United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

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October 2002

Reregistration Eligibility Decision (RED)

THIABENDAZOLE

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-02-002 May 2002

EPA R.E.D. FACTS

Thiabendazole and Salts

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2760, Thiabendazole and Salts.

Use Profile

Thiabendazole is used to control a variety of fruit and vegetable diseases such as mold, blight, rot and stains caused by various fungi. Thiabendazole is formulated as a ready-to-use, dusts, flowable concentrates, emulsifiable concentrates, wettable powders, granules, and water dispersable granules. It's registered for use as a pre-planting dust treatment to potato seed-pieces, sweet potato seed pieces, soybean, and wheat. It is also registered for use on mushrooms and is mostly used post-harvest as a dip or spray on citrus fruits, apples, pears, bananas, mangos, papaya, plantain, carrots, avocados, peas, and potatoes. Thiabendazole salt uses include a ready-to-use formulation for ornamental bulbs, elm and sycamore trees. Thiabendazole salt is also used as a preservative in paints, carpets, adhesives and textiles.

Thiabendazole can be applied by dipping, spraying, or application during the waxing procedure for fruits and vegetables. Seed treatments are applied with a

ready-mix or slurry-mix. A ready-to-use formulation is added to paints, carpets, textiles and adhesives.

Regulatory History

Thiabendazole was first registered as a pesticide in the U.S. in 1969 by Merck and Company, Inc. Merck and Company, Inc. manufactured the technical product and other companies manufactured end-use products. The primary registrant of end use products has been Syngenta Crop Protection, Inc. Merck and Company, Inc. held the registration of the technical product until 1998. Technical product was later transferred to Syngenta Crop Protection,Inc. and retained it's name as Mertect Fungicide. Currently, 62 Thiabendazole pesticide products are registered. A Data Call-In (DCI) was issued in 1991 for thiabendazole requiring the submission of additional data on product chemistry, toxicity, environmental fate and ecological effects. A subsequent DCI was issued in 1995 requiring data to help estimate post-application exposure. The Reregistration Eligibility Decision (RED) reflects a reassessment of all data which were submitted in response to the DCI's.

Human Health Assessment

Toxicity

Thiabendazole generally has been shown to have low acute dermal toxicity. It is neither irritating to the eyes or skin nor is a dermal sensitizer. Toxicity Categories, which range from 1 (most toxic) to 4 (least toxic), were mostly 4 for thiabendazole. The thyroid and liver are the primary target organs of thiabendazole. In a rat subchronic study, there were increases in liver and thyroid weights. Also, in a chronic dog study, thiabendazole produced a similar effect in increased liver weight.

Thiabendazole generally is of low acute toxicity, however, the Agency has classified thiabendazole as likely to be carcinogenic at doses high enough to cause disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance. After consideration of expected exposure authorized under current EPA registered use patterns as well as consideration of allowable dietary exposure from imported crops treated with thiabendazole, the Agency has determined that individuals would be exposed to levels which are far less than those sufficient to cause cancer. The Agency is using the MOE approach for the human cancer risk assessment. Use of Pesticide Data Program (PDP) monitoring data, field trial data, tolerance level residues and calculated livestock residues have resulted in a MOE approach of 13,000 for the general U.S. population which is below the Agency's level of concern. A MOE of 13,000 means that potential exposures to humans is 13,000 times less than the exposure to rats at which no adverse effects were observed. Rats have also demonstrated an increased sensitivity compared to humans to thyroid induced tumors which adds an even greater comfort level to the significance of the calculated MOE.

Dietary Exposure

People may be exposed to residues of thiabendazole through the diet. Tolerances or maximum residue limits have been established for the following agricultural and livestock commodities in 40 CFR§180.242: apples (post-harvest), avocados, bananas (pre and post-harvest), banana pulp (pre and post-harvest, dry beans, sugar beets pulp (dried/and or dehydrated), sugar beets tops (pre-harvest), sugar beets tops, cantaloupes, carrots (post-harvest), citrus fruits (post-harvest), citrus pulp dried (post-harvest), mangos, mushrooms, papayas (post-harvest), pears (post-harvest), potato processing waste (pre and post-harvest), potatoes (pre and post-harvest), rice hulls, rice rough, rice straw, soybeans, strawberries, sweet potatoes (post-harvest to sweet potatoes only intended for use as seed), Hubbards squash, wheat grain, wheat milled fractions (except flour), wheat straw, cattle fat, meat byproduct, meat; eggs, poultry meat, meat byproduct; goats fat, meat byproduct, meat; hogs fat, meat byproduct, meat; horses fat, meat, meat byproduct; milk, sheep fat, meat byproduct and meat. EPA has assessed the Thiabendazole tolerances and found that some are acceptable, others must be revoked. The Agency is proposing to revoke the tolerances for residues in poultry meat, meat by products and eggs. Based upon the maximum dietary burden for poultry and data, tolerances for residues in poultry meat, meat by products, and eggs should be revoked. In addition, based upon the maximum dietary burden for beef cattle and swine and data, tolerances for residues in fat of cattle, hogs, horses, goats and sheep should be revoked.

The Agency is proposing to revoke the tolerance for thiabendazole residues in banana pulp. The tolerance already established for bananas will include the banana pulp. New tolerances must be established for residues in/on wet apple pomace, citrus oil, pome fruits, wheat forage and hay. Residue data is required before an appropriate tolerance can be determined for residues in/on wheat forage and hay; however, sufficient data is currently available to determine the appropriate tolerance for residues in wet apple pomace and citrus oil.

