltd. 34 p.

43917217 mixture Toy, R.; Gray, A. (1992) Dimethomorph: Acute Toxicity of Dimethomorph/Mancozeb 75/667 g/kg WP (SYS50588 R) to Oncorhynchus mykiss, Daphnia magna and Selenastrum capricornutum: Lab Project Number: SBGR.92.177: 5640. Unpublished study prepared by Shell Research Ltd. 42 p.

44950503 Rhodes, J.; Bucksath, J. (1998) Acute Flow-Through Toxicity of Dithane/RH-117,281 DG Blend to Rainbow Trout (Oncorhynchus mykiss): Lab Project Number: 43357: 97RC-0128: 95P-278. Unpublished study prepared by ABC Laboratories, Inc. 110 p.

45934701 Rhodes, J. (2000) Acute Toxicity of Dithane M-45 to the Rainbow Trout (Oncorhynchus mykiss) Determined Under Flow-Through Test Conditions: Lab Project Number: 46040: 00RC-0114. Unpublished study prepared by ABC Laboratories, Inc. 77 p. {OPPTS 850.1075}

45934702 Rhodes, J. (2000) Acute Toxicity of Dithane M-45 to the Bluegill Sunfish (Lepomis macrochirus) Determined Under Flow-Through Test Conditions: Lab Project Number: 46041: 00RC-0115. Unpublished study prepared by ABC Laboratories, Inc. 75 p. {OPPTS 850.1075}

46020903 45910401 Zok, R. (2001) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss Walbaum 1792) in a Static System (96 Hours). Project Number: 12F0533/005042, 146099. Unpublished study prepared by BASF Aktiengesellschaft. 43 p.

46161001 Douglas, M.; Handley, J.; Macdonald, I. (1987) The Acute Toxicity of Mancozeb Technical to Rainbow Trout (Salmo gairdneri). Project Number: PWT/63/B/88167. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 24 p.

46023701 Wuthrich, M. (1993) Dithane DG: 21-Day Prolonged Toxicity Study in the Rainbow Trout Under Flow-Through Conditions. Project Number: 336060, 93/RC/1021. Unpublished study prepared by RCC Umweltchemie Ag. 67 p.

46056401 Dickson, J.; Knight, B. (1998) Dithane/RH-7281 80 EP (10:1): Determination of Acute Toxicity (LC50) to Rainbow Trout (96h, Continous Flow). Project Number: 16697,

97RC/0214, 392008. Unpublished study prepared by Inveresk Research International. 42 p.

46818701 Jatzek, J. (2006) BAS 551 09 F: Acute Toxicity Study on the Rainbow Trout (Onchorhynchus mykiss) in a Static System over 96 Hours. Project Number: 12F0411/045074, 2006/1010690. Unpublished study prepared by BASF Aktiengesellschaft, Experimental Toxicology and Ecology. 45 p.

5001997 Hashimoto, Y., J. Fukami (1969) Toxiocity of Orally and Topically Applied Pesticide Ingredients to Carp, Cyprinus carpio Linne. Botyu- Kagaku . Scientific Pest Control. 34(2): 6366.

47729301 Kramer, V. (2009) Rationale for Classification of Existing Sheepshead Minnow Acute Toxicity Studies as Core MRID No. 41844901 and Bluegill Acute Toxicity Study as Core: MRID No. 45934702. Project Number: MZTF/2009/01, 96R/1010. Unpublished study prepared by Dow AgroSciences, LLC. 31 p.

Non Guideline Fish Acute Toxicity

46144601 Madsen, T. (2002) Mancozeb: Static Acute Toxicity Tests Conducted with Ten Species of Freshwater Fish Exposed in a Sediment-Water System. Project Number: 47737. Unpublished study prepared by Analytical Bio-Chemistry Labs, Inc. 120 p.

72-2 Acute Toxicity to Freshwater Invertebrates

40118503 US EPA (1980) Biological Report of Analysis of Dithane-45; 48-hour EC50 (Daphnia magna): Jar Test 2460. Unpublished study prepared by Terrestrial and Aquatic Biology Laboratory. 3

40467502 Forbis, A. (1987) Acute Toxicity of Dithane Flowable (F-45) to Daphnia magna: Final Report: ABC Laboratory Project ID #36282: Rohm and Haas Report #87RC-0041. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 17 p.

40467503 Forbis, A. (1987) Acute Toxicity of Dithane M-45 Fungicide to Daphnia magna: Final Report: ABC Laboratory Project ID #36322: Rohm and Haas Report #87RC-0044. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 16 p.

43917215 Toy, R. (1991) CME 151/Mancozeb 90/600 g/kg WP (SYS50586): Acute Toxicity to Salmo Gairdneri and Daphnia magna: Lab Project Number: SBGR.90.159: 4467. Unpublished study prepared by Shell Research Ltd. 37 p.

43917216 Toy, R.; Gray, A. (1991) Dimethomorph: CME 151/Mancozeb 90/600 g/kg WP (SYS50579): Acute Toxicity to Oncorhynchus mykiss and Daphnia magna: Lab Project Number: SBGR.90.250: 4901. Unpublished study prepared by Shell Research Ltd. 34 p.

43917217 Toy, R.; Gray, A. (1992) Dimethomorph: Acute Toxicity of Dimethomorph/Mancozeb 75/667 g/kg WP (SYS50588 R) to Oncorhynchus mykiss, Daphnia magna and Selenastrum capricornutum: Lab Project Number: SBGR.92.177: 5640. Unpublished study prepared by Shell Research Ltd. 42 p.

44950502 Madsen, T.; Leak, T. (1998) Acute Toxicity of Dithane/RH-117,281 DG Blend to Daphnia magna: Lab Project Number: 44179-97: 97RC-0068. Unpublished study prepared by ABC Laboratories, Inc. 79 p.

45934703 Rhodes, J. (2001) Acute Toxicity of IR6141 M to the Water Flea, Daphnia magna, Under Flow-Through Test Conditions: Lab Project Number: 43612. Unpublished study prepared by ABC Laboratories, Inc. 62 p. {OPPTS 850.1010}

46020901 Hisgen, M. (2003) Reg No. 146099: Determination of the Acute Effect on the Swimming Ability of the Water Flea Daphnia Magna Straus: Final Report. Project Number: 00/0533/50/1. Unpublished study prepared by BASF Aktiengesellschaft. 25 p.

46096901 Mancozeb + Zoxamide Buchanan, J.; Knight, B.; Dickson, J. (1998) Dithane/RH-7281 80WP (10:1): Determination of Acute Toxicity (EC50) to Daphnia (48h, Continuous Flow). Project Number: 16564, 97RC/0215, 392029. Unpublished study prepared by Inveresk Research International. 42 p.

46656601 Slabbert. J.L. (1994) Determination of the Acute Toxicity of Sanachem Technical Mancozeb (sancozeb) to the Water Flea (Daphnia pulex). Division of Water Technology. CSIR, Building 21, Pretoria, South Africa, Laboratory Report Number: 0003D, Submitted by Dow Chemical Co., Study ID:0003D, Full Study Completion Date: May 11 through May 27, 1994.

850.1735 Whole sediment: acute freshwater invertebrates

47410101 Hughes, C. (2007) Mancozeb: Whole Sediment Acute Toxicity Test with Midge Larvae (Chironomus dilutus): Amended Final Report. Project Number: 60700, 2005/02. Unpublished study prepared by ABC Laboratories, Inc. 70 p.

47410102 Hughes, C. (2008) Non-Extractable Residues of Mancozeb: Whole Sediment Acute Toxicity Test with Midge Larvae (Chironomus dilutus). Project Number: 60701, 2005/01, RS/19750. Unpublished study prepared by ABC Laboratories, Inc. 80 p.

72-3 Acute Toxicity to Estuarine/Marine Invertebrates

97161 Bentley, R.E. (1973) Acute Toxicity of Dithane M-45 to Grass Shrimp (Palaemonetes vulgaris) and Fiddler Crab (Uca pugilator). (Unpublished study received Jan 3, 1974 under 707- 78; prepared by Bionomics, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:120481-J)

40586801 Ward, G. (1988) Acute Toxicity of Dithane M-45 Fungicide to Mysid Shrimp (Mysidopsis bahia) under Static Conditions: Rohm and Haas Company Protocol No. 87P-258: Rohm and Haas Report No. 87RC- 0065. Unpublished study prepared by Environmental Science and Engineering, Inc. 49 p.

40586802 Ward, G. (1988) Acute Toxicity of Dithane M-45 Fungicide to Sheepshead Minnow (Cyprinodon variegatus) under Static Conditions: ESE No. 87369-0200-2130. Unpublished study prepared by Environmental Science and Engineering, Inc. 45 p.

40586803 Ward, G. (1988) Acute Toxicity of Dithane Flowable F-45 to Mysid Shrimp (Mysidopsis bahia) under Static Conditions: Laboratory Project ID ESE No. 87369-0500-2130. Unpublished study prepared by Environmental Science and Engineering, Inc. 50 p.

40885101 Manning, C. (1988) Dithane F-45: Acute Toxicity on Shell Growth of the Eastern Oyster (Crassostrea virginica): ESE No. 89328-0300- 2130: 88RC-0049. Unpublished study prepared bt Environmental Science and Engineering, Inc. 409 p.

40885102 Manning, C. (1988) Dithane M-45: Acute Toxicity on Shell Growth of the Eastern Oyster (Crassostrea virginica): ESE No. 89328-0200- 2130: 88RC-0048. Unpublished study prepared by Environmental Science and Engineering, Inc. 421 p.

41822901 Scott Ward, G.; Leak, T. (1990) Acute Toxicity of Dithane M-45 Fungicide to Mysids (Mysidopsis bahia) Under Flow-through Conditions: Lab Project Number: 89328-0500-2130: 88RC-0069. Unpublished study prepared by Hunter/ESE, Inc. 288 p.