The registrant is not supporting domestic treatment of thiabendazole on sugar beet raw agricultural commodities (RACs), grapes, rice RACs, processed fractions, and Hubbards squash, and therefore these tolerances should all be revoked. The Agency is proposing to revoke tolerances for residues in dried citrus pulp, potato processing waste, and wheat milled fractions since thiabendazole does not concentrate in potato, wheat processed fractions, and dried citrus pulp in excess of the tolerance on whole citrus fruits.

Risk From Food

For thiabendazole, acute, chronic, and carcinogenic dietary risk from food is not of concern.

Risk From Food +Drinking Water

Model estimates of potential drinking water exposure from ground and surface water sources are not of concern for thiabendazole. Also, acute and chronic dietary risk is below the Agency's level of concern. Therefore, risks from food and drinking water combined are below the Agency's level of concern.

Risk From Non-dietary Exposure

There are no thiabendazole pesticide products registered for use by homeowners. Thiabendazole-treated carpets and paints, can however, be used by homeowners. The Agency does not believe that homeowners exposed to thiabendazole-treated carpets are at a risk since thiabendazole is applied to the backing of carpets during the manufacturing process and estimates are extremely conservative. Also, due to thiabendazole's use profile, the Agency has concluded that there is a low potential for residential exposure. The low concentrations of thiabendazole incorporated in paints, adhesives, paper and carpet greatly reduces the potential for exposure. In all cases, residential exposure is not expected to exceed occupational post-application exposure and therefore would not be expected to exceed the Agency's level of concern.

Aggregate Risk

The short- and intermediate-term aggregate risk assessment includes exposure from nonoccupational settings in addition to the dietary (food and water) exposure. Two short-term (1-7 days) and intermediate term (1-6 months) exposure scenarios were identified for the adult populations: exposure to thiabendazole-treated carpets and paints. These two scenarios were aggregated with the average dietary exposure since they can occur simultaneously. For infants and children, only the carpet exposure was aggregated with average dietary exposure. Estimated average concentrations of thiabendazole in surface and ground water are below the Agency's level of concern.

Occupational Risk

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to thiabendazole applications in agricultural and other settings. However, the Agency has concluded that there is low potential for residential exposure. The low concentrations of thiabendazole incorporated in paints, adhesives, paper and carpet greatly reduces the potential for exposure. The margin of exposure (MOE) for all residential and occupational scenarios is well below the Agency's level of concern, and therefore risk is minimal.

Exposure and risk to workers will be mitigated by the use of PPE required by the WPS, as required by this RED. Post-application reentry workers will be required to observe a 12 hour Restricted Entry Interval, which is set by the WPS.

FQPA Considerations

EPA has determined that the established tolerances for thiabendazole, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is reasonable certainty of no harm for infants and children. The safety determination for infants and children takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of thiabendazole residues in this population subgroup.

In determining whether infants and children are particularly susceptible to toxic effects from thiabendazole residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. for thiabendazole, the FQPA safety factor of 10 was **reduced** to 1 because: (1) the toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. (2) There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. (3) The Agency believes that its exposure assessments will not underestimate the potential risk for infants and children from thiabendazole. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

Environmental Assessment

Ecological Effects

Thiabendzole is highly toxic to freshwater estuarine fish and freshwater/estuarine invertebrates. Thiabendazole is practically non-toxic to birds and mammals. Typically, birds and mammals can be exposed to pesticides applied as foliar sprays or granulars by a variety of routes, including ingestion, dermal contact, and inhalation. For thiabendazole, which is applied indoor as a seed treatment for wheat, exposure to wildlife is not relevant until treated seeds are planted back in the fields. Applications to and treatment of mushroom houses are also indoor uses, and therefore are of minimal danger to birds and mammals. Exposure of terrestrial wildlife from direct injection of thiabendazole and its salts into trees may occur but is also expected to be a minimal means of exposure. Results of avian reproduction studies on northern bobwhite quail and mallard duck yielded results that show thiabendazole having no adverse effects on avian reproduction.

The ecological risks due to the use of thiabendazole are considered below the Agency's level of concern. Currently registered use patterns for thiabendazole

result in low exposures and with the relatively low toxicity of thiabendazole, no environmental mitigation is necessary.

Risk Mitigation

To lessen the risks of dietary exposure posed by thiabendazole, EPA is requiring the following risk mitigation measures:

-To mitigate acute dietary risk to children 1-6 years of age, Syngenta amended the label to remove the spray application to mushrooms.

To lessen the risks of occupational exposure posed by thiabendazole, EPA is requiring the following risk mitigation measures:

-To mitigate risks to agricultural workers (applicators) during spray application to mushroom houses:

- label language will be changed to specify chemical resistant gloves be worn while applying thiabendazole to mushroom houses during spawning only.

-To mitigate risks to agricultural workers (mixers/loaders/applicators) during manual seed treatment:

-since this use was found to be virtually non-existent. The Agency will be changing the label language to prohibit this use.