41822902 Ward, G.S. and T. Leak (1990) Acute Toxicity of Dithane ® F-45 Fungicide to Mysids (Mysidopsis bahia) Under Flow-Through Conditions. Laboratory Project ID. 89328-0600-2130. Rohm and Haas Report No. 88RC-0073. Prepared by Hunter/ESE, Inc., Gainesville, Fl. Submitted by Rohm and Haas Company, Spring House, PA.

850.1740 Whole sediment: acute marine invertebrates

47499601 Aufderheide, J. (2008) Mancozeb: Whole Sediment Acute Toxicity with a Marine Amphipod (Leptocheirus plumulosus). Project Number: 63400, 2007/03. Unpublished study prepared by ABC Laboratories, Inc. 69 p.

850.1075 Fish acute toxicity test Marine/Estuarine species

40586804 Ward, G. (1987) Acute Toxicity of Dithane Flowable F-45 to Sheeps- head Minnow (Cyrinodon variegatus) under Static Conditions: Laboratory Project ID ESE No. 87369-0400-2130. Unpublished study prepared by Environmental Science and Engineering, Inc. 45 p.

41844901 Manning, C.; Ward, G.; Leak, T. (1990) Acute Toxicity of Dithane M-45 Fungicide to Sheepshead Minnows (Cyprinodon variegatus) Under Flow-Through Conditions: Lab Project Number: 89328-0800-21 30: 88RC-0068. Unpublished study prepared by Hunter/ESE, Inc. 224 p.

41844902 Manning, C.; Ward, G.; Leak, T. (1990) Acute Toxicity of Dithane F-45 Fungicide to Sheepshead Minnows (Cyprinodon variegatus) Un- der Flow-Through Conditions: Lab Project Number: 89328-0700-2130 88RC-0072. Unpublished study prepared by Hunter/ESE, Inc. 254 p.

47729301 Kramer, V. (2009) Rationale for Classification of Existing Sheepshead Minnow Acute Toxicity Studies as Core MRID No. 41844901 and Bluegill Acute Toxicity Study as Core: MRID No. 45934702. Project Number: MZTF/2009/01, 96R/1010. Unpublished study prepared by Dow AgroSciences, LLC. 31 p.

48243201 Ollinger, J.; Kramer, V. (2010) Rationale for Classification of Existing Sheepshead Minnow Acute Toxicity Studies as Core: MRID No. 41844901 and Bluegill Acute Toxicity Study as Core: MRID No. 45934702: (Mancozeb) . Project Number: MZTF/2010/01. Unpublished study prepared by Mancozeb Task Force and Dow Agrosciences, LLC. 26 p.

72-4 Freshwater Invertebrate Life Cycle Study

40786201 Burgess, D. (1988) Chronic Toxicity of Dithane M-45 to Daphnia magna under Flow-through Test Conditions: Raw Data Report #36733: Rohm and Haas Report No. 88RC-0053. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 305 p.

40953802 Burgess, D. (1988) Chronic Toxicity of Dithane M-45 to Daphnia magna Under Flow-through Test Conditions: Final Report No. 36733; Rohm and Haas Report No. 88RC-0053. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 341 p.

43917219 Toy, R.; Gray, A. (1991) Dimethomorph: CME 151/Mancozeb 90/600 g/kg WP (SYS50579): Chronic Toxicity to Daphnia magna: Lab Project Number: SBGR.91.010: 4698. Unpublished study prepared by Shell Research Ltd. 42 p.

46023702 Wuthrich, V. (1993) Influence of Dithane DG on the Reproduction of Daphnia Magna Under Flow-Through Conditions. Project Number: 336058, 93/RC/1024. Unpublished study prepared by RCC Umweltchemie Ag. 73 p.

850.1350 Marine Invertebrate - Mysid chronic toxicity test

48627701 Hicks, S. (2011) Mancozeb: Life-Cycle Toxicity Test of the Saltwater Mysid, Americamysis bahia, Conducted Under Flow-Through Conditions. Project Number: 2010/1, 66201. Unpublished study prepared by ABC Laboratories, Inc. 90p.

850.1400 Fish early-life stage toxicity test Fresh and Marine species

40786202 or 40953801 McAllister, W. (1988) Early Life Stage Toxicity of Dithane M-45 to Fathead Minnows (Pimephales promelas) in a Flow-through System: Final Report #36732: Rohm and Has Report No. 88RC-0052. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 418 p.

42114601 Reinert, K. (1991) Supplemental to the Early Life-Stage Toxicity of Dithane M-45 to Fathead Minnows (Pimephales promelas) in a Flow- through System: Lab Project Number: R&H 88RC-0052B. Unpublished study prepared by Rohm & Haas Co. 93 p.

43230701 Rhodes, J.; Downing, J.; Bielefeld, T. (1994) Early Life-Stage Toxicity of Mancozeb to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions: Lab Project Number: 41148. Unpublished study prepared by ABC Labs., Inc. 247 p.

43917218 Toy, R.; Gray, A. (1991) Dimethomorph: CME 151/Mancozeb 90/600 g/kg WP (SYS50579): Prolonged Toxicity to Rainbow Trout: Lab Project Number: SBGR.91.058: 4699. Unpublished study prepared by Shell Research Ltd. 29 p.

46023701 Wuthrich, M. (1993) Dithane DG: 21-Day Prolonged Toxicity Study in the Rainbow Trout Under Flow-Through Conditions. Project Number: 336060, 93/RC/1021. Unpublished study prepared by RCC Umweltchemie Ag. 67 p. (Repeated under Acute Toxicity section)

48627702 Hicks, S. (2011) Mancozeb: Early Life-Stage Toxicity Test with the Sheepshead Minnow, Cyprinodon variegatus, Under Flow-Through Conditions. Project Number: 2010/2, 66202. Unpublished study prepared by ABC Laboratories, Inc. 78p.

850.1500 Full Fish life cycle toxicity

49030601 Hicks, S. (2012) Mancozeb: Life-Cycle Toxicity Test with the Fathead Minnow, Pimephales promelas, Under Flow-Through Conditions. Project Number: 2010/3, 66203. Unpublished study prepared by ABC Laboratories, Inc. 186p.

72-5 Aquatic Field Study

44944401 Memmert, U. (1999) Ecological Effects of Penncozeb RT 80 WP in a Freshwater Mesocosm Study: Lab Project Number: 681030. Unpublished study prepared by RCC, Ltd. 232 p.

46153001

Memmert, U. (1999) Ecological Effects of Penncozeb 80 WP in a Freshwater Mesocosm Study. Project Number: 681030. Unpublished study prepared by RCC Ltd. 250 p. Laboratory: RCC Ltd., Itingen, Switzerland Study Dates: Experimental: June 17, 1998 – October 28, 1998. Study Completion Date: October 7, 1999

850.4100 850.4150 122-1 Seed Germination/Seedling Emergence and Vegetable Vigor

44283401 Chetram, R.; Christensen, G.; Goodman, V. et al. (1997) Nontarget Terrestrial Plant Phytotoxicity Studies Using a 9%/60% WP Co-formulation of AC 336379 (Dimethomorph) and Mancozeb: (Final Report): Lab Project Number: 954-96-107: 954-96-108: 954-96-149. Unpublished study prepared by ABC Laboratories California. 250 p.

47486101 Lee, B. (2008) Mancozeb: Effects of the Vegetative Vigor of Non-Target Terrestrial Plants (Tier 1). Project Number: 2007/01, 63399. Unpublished study prepared by ABC Laboratories, Inc. 51 p.

47486102 Aufderheide, J. (2008) Mancozeb: Effects on the Seedling Emergence of Non-Target Terrestrial Plants (Tier 1). Project Number: 63398, 2007/02. Unpublished study prepared by ABC Laboratories, Inc. 58 p.

49183304 Martin, K.; Van Hoven, R.; Sindermann, A.; et al. (2011) Gavel **(Mancozeb 66.7%, Zoxamide 8.3%)**: A Tier 1 Toxicity Test to Determine the Effects of the Test Substance on Vegetative Vigor of Ten Species of Plants: Final Report. Project Number: 334/127. Unpublished study prepared by Wildlife International, Ltd. 96p.

49183405 Sindermann, A.; Porch, J.; Krueger, H.; et al. (2012) Gavel (Mancozeb 66.7%, Zoxamide 8.3%): A Tier 1 Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants: Final Report. Project Number: 334/126. Unpublished study prepared by Wildlife International, Ltd. 99p.

122-2 Aquatic plant growth

40845001 Ellgehausen, H. (1982) Determination of the Toxicity of Dithane Ultra to the Green Algae Scenedesmus Subspicatus Chodat: Evaluation of EC10 AND EC50: Project No. 002125. Unpublished study prepared by RCC Research & Consulting. 15 p.

43664701 Forbis, A. (1990) Acute Toxicity of Dithane M-45 Fungicide to Selenastrum capricornutum Printz: Final Report: Lab Project Number: 37735: 89RC-0045. Unpublished study prepared by ABC Labs, Inc. 208 p.

44950501 mixture with Zoxamide	Ward, C.; Murdock, C. (1998) Toxicity of Dithane/RH-117,281 DG Blend to Selenastrum capricornutum Printz: Lab Project Number: 44178: 97RC-0069. Unpublished study prepared by ABC Laboratories, Inc. 181 p.
46056403 Mixture with Zoxamide	Rhodes, J. (1999) Acute Toxicity of Dithane/RH-7281 (11.2:1) DG Blend to the Green Alga, Selenastrum capricornutum. Project Number: 45118, 98RC/0238. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 156 p.