-To mitigate risks to agricultural workers during post-harvest sorting/packing/culling of fruit:

-the Agency recalculated exposure numbers for workers sorting/culling/packing after harvest based on transfer coefficiency information that was not available at the time of the original assessment. The newer data provided an MOE of 1600, well below the Agency's level of concern and therefore no additional risk mitigation is necessary.

Additional Data Required

EPA is requiring the following additional generic studies for thiabendazole to confirm its regulatory assessments and conclusions:

(1) *In vitro* mammalian gene mutation (870.5300)

(2) *In vitro* chromosome aberration assay (870.5375)

(3) UV/visible absorption (830.7050)

(4) Multi-residue method testing (860.1360)

(5) Additional storage stability data for sweet potatoes (860.1380)

(6) Additional residue data for benzimidazole (free and conjugated) in/on cantaloupe and strawberry for foliar application (860.1500)

(7) Residue data on wheat, dry beans, and soybeans (860.1500)

(8) Processing study for the processed fractions of soybeans (860.1520)

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All thiabendazole end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the thiabendazole RED document.

Regulatory Conclusion

The use of currently registered products containing thiabendazole in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Thiabendazole products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for thiabendazole during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the thiabendazole RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the thiabendazole RED, or reregistration of individual products containing thiabendazole please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is http://npic.orst.edu.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the pesticide thiabendazole. Based on EPA's review, the Agency believes risk mitigation measures have been identified that are necessary to address the human health risks associated with the current use of thiabendazole. The EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of thiabendazole and its associated human health and environmental risks. The enclosed " Reregistration Eligibility Decision for Thiabendazole," which was approved on May 1, 2002, contains the Agency's decision on thiabendazole.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for thiabendazole is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See http:www.epa.gov/ pesticides/reregistration.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA)**,** the Agency is undertaking a special effort to maintain open public dockets on pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The U.S. Department of Agriculture held a meeting in conjunction with the Agency on August 15, 2001, and provided the Agency with information on thiabendazole usage and use/agricultural practices. The human health and environmental risk assessments were placed in the public docket and an invitation for public comment was announced in the *Federal Register* on August 30, 2001. In addition, a second conference call was held September 27, 2001 during which the Agency presented a summary of the risk assessments and risk management decisions for the registrants, USDA, and

other stakeholders. Finally, the Agency held the closure conference call for thiabendazole on March 20, 2002 in order to provide all stakeholders involved with the Agency's final risk management decisions.

Please note that the thiabendazole risk assessment and the attached RED concern only this particular chemical. Thiabendazole is a member of the benzimidazole class of fungicides. While current data are limited, EPA has evidence that compounds within a class may share a common mechanism of toxicity. At this time, the Agency does not have sufficient data concerning common mechanism issues to determine whether or not thiabendazole shares a common mechanism of toxicity with other substances, including other benzimidazoles or other probable human carcinogens. Therefore, for the purposes of this risk assessment, the Agency has assumed that thiabendazole does not share a common mechanism of toxicity with any other chemicals.

This document contains a draft copy of the generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a final DCI, with all pertinent instructions, is being sent to all applicable registrants under separate cover.

In this RED, the Agency has determined that thiabendazole will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of thiabendazole may pose unreasonable adverse effects to human health, and that such effects can be mitigated with the risk mitigation measures identified in this RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this RED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by thiabendazole. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes necessary for reregistration, please contact the Chemical Review Manager, Lorilyn Montford, at (703)308-8170 For questions about product reregistration and/or the product DCI that accompanies this document, please contact Moana Appleyard at (703) 308-8175.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

Reregistration Eligibility Decision
for
Thiabendazole
and
Salts
Case 2670

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THIABENDAZOLE TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
DCI	Data Call-In
aPAD	Acute Population Adjusted Dose
CAS	Chemical Abstracts Service
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EFED	EPA's Environmental Fate and Effects Division
e.g.	*Lat*. Exampli gratia (for example)
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory. The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HED	EPA's Health Effects Division
HDT	Highest Dose Tested
i.e.	*Lat*. Id est (that is)
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PR	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of thiabendazole, and its salt, thiabendazole hypophosphate, hereafter referred to as thiabendazole. EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for thiabendazole. The decisions outlined in this document include the final tolerance reassessment decision for thiabendazole. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on thiabendazole. After considering the revised risks, as well as mitigation proposed by Syngenta, the technical registrant of thiabendazole, and comments and mitigation suggestions from other interested parties including American Mushroom Institute, Florida Fruit and Vegetable Association, Dole Food, Northwest Horticultural Council, Florida Citrus Packers and a host of other stakeholders such as state agricultural departments, agricultural extension organizations and universities, EPA developed its risk management decision for uses of thiabendazole that pose risks of concern. This decision is discussed fully in this document.