850.5400 123-2 Aquatic plant growth

43917217 Mixture	Toy, R.; Gray, A. (1992) Dimethomorph: Acute Toxicity of Dimethomorph/Mancozeb 75/667 g/kg WP (SYS50588 R) to Oncorhynchus mykiss, Daphnia magna and Selenastrum capricornutum: Lab Project Number: SBGR.92.177: 5640. Unpublished study prepared by Shell Research Ltd. 42 p.
44283402	Canez, V.; Christensen, G.; Hughes, J.; et al. (1997) Effects of a 9%/60% WP Co-formulation of AC 336379 (Dimethomorph) and Mancozeb on the Growth of Navicula pelliculosa, Selenastrum capricornutum, Anabaena flos-aquae, Skeletonema costatum, and Lemna gibba: (Final Report): Lab Project Number: 954-96-113: 954-96-166: 954-96-111. Unpublished study prepared by Carolina Ecotox. Inc. 457 p.
46056403 Repeated in 122-2	Rhodes, J. (1999) Acute Toxicity of Dithane/RH-7281 (11.2:1) DG Blend to the Green Alga, Selenastrum capricornutum. Project Number: 45118, 98RC/0238. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 156 p.
46020902 and 45910402	Reuschenbach, D. (2000) Reg No. 146099: Determination of the Inhibitory Effect on the Cell Multiplication of Unicellular Green Algae: Final Report. Project Number: 00/0533/60/1. Unpublished study prepared by BASF Aktiengesellschaft. 27 p.

141-1 Honey bee acute contact

44950504 Mixture with Zoxamide	Milligan, D. (1997) Dithane/RH-117,281 DG Blend (8:1): Laboratory Oral and Contact Test with the Honeybee, Apis mellifera: Final Report: Lab Project Number: 97-071-1007: 97RC-0070: 1007.030.265. Unpublished study prepared by Springborn Laboratories AG. 48 p.
18842	Atkins, E.L., L.D. Anderson and E.A. Greywood (1969) Effect of Pesticides on Apiculture: Project No. 1499; Research Report CF-7501. (Unpublished Study Received May 8, 1971 under 1F11741; Prepared by University of California – Riverside, Dept. of Entomology, Submitted by Ciba Agrochemical Co., Summit, New Jersey. CDL:090973-B).
41941	Atkins, E.l., Jr. and C. Johansen (1969) Study on the Toxicity of U-27, 415 to Bees. (Unpublished Study Received on Unknown Date Under 0G0962; Prepared by University of California – Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology and Washington State University, Dept . of Entomology, Submitted by Upjohn Co., Kalamazoo, Michigan. CDL: 094605-B.
1949	Johansen, C., J. Eves (1969) Bee Research Investigations, 1969: Small-scale Bee Poisoning Tests with Honey Bees (HB) and Alfalfa Leafcutter Bees (LB). (Unpublished Study Received September 15, 1971 Under 1F1032; Prepared by Washington State University, Submitted by Hercules, Inc., Wilmington, Delaware. CDL: 091917-H

Non Guideline Studies

45212901 Ravenzwaay, B.; Ollinger, J. (2000) EBDC Fungicides Do Not Share a Common Mechanism of Toxicity with Cholinesterase Inhibitors: Lab Project Number: 2000 MECH. Unpublished study prepared by EBDU/ETU Task Force. 9 p.

45534701 Lamb, IV, J.; Hentz, K.; Matthews, S.; et al. (2001) Analysis of Common Mechanisms of Toxicity for Ethylenebisdithiocarbamates and Other Dithiocarbamates. Unpublished study prepared by BBL Sciences. 111 p.

45577201 Nienstedt, K. (2001) Dithane M-45 Fungicide: An Extended Laboratory Dose Response Toxicity Test on Detached Bean Leaves with the Predatory Mite, Typhlodromus pyri Scheuten (Acari: Phytoseiidae): Lab Project Number: 01RC-0134: 1007.075.568: 01P-134. Unpublished study prepared by Springborn Laboratories (Europe) AG. 40 p.

46023704 Nienstedt, K. (1999) A Chronic Toxicity and Reproduction Test Exposing the Earthworm Eisenia fetida to Dithane M-45 in OECD Artificial Soil. Project Number: 99RC/0124, 1007/054/630. Unpublished study prepared by Springborn Laboratories (Europe) Ag. 64 p.

47164601 Moore, D.; Breton, R.; Rodney, S.; et al. (2007) Generic Problem Formulation for California Red-Legged Frog. Project Number: 89320, 05232007. Unpublished study prepared by Cantox Environmental Inc. 87 p.

47164602 Holmes, C.; Vamshi, R. (2007) Data and Methodology Used for Spatial Analysis of California Red Legged Frog Observations and Proximate Land Cover Characteristics. Project Number: 3152007, WEI/252/03. Unpublished study prepared by Waterborne Environmental, Inc. (WEI). 19 p.

47327001 Ollinger, J. (2008) Mancozeb Task Force Response to EPA's California Red Legged Frog Effects Determinations for Mancozeb: "Effects Determinations for Mancozeb and Maneb Relative to the California Red-Legged Frog and Designated Critical Habitat," October 18, 2007. Project Number: MZTF200804, MZ/TF200804. Unpublished study prepared by Mancozeb Task Force. 37 p.