Use Summary

Thiabendazole is a fungicide used on a variety of fruit and vegetables to control mold, rot, blight and stain, mainly as a post-harvest treatment. It is also used as a seed treatment and is used to control Dutch elm disease and as a preservative in paints, carpets, textiles, paper products and adhesives. Thiabendazole is used medicinally as a chelating agent to bind metals; in addition, it is administered to treat several helminth species such as roundworms in livestock and humans. However, medicinal uses of thiabendazole are regulated by FDA, and have not been included in this reregistration document. First registered in 1969, thiabendazole is registered for use on bananas, carrots, citrus fruits, mushrooms, pome fruits, potatoes, soybeans, and wheat. Usage data from 1987 - 1997 indicates an average domestic use of approximately 41,000 lbs. a.i. per year for pre-harvest usage and approximately 109,000 lbs. a.i. per year for post-harvest usage**.**

Dietary Risks

EPA's human health risk assessment for thiabendazole indicates some risk concerns. The preliminary dietary risk assessment indicated that acute dietary food risk was above the Agency's level of concern for children 1-6 years of age, with mushrooms driving the risk. To mitigate this risk the registrant has modified their label to delete the use of thiabendazole as a spray application to mushrooms, and to apply the spray application only during the spawning stage of mushroom growth. Deletion of the spray application use of thiabendazole to mushrooms results in an acceptable acute dietary risk for children 1-6 years of age. Chronic dietary food risk is below the Agency's level of concern. Similarly, drinking water risk estimates based on screening models, from both ground and surface water for acute and chronic exposures, are not of concern.

Carcinogenicity Classification

The Agency has classified thiabendazole as likely to be carcinogenic at doses high enough to cause disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance. After considering the expected exposure authorized under EPA currently registered use patterns as well as consideration of allowable dietary exposure from imported crops treated with thiabendazole, the Agency has determined that individuals would be exposed to levels which are far less than those sufficient to cause cancer. The Agency is using the MOE approach for the human cancer risk assessment rather than a linear approach since the mode of action for the carcinogenic effect is known and the pesticide does not produce tumors by a mutagenic mechanism. Use of Pesticide Data Program (PDP) monitoring data, field trial data, tolerance level residues and calculated livestock residues have resulted in a MOE of 13,000 for the general U.S. population which is below the Agency's level of concern. (This MOE includes the deletion of the mushroom overspray use.) A MOE of 13,000 means that potential exposures to humans is 13,000 times less than the exposure to rats at which no adverse effects were observed. Rats have also demonstrated an increased sensitivity compared to humans to thyroid induced tumors which adds an even greater comfort level to the significance of the calculated MOE. Children are not expected to be more susceptible to thiabendazole-induced thyroid effects than adults.

Acute and chronic dietary risk assessments for food and drinking water do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to thiabendazole.

Occupational Risk

Occupational exposure to thiabendazole was of concern to the Agency during the preliminary risk assessment for two occupational scenarios: manual seed treatment and post-harvest sorting/packing/culling of fruit. Since the preliminary assessment, several changes have occurred based on information that was not available to the Agency during the original assessment.

First, manual seed treatment originally showed an MOE above the Agency's level of concern. Since the original assessment, this use was found to be virtually nonexistent in the grower community. Therefore, the Agency will be changing the label language to prohibit manual seed use. Also, in the original assessment, the Agency determined that the post-harvest application exposure to sorters/packers/cullers was above the Agency's level of concern. However, since that time the Agency has received new transfer coefficiency data that indicates a 50 fold decrease in exposure resulting in a 50 fold increase in the margin of exposure (MOE). Originally, the Agency believed that personal protective equipment (gloves) were necessary during this occupational scenario in order to protect sorters/packers/cullers from thiabendazole exposure. Now, the MOE is well below the Agency's level of concern and therefore, no mitigation is necessary at this time. Additionally, although the registrant, Syngenta, has deleted the mushroom overspray application, there is still occupational concern for applicators applying thiabendazole during the spawning stage of mushroom growth. Therefore, the use of chemical resistant gloves (PPE) will be necessary for applicators applying thiabendazole during the spawning stage.

Ecological Risk

Ecological risks are not of concern to the Agency. Although thiabendazole is highly toxic to fish and aquatic invertebrates and is very persistent in soils, the Agency believes that there will be minimal potential risk to terrestrial animals or aquatic animals resulting from the use of this fungicide to control diseases in mushrooms, as a seed treatment, and as a post-harvest treatment. In addition, the Agency does not expect parent thiabendazole and its degradates to enter the drinking water resources at any significant level.

The Agency is issuing this Reregistration Eligibility Document (RED) for thiabendazole, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any necessary label changes for products containing thiabendazole. The Agency provided a public comment period for this chemical. The comment period lasted 60 days. It began on July 30, 2001 and closed October 1, 2001.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

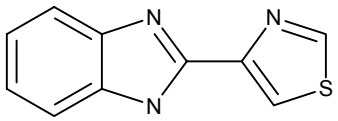
On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency's revised human health and ecological risk assessments; its tolerance reassessment decision; and the decision on the reregistration eligibility of thiabendazole.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

II. Chemical Overview

A. Chemical Identification



- **Common Name:** Thiabendazole
- **Chemical Name:** [2-(4-thiazolyl) benzimidazole]
  [2-(4-thiazolyl) benzimidazole] hypophosphite salt
- **Chemical family:** Benzamidazole
- **Case number:** 2670
- **CAS registry number:** 148-79-8
  28558-32-9
- **OPP chemical code:** 060101
  060102 (hypophosphite salt)
- **Empirical formula:** $C_{10}H_7N_3S$
- **Molecular weight:** 201.26
- **Trade and other names:** Mertec, Arbotect, Vitavax, Agrosol,, Metasol, Sealbrite
- **Basic manufacturer:** Syngenta

Technical thiabendazole is a colorless crystalline solid with a melting point of 304-305 C, bulk density of 25-30 cc (tapped), octanol/water partition coefficient (K_{ow}) of 240-285 at pH7, and vapor pressure of 4 X 10^{-9} mm Hg at 25C. Thiabendazole is soluble in water at 0.028-0.030 mg/mL at 25C, and is soluble in several organic solvents.

B. Use Profile

The following information is based on the currently registered uses of thiabendazole:

Type of Pesticide

Fungicide

Use Sites:
Thiabendazole is registered for use as a pre-planting dust treatment to the following types of seeds: potato seed-pieces, sweet potato seed-pieces, soybean, and wheat. It is also registered for use on mushrooms for irrigation applications. In addition, thiabendazole is registered as a spray and dip application during the waxing procedure for the following fruits and vegetables: peas (field), peas (dried), citrus fruits, avocados, lemons, apples, pears, bananas, mangos, papaya, plantain, carrots (root crop vegetable), potatoes, sweet potato, beans (dried), crimson clover (forage fodder), and rice. Thiabendazole salt uses include a ready-to-use formulation for the following non-food uses: ornamental bulbs, elm and sycamore trees. Thiabendazole salt is also used as a preservative in paints, carpets, adhesives and textiles.

Target Pests:
A variety of molds, mildews, rot, blight and stains caused by various fungi including species in the following genera: *Verticillium fungicola, Mycogone perniciosa, Trichoderma harzianum, Trichoderma virdi, Aspergillus, Trichoderma spp.* and more.

Formulation Types Registered:
The following thiabendazole formulation types are registered: a ready-to-use, dusts, flowable concentrates, emulsifiable concentrates, wettable powders, granules, and water dispersable granules. End use products are sold in the U.S. under the trade names Mertec® LSP, Mertec® 340-F, Arbotect® 20-S, Mertec® 40, Vitavax-Plus, Vitavax Extra, Agrosol T, Granox Plus, Metasol TK-100, Calgon Thiabendzole Dispersion, Metasol TK-25 AD, Metasol TK-50 AD, Citrus Lustre-256, Decco Salt No. 19, Gustafson LSP, Freshguard 500 and many more.

Method and Rates of Application:
Post harvest applications can be done by dipping, spraying, or application during the waxing procedure for fruits and vegetables. Seed treatments are applied with a ready-mix or slurry seed treatment. A dusting machine is also used for seed treatments. A ready-to-use formulation is mixed into paints, carpets, adhesives and textiles. A soluble concentrate is diluted with water for injection of dutch elm and sycamore trees.

Use rates vary widely depending on the crop/target, as follows:

For wheat seed treatment:
2.0 - 6.0 fl. oz. ai per equal amounts of water
For chickpeas treatment:
14.0 fl. oz. ai per equal amounts of water
For mushroom treatment:
0.24 - 0.61 lb. ai/1000 sq. ft.
For pome fruits (apples and pears) treatment:
16.0 fl. oz. ai per 100 gallons of water

For potato treatment:
0.42 fl. oz. ai per gallon of water
For ornamental bulbs and corms treatment:
30 fl. oz. per 100 gallons of water
For elm and sycamore tree treatment: (minimum to maximum)
(For each 5 inches of trunk diameter, inject 1 fl. oz. ai per 40 fl. oz. of water - For each 5 inches of trunk diameter, inject 4 fl. oz. ai per 80-160 oz. of water)
For paints, carpets, and adhesive treatment:
range from 0.04% to 0.20% diluted product per 1gallon of adhesive, paint, or carpet.

Use Classification:
General Use Pesticide

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of thiabendazole, based on available pesticide usage information for 1987 - 1997. A full listing of all uses of thiabendazole, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 150,000 lbs. a.i. of thiabendazole are used annually, according to registrant and Agency estimates. Table 1 below does not include all representative crops for thiabendazole. Mushrooms have not been included in Table 1 because they are cultivated indoors, and data collected on indoor crops contain a wide range of reporting variability.

Table 1. Thiabendazole Estimated Usage for Representative Sites

Crop	Lbs. Active Ingredient Applied (Wt. Avg.)[1]	Percent Crop Treated (Likely Maximum)
Apples	15,448	62% (pre-storage) 23% (post-storage)
Potatoes	76,473	50% (pre-storage)
Pears	76,473	90% (pre-storage)
Bananas	14	50% (post-storage)
Grapefruit	1,591	45% (post-storage)
Oranges	7,559	75% (post-storage)
Wheat, Winter	5	<1
Peanuts	2	<1

[1] Weighted Average is based on data for 1987-1997; the most recent years and more reliable data are weighted more heavily.

D. Regulatory History

Thiabendazole was first registered in the United States in 1969 by Merck and Company, Incorporated. The chemical was formulated as Mertect® Antimyotic. Merck and Company, Inc. manufactured the technical product and other companies manufactured end-use products. The primary registrant of end use products has been Syngenta Crop Protection, Incorporated. Merck and Company, Inc. held the registration of the technical product until 1998. The registration for the technical product was later transferred to Syngenta Crop Protection, Inc. but retained its name as Mertect Fungicide.

III. Risk Assessments for Thiabendazole

The following is a summary of EPA's revised human health and ecological risk findings and conclusions for the pesticide Thiabendazole, as presented fully in the documents, *"Thiabendazole (060101) and Thiabendazole Salts (060102): A Revised HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document."* dated June 21, 2001*, and "EFED Reregistration Document for Thiabendazole."*dated February 4, 1999.