ETU Studies

850.2100 71-1 Avian acute oral toxicity test

48437501 Hubbard, P.; Beavers, J. (2011) Ethylenethiourea: An Acute Oral Toxicity Study with the Zebra Finch (Poephila guttata). Project Number: 697/102, 2010/2. Unpublished study prepared by Wildlife International Ltd. 60 p.

48343001 Hubbard, P.; Beavers, J. (2010) Ethylenethiourea: An Acute Oral Toxicity Study with the Northern Bobwhite. Project Number: 697/101, 2010/1. Unpublished study prepared by Wildlife International, Ltd. 57 p.

850.2200 71-2 Avian Dietary Toxicity

48417801 Hubbard, P.; Beavers, J. (2011) Ethylenethiourea: A Dietary LC 50 Study with the Northern Bobwhite. Project Number: 697/103, 2010/3. Unpublished study prepared by Wildlife International, Ltd. 66 p.

48417802 Hubbard, P.; Beavers, J. (2011) Ethylenethiourea: A Dietary LC50 Study with the Mallard. Project Number: 697/104, 2010/4. Unpublished study prepared by Wildlife International, Ltd. 65 p.

850.2300 71-4 Avian Reproduction

48819701 Temple, D.; Martin, K.; Beavers, J. et al. (2012) Ethylenethiourea: A Reproduction Study with the Northern Bobwhite: Final Report. Project Number: 697/107, 2010/5. Unpublished study prepared by Wildlife International, Ltd. 195p.

48819702 Temple, D.; Martin, K.; Beavers, J. et al. (2012) Ethylenethiourea: A Reproduction Study with the Mallard: Final Report. Project Number: 697/108, 2010/6. Unpublished study prepared by Wildlife International, Ltd. 196p.

72-1 Acute Toxicity to Freshwater Fish

45910401 Zok, S. (2001) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss Walbaum 1792) in a Static System (96 Hours): Ethylenethiourea (ETU): Lab Project Number: 12F0533/005042: 2001/1001877: PCP06082. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.

46020903 Zok, R. (2001) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss Walbaum 1792) in a Static System (96 Hours). Project Number: 12F0533/005042, 146099. Unpublished study prepared by BASF Aktiengesellschaft. 43 p.

850.1075 Fish acute toxicity test, freshwater and marine

46462902 Palmer, S.; Kendall, T.; Krueger, H. (2001) Ethylene Urea: A 96-Hour Static Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Final Report. Project Number: 299A/115. Unpublished study prepared by Wildlife International, Ltd. 37 p.

47441201 Soucy, K. (2008) Ethylenethiourea-Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Static Conditions, Following OPPTS Draft Guideline 850.1075. Project Number: 13921/6105, 2007/04. Unpublished study prepared by Springborn Smithers Laboratories. 55 p.

47441202 Soucy, K. (2008) Ethylenethiourea- Acute Toxicity to Bluegill Sunfish (Lepomis macrochirus) Under Static Conditions, Following OPPTS Draft Guideline 850.1075. Project Number: 13921/6104, 2007/05. Unpublished study prepared by Springborn Smithers Laboratories. 55 p.

45910401 Zok, S. (2001) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss
46020903 Walbaum 1792) in a Static System (96 Hours): Ethylenethiourea (ETU): Lab Project Number: 12F0533/005042: 2001/1001877: PCP06082. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.

72-2 Acute Toxicity to Freshwater Invertebrates

45910402 Hisgen, M. (2000) Determination of the Acute Effect on the Swimming Ability of the Water Flea Daphnia magna Straus: Ethylenethiourea (ETU): Lab Project Number: 00/0533/50/1:

2000/1017216: PCP05988. Unpublished study prepared by BASF Aktiengesellschaft. 27 p.

46020901 see 45910402 Hisgen, M. (2003) Reg No. 146099: Determination of the Acute Effect on the Swimming Ability of the Water Flea Daphnia Magna Straus: Final Report. Project Number: 00/0533/50/1. Unpublished study prepared by BASF Aktiengesellschaft. 25 p.

46462903 Palmer, S.; Kendall, T.; Krueger, H. (2001) Ethylene Urea: A 48-Hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report. Project Number: 299A/114. Unpublished study prepared by Wildlife International, Ltd. 37 p.

850.1025 Oyster acute toxicity test (shell deposition)

47474301 York, D. (2008) Ethylenethiourea-Acute Toxicity to Eastern Oyster (Crassostrea virginica) Under Flow-Through Conditions. Project Number: 13921/6102, 2007/02. Unpublished study prepared by EBDC/ETU Task Force. 66 p.

850.1035 Mysid acute toxicity test

47441204 Soucy, K. (2008) Ethylenethiourea-Acute Toxicity to Mysids (Americamysis bahia) Under Static Conditions, Following OPPTS Guideline 850.1035. Project Number: 13921/6103, 2007/03. Unpublished study prepared by Springborn Smithers Laboratories. 57 p.