The purpose of this decision document is to summarize the key features and findings of this risk assessment in order to help the reader better understand the conclusions reached in the assessment. While the risk assessments and related addenda are not included in this document, they are available on the Agency's web page at *www.epa.gov/pesticides,* and in the OPP Public Docket.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for thiabendazole and its salts in July 2001 (Phase 3). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined.

1. Toxicity of Thiabendazole

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database for thiabendazole is complete, supports a reregistration eligibility determination for all currently registered uses. Further details on the toxicity of thiabendazole can be found in the *HED toxicology chapter for the Reregistration Eligibility Decision document (RED)* dated October 12, 1999.

Thiabendazole has low acute toxicity via the oral and dermal routes (Category III). It is not an eye or dermal irritant nor a dermal sensitizer. Thiabendazole has little opportunity for vaporization or aerosolization since it is used for direct injection in root flares. Therefore, there is negligible risk of inhalation exposure to vapor or aerosol during use. Thiabendazole base is known to have a very low vapor pressure and is not expected to contribute greatly to exposures via the inhalation route. In primary eye and primary skin irritation studies, thiabendazole was found to be non-toxic.

The Agency has classified thiabendazole as "likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance." A mode of action was established in which these tumors were attributed to interference with thyroid-pituitary homeostasis. The MOE approach is used in this risk assessment to estimate the cancer risk. Thiabendazole also causes increased liver weight and hepatocellular hypertrophy presumably via induction of microsomal enzymes. However, thiabendazole is not a mutagen. In a chronic rat study, thiabendazole induced thyroid tumors in males. There is no evidence of increased susceptibility of rat, rabbit, or mouse fetuses to in utero exposure in developmental studies. Acceptable genetic toxicology studies on thiabendazole indicate that it is nongenotoxic/mutagenic *in vivo* and *in vitro* assays. Therefore, the FQPA Safety Factor committee concluded that the safety factor could be removed for thiabendazole.

2. Dose Response Assessment

The Agency evaluated the toxicology database of thiabendazole, and established acute and chronic endpoints and reference doses for dietary exposure. Toxicological endpoints were selected for various exposure scenarios which are summarized in Table 2. The absorbed fraction of each exposure was calculated in order to convert dermal and inhalation exposures to an equivalent oral dose using a dermal absorption rate of 60% and an inhalation absorption factor of 100%. Thiabendazole has been shown to induce thyroid tumors in male and female rats. The Agency has concluded that thiabendazole is likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance. A mode of action was established in which these tumors were attributed to interference with thyroid-pituitary homeostasis.

a. Summary of Endpoints Selected

A brief overview of the studies used for the dietary risk assessment is outlined in Table 2.

Table 2. Summary of Toxicological Dose and Endpoints for Thiabendazole for Use in Human Dietary Risk Assessment

Exposure Scenario	Endpoint (mg/kg/day)	FQPA Safety Factor	UF	Study/Effect	PAD (mg/kg/day)
Acute Dietary (females 13+)	NOAEL=10 LOAEL=40	1X	100	Oral Developmental Study - Rat/ decreased fetal body weight	0.1
Acute Dietary (general population)	NOAEL= 10 LOAEL= 40	1X	100	Oral Developmental Study - Rat/ decreased maternal body weight seen during gestation (general population)	0.1 mg/kg/day
Chronic Dietary	NOAEL=10 LOAEL=30	1X	100	Combined Chronic Toxicity-Carcinogenicity/ based on decreased body weight gains and liver hypertrophy	0.1
Cancer Dietary	NOAEL=10 LOAEL=30	1X	N/A	Combined Chronic Toxicity-Carcinogenicity/ based on increased incidence of thyroid follicular cell adenomas and combined adenomas/carcinomas.	

b. Acute Dietary Endpoint

Two acute dietary endpoints were selected for thiabendazole: one for females 13+ and the other for the general U.S. population. A developmental toxicity study was used to establish the acute dietary endpoint for females 13+. The endpoint (NOAEL of 10mg/kg/day) was based on decreased fetal body weight gains presumed after a single dose of thiabendazole. The LOAEL is 40mg/kg/day. The acute dietary endpoint selected for the general U.S. population was based on a developmental rat study as well. The endpoint (NOAEL of 10mg/kg/day) for the general U.S. population was based on decreased maternal body weight gain seen during the gestation period. The LOAEL is 40mg/kg/day.

c. Chronic (non-cancer) Dietary Endpoint

The chronic dietary endpoint (NOAEL of 10mg/kg/day) was based on decreased body weight gains and liver hypertrophy at the LOAEL of 30mg/kg/day. Reduced body weight gains for the mid and high dose males and high-dose females, respectively, compared to the controls were observed at week 103. A reduced body weight gain was also noted at this time for the mid-dose females.

d. Chronic (cancer) Dietary Endpoint

In accordance with the Cancer Assessment Review Committee, a non-linear, MOE approach was used to characterize human health risk. A chronic toxicity/carcinogenicity study in rats was used. Male rats had significant increasing trends for thyroid follicular cell adenomas and combined adenomas/carcinomas, and significant differences in the pair-wise comparisons of the 90mg/kg/day dose group. There were also significant differences in the pair-wise comparisons of the 30mg/kg/day dose group with controls. Female rats had significant increasing trends in thyroid follicular cell adenomas and combined adenomas/carcinomas. The study demonstrated that thiabendazole induces thyroid adenomas in male rats at dosages of > 30 mg/kg/day. (Point of Departure (POD) = 10mg/kg/day). The systemic LOAEL is 30mg/kg/day and is based on reduced body weight and reduced body weight gains and liver hypertrophy. The systemic NOAEL is 10mg/kg/day.

e. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X based on the following factors: first, the toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment.