850.1300 72-4 Daphnid chronic toxicity test

46462901 Graves, W.; Mank, M.; Swigert, J. (1995) Ethylene Thiourea (ETU): A Flow-Through Life-Cycle Toxicity Test with the Cladoceran (Daphnia Magna): Final Report. Project Number: 129A/116, 94RC/0001. Unpublished study prepared by Wildlife International, Ltd. 122 p.

850.4400 Aquatic plant toxicity test using Lemna spp. Tiers I and II

47441203 Softcheck, K. (2008) Ethylenethiourea-7-Day Toxicity Test with Duckweed (Lemna gibba) Following OPPTS Draft Guideline 850.4400. Project Number: 13921/6101, 2007/01. Unpublished study prepared by Springborn Smithers Laboratories. 69 p.

850.5400 123-2 Algal toxicity, Tiers 1 and II

46462904 Palmer, S.; Kendall, T.; Krueger, H. (2001) Ethylene Urea: A 96-Hour Toxicity Test with the Freshwater Alga (Selenastrum capricornutum): Final Report. Project Number: 299A/116. Unpublished study prepared by Wildlife International, Ltd. 49 p.

46020902 see 45910403 Reuschenbach, D. (2000) Determination of the Inhibitory Effect on the Cell Multiplication of Unicellular Green Algae: Ethylenethiourea (ETU): Lab Project Number: 00/0533/60/1: 2000/1017191: PCP05997. Unpublished study prepared by BASF Aktiengesellschaft. 28 p.

850.7100 Data reporting for environmental chemistry methods

46623335 Tilting, N. (2004) Residues of Metiram and ETU in Potential Feed Items of Birds and Wild Mammals Following Application of Polyram WG (BAS 222 28 F) in Potatoes: (Final Report). Project Number: 136963, 13512075, 2004/1006523. Unpublished study prepared by BASF Aktiengesellschaft and Institut fuer Biologische Analytik und Consulting IBACON. 136 p.

157594 E.I. du Pont de Nemours & Co., Inc. (1982) Manzate (IN-7331): Determination of Ethylenethiourea (ETU) Liquid Chromatographic Method: Method No: M20.1842(R). Unpublished study. 4 p.

45151401 Connolly, P. (2000) Independent Laboratory Analytical Method: Method for the Analysis of Ethylenethiourea (ETU) in Water by LC/MS/MS (MS 178.00) Revision 2: Lab Project Number: 002-342: 00P-002-342: MS 178.00. Unpublished study prepared by Centre Analytical Laboratories, Inc. 88 p. {OPPTS 850.7100}

Non-Guideline Study

42610001 Ruckert, E. (1992) Letter Sent to S. Lewis, dated Dec. 28, 1992: Regarding Ethylene thiourea 104 week chronic toxicity (feeding) study in rats: Source of information from final report RCC project number 256803. Prepared by EBDC/ETU Task Force. 3 p.

43641401 Weinberg, D.; Weiss, D. (1987) Response of the Maneb Data Task Force and Pennwalt Corporation to the Environmental Protection Agency's Initiation of Special Review of the EBDC Pesticides: (Risk Exposure Assessment). Unpublished study prepared by Fox, Weinberg & Bennett. 28 p.

43641501 Weinberg, D.; Weiss, D. (1987) Response of Pennwalt Corporation to the Environmental Protection Agency's Initiation of Special Review of the EBDC Pesticides/Mancozeb: (Risk Assessment): (Includes "EBDC Special Review: Toxicological Issues"). Unpublished study prepared by Fox, Weinberg & Bennett. 51 p.

44418801 Waylett, D.; Slesinski, R.; Sert, M. et al. (1997) Acute Dietary Exposure and Risk Assessment: Ethylenebisdithiocarbamates (EBDCs) and Their Common Metabolite, Ethylene Thiourea (ETU): Lab Project Number: EBDC 97-01. Unpublished study prepared by Tas-Environ. 95 p.

45225404 Hurt, S. (2000) Toxicity Endpoints and Reference Doses for Ethylenethiourea: Lab Project Number: 00R-1061. Unpublished study prepared by EBDC/ETU Task Force. 22 p.

45924404 Chernoff, N.; Kavlock, R.; Rogers, E.; et al. (1979) Perinatal Toxicity of Maneb, Ethylene Thiourea, and Ethylenebisisothiocyanate Sulfide in Rodents. Journal of Toxicology and Environmental Health 5: 821-834.

46268301 Arce, G. (2003) The Influence of Perinatal Exposure to ETU in the Development of Thyroid Effects and Other Critical Toxicological Parameters. Project Number: 2/03/EBDC. Unpublished study prepared by EBDC/ETU Task Force. 20 p.

46319901 Ollinger, J. (2004) EBDC/ETU Task Force Response to U.S. EPA's Draft Science Chapter for the Environmental Fate and Ecological Risk Assessment for Ethylenethiourea (ETU) Dated June 2, 2004. Project Number: EBDC/FQPA/2004/01. 38 p.

46480002 Ollinger, J. (2005) EBDC/ETU Task Force Response to U.S. EPA's Draft Science Chapter for the Environmental Fate and Ecological Risk Assessment for Ethylenethiourea (ETU) Dated October 20, 2004. Project Number: EBDC/FQPA/2005/01. Unpublished study prepared by EBDC/ETU Task Force. 24 p.

46480003 Ollinger, J. (2005) Ethylenebisdithiocarbamate Fungicides - Benefits to United States Agriculture. Project Number: EBDC/FQPA/2005/03. Unpublished study prepared by EBDC/ETU Task Force. 261 p

47292002 Wuest, P.; Singh, H. (1983) Assessment of Zineb Residue Levels Through Dermal and Inhalation Exposures and its Major Metabolite [Ethylenethiourea (ETU)] in Biological Fluids: Final Report. Project Number: 59/2421/0/2/012/0. Unpublished study prepared by Pennsylvania State University and Enviro-Bio-Tech, Ltd. 43 p.

47432128 Wang, G. (1988) Regulatory Decision Making and the Need for and the Use of Exposure Data on Pesticides Determined to Be Teratogenic in Test Animals. Teratogenesis, Carcinogenesis, and Mutagenesis 8:117-126.

48597301 Marty, M.; Chukwdebe, A.; McCoy, A. (2011) Exposure to ETU during Different Life Stages: Kinetic Considerations. Project Number: EOGRTS/TK. Unpublished study prepared by EBDC/ETU Task Force. 18p.

49254303 Thienpont, B.; Tingaud-Sequeira, A.; Prats, E.; et al. (2011) Zebrafish Eleutheroembryos Provide a Suitable Vertebrate Model for Screening Chemicals that Impair Thyroid Hormone Synthesis. Environmental Science & Technology 45(X): 7525-7532.

Appendix B. SIP Output

Table 1. Inputs

Parameter	Value
Chemical name	Mancozeb
Solubility (in water at 25ºC; mg/L)	6
Mammalian LD_{50} (mg/kg-bw)	5000
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Mammalian NOAEL (mg/kg-bw)	120
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Avian LD_{50} (mg/kg-bw)	
Avian test species	mallard duck
Body weight (g) of "other" avian species	
Mineau scaling factor	1.15
Mallard NOAEC (mg/kg-diet)	125
Bobwhite quail NOAEC (mg/kg-diet)	125
NOAEC (mg/kg-diet) for other bird species	
Body weight (g) of other avian species	
NOAEC (mg/kg-diet) for 2nd other bird species	
Body weight (g) of 2nd other avian species	

Table 2. Mammalian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	1.0320	1.0320
Adjusted toxicity value (mg/kg-bw)	3845.8028	92.2993
Ratio of exposure to toxicity	0.0003	0.0112
Conclusion*	**Drinking water exposure alone is NOT a potential concern for mammals**	**Drinking water exposure alone is NOT a potential concern for mammals**

Table 3. Avian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	4.8600	4.8600
Adjusted toxicity value (mg/kg-bw)	0.0000	6.2016
Ratio of exposure to acute toxicity	0.0000	0.7837
Conclusion*	**Due to insufficient data, risk cannot be precluded**	**Drinking water exposure alone is NOT a potential concern for birds**

*Conclusion is for drinking water exposure alone. This does not combine all routes of exposure. Therefore, when aggregated with other routes (*i.e.*, diet, inhalation, dermal), pesticide exposure through drinking water may contribute to a total exposure that has potential for effects to non-target animals.

Appendix C. STIR Output

Input	
Application and Chemical Information	
Enter Chemical Name	Mancozeb
Enter Chemical Use	
Is the Application a Spray? (enter y or n)	y
If Spray What Type (enter ground or air)	ground
Enter Chemical Molecular Weight (g/mole)	265
Enter Chemical Vapor Pressure (mmHg)	1.32E-10
Enter Application Rate (lb a.i./acre)	19
Toxicity Properties	
Bird	
Enter Lowest Bird Oral LD_{50} (mg/kg bw)	
Enter Mineau Scaling Factor	1.15
Enter Tested Bird Weight (kg)	1.58
Mammal	
Enter Lowest Rat Oral LD_{50} (mg/kg bw)	5000
Enter Lowest Rat Inhalation LC_{50} (mg/L)	5.14
Duration of Rat Inhalation Study (hrs)	4
Enter Rat Weight (kg)	0.35

Output		
Results Avian (0.020 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	1.88E-06	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	2.37E-07	
Adjusted Inhalation LD_{50}	0.00E+00	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	#DIV/0!	**#DIV/0!**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	2.01E+00	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	#DIV/0!	**#DIV/0!**
Results Mammalian (0.015 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	1.88E-06	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	2.97E-07	
Adjusted Inhalation LD_{50}	3.06E+02	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	9.72E-10	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	2.52E+00	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	8.25E-03	**Exposure not Likely Significant**