Second, the Agency believes that its exposure assessments will not underestimate the potential risk for infants and children from thiabendazole. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

2. Hazard Determination

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). The RfD is an estimated level of daily exposure to a pesticide residue which, over a 70-year human life span, is believed to have no significant deleterious effects. Where the FQPA SF has been removed (equivalent to 1X), the acute or chronic RfD is equivalent to the acute or chronic PAD. In the case of thiabendazole, the FQPA safety factor has been removed (equivalent to a factor of 1X) for the acute and chronic dietary assessments.

a. Acute PAD

Reference doses were established for the two acute dietary endpoints. For the first population subgroup (general U.S. population), an acute RfD of 0.1mg/kg/day was derived based on decreased maternal body weight seen during gestation at the NOAEL of 10 mg/kg/day in the developmental rat study, and an uncertainty factor (UF) of 100 (10x for interspecies extrapolation and 10x for intraspecies variation). The FQPA Safety Factor was removed (equivalent to a factor of 1X) for this population. Consequently, the acute PAD (aPAD) is numerically equivalent to the acute RfD at 0.1mg/kg/day for this population. For the second population subgroup (Females 13+), an acute RfD of 0.1mg/kg/day was derived based on decreased fetal body weight at the NOAEL of 10 mg/kg/day in the developmental rat study, and an uncertainty factor (UF) of 100. The FQPA was removed . Consequently, the acute PAD (aPAD) is numerically equivalent to the acute RfD at 0.1 mg/kg/day for this population.

b. Chronic (Non-cancer) PAD

A chronic (non-cancer) RfD of 0.1 mg/kg/day was derived based on a NOAEL of 10 mg/kg/day in the 2-Year Feeding/chronic carcinogenicity study in rats with an uncertainty factor of 100 (10x for interspecies extrapolation and 10x for intraspecies variation). The FQPA SF was removed (equivalent to a factor of 1X) for this population. Consequently, the chronic PAD (cPAD) is 0.1mg/kg/day.

c. Chronic (Cancer) MOE Approach

The Agency has classified thiabendazole as "likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance." This classification is by the oral route and recommends in accordance with the Cancer Assessment Review Committee, a non-linear, MOE approach to characterize the human health risk. This extrapolation is supported by the weight-of-the evidence which suggests that thiabendazole may

interfere with thyroid-pituitary homeostasis. Children are not expected to be more susceptible than adults.

3. Exposure Assumptions

Revised acute and chronic dietary risk analyses for thiabendazole were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91. For the acute dietary risk assessment, the entire distribution of single day food consumption events was combined with a distribution of residues. This is known as a (Monte Carlo) probabilistic analysis. Risk is reported at the 99.9th percentile of exposure to obtain a distribution of exposure in mg/kg/day. For the chronic dietary risk assessment, the three-day average of consumption for each sub-population is combined with average residues in commodities to determine average exposure in mg/kg/day. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) were used in the assessment. Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns.

4. Dietary Risk from Food

a. Acute Dietary Risk

Acute dietary risk was calculated considering what is eaten in one day and the entire distribution of residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's concern.

PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) were used in the assessment. Several commodities which had PDP monitoring data contained overtolerance residues. An analysis was conducted by lowering these overtolerance residue values to the tolerance for the given commodity. Non-blended food forms require decompositing the PDP composite residue values. Decompositing these values resulted in overtolerance residue values. Overtolerance values were set back to the tolerance. For partially blended food forms which do not require decompositing, the original overtolerance values were used as is since no clear pattern of tolerance violation was observed.

A Monte Carlo analysis was used to estimate acute dietary risk. The Monte Carlo analysis is a highly refined probabilistic risk assessment that takes an entire distribution of consumption events for individuals and multiplies it by a distribution of residues to obtain a distribution of exposures in mg/kg/day. Truncating decomposited PDP data at tolerance, and using mushroom field trial residues from the chemigation use, resulted in risk estimates below the Agency's level of concern. The risk estimate for children 1-6 years of age, the highest exposed population subgroup of concern, is 77% of the aPAD, and thus is not of concern. The results of the analysis are shown in Table 3 below.

Table 3. Acute Dietary risk (Food Only)

Subgroup	99.9th Percentile Probabilistic		99.9th Percentile Probabilistic (truncating at tolerance)		99.9th Percentile Probabilistic (using mushroom residues from chemigation only)		99.9th Percentile Probabilistic (truncating at tolerance and using mushroom residues from chemigation only)	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	%a PAD	Exposure (mg/kg/day)	% aPAD
Children 1-6 years of age	0.117065	117	0.100221	100	0.090203	90	0.076947	77
All infants (<1 year)	0.057494	57	0.056250	56	0.059941	60	0.056188	56
Females (13-50 years)	0.053284	53	0.048900	49	0.024184	24	0.025227	25

b. Chronic (Non-Cancer) Dietary Risk

Chronic (non-cancer) dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern.

Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) resulted in a maximum risk of 2% of the chronic PAD (cPAD) for children 1-6 years of age, the only subgroup of concern, and thus is not of concern. The results of the analysis are shown below in Table 4.

Table 4. Chronic (Non-Cancer) Risk (Food Only)

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.001026	1
All infants (<1yr)	0.001623	2
Children (1-6 yrs)	0.002120	2

c. Chronic (Cancer) Dietary Risk

In accordance with the Cancer Assessment Review Committee, the Margin of Exposure (MOE) approach was used to assess cancer dietary risk. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) were used in the assessment. The results of the chronic (cancer) dietary assessment indicate an MOE of 13,000 for the general U.S. population, with the deletion of the mushroom overspray use, and are below the Agency's level of concern.

5. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate of risk. To determine

the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether or not modeled or monitored concentrations exceed this level. Estimated environmental concentrations (EECs) that are above the corresponding DWLOC exceed the Agency's level of concern.

Since no thiabendazole water monitoring data were available, the EPA estimated thiabendazole concentrations with Tier I screening model, GENEEC for surface water sources, and SCI-GROW for groundwater sources. These models estimate levels of thiabendazole only, and not its degradates. The results used in both models were based on seeds treated at a maximum application rate of 3.6 oz ai/100lbs seed (0.2 lbs ai/A) and one application. Results of the acute and chronic drinking water assessments, EECs and DWLOCs are summarized in Tables 5 and 6.

a. Surface Water

For surface water, GENEEC was used to estimate peak (acute) and 56-day concentrations resulting from the use of treated wheat seeds planted in the field. Treatment to wheat seed is done indoors, but drinking water concern may arise since the treated wheat seeds are later planted in the fields. The GENEEC program uses basic environmental fate values and pesticide label information to estimate the EECs in a one-hectare, two-meter deep pond following the planting of the treated seeds in a 10 ha field. Seeds are treated indoor during storage, then later planted in the field. Based on the fate properties, if available in the field after planting, thiabendazole should not dissolve, but will predominantly move off-site on entrained sediments into surface water. When it reaches surface water, thiabendazole is not expected to persist, especially in shallow and clear water, as this chemical is extremely susceptible to direct photolysis (t ½ = 29 hours). The run-off event occurs two days after planting. GENEEC takes into account adsorption to the soil or sediment, degradation in soil before runoff, and degradation within the water body, then reports estimated concentrations of thiabendazole in surface water. It is not certain on how deep the seeds will be incorporated into the ground at planting. However, for this use, GENEEC assumes no seed incorporation. For surface water, GENEEC estimates a peak concentration of 2.4 ppb and an average 56 day concentration of 1.6 ppb. These results were based on the 3.6 oz ai/100 lbs, and 90 lbs of seed planted per one acre. It is important to note that estimations based on the typical application rate results in a much lower peak EEC (less than 0.2 ppb).

b. Ground Water

Ground water concentrations of thiabendazole were estimated using the SCI-GROW (Tier I) computer model. The extremely high soil-water partitioning coefficients K_d values of thiabendazole tend to reduce the potential for this chemical to leach through soils and contaminate ground water. This was confirmed in the terrestrial field studies, where no residues of this fungicide were detected in the layers deeper than 12 inches. Model simulations indicate less than 0.01 ppb of thiabendazole residues in ground water, based on a maximum application rate of 3.6 oz. ai/100lbs.

The results of both surface and ground water model estimates and their comparisons with the DWLOCs are summarized in Table 5. For more information on drinking water risks and the calculations of the DWLOCs, see the *Drinking Water Exposure section of the June 21, 2001 February 4, 1999 Revised Human Health HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document for Thiabendazole, as well as the Exposure Characterization section of the February 4, 1999 section of the EFED Reregistration document for Thiabendazole.*

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern. The Agency's default body weight and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), 30 kg/1L (child) and 10 kg/1L (infant).

The results of the Agency's drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the *Revised Health Effects Division (HED) Human Human Health Risk Assessment,"* dated June 21, 2001.

d. DWLOCs for Acute Exposure

Acute DWLOCs were calculated based on the acute dietary exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the acute DWLOCs for all subpopulations. The table below presents the calculations for the acute drinking water assessment.

Table 5. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb) (SCI-GROW)	Surface Water (ppb) (GENEEC)	DWLOC (ppb)
U.S. Population	0.1	0.057	0.043	0.01	2	1500
Females 13-50	0.1	0.053	0.047	0.01	2.4	1400
Children 1-6	0.1	0.76[1]	0.023	0.01	2	230

1 0.76 is amount of mg/kg/day with mitigation of mushroom over-spray.

The Agency has determined that the acute drinking water risk from the uses of thiabendazole is not of concern.

e. DWLOCs for Chronic Exposure

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the chronic DWLOCs, indicating that chronic exposure to thiabendazole in food and water is less than the Agency's level of concern. The EECs for groundwater (SCI-GROW) were less than the chronic DWLOCs, indicating that chronic exposure to thiabendazole in food and water is less than the Agency's level of concern. To calculate the chronic DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD. See Table 6.

Table 6. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb)	Surface Water (ppb) (GENEEC)	DWLOC (ppb)
U.S. Population	0.1	0.0010	0.099	0.01	0.5	3500
Females (13-50 yrs)	0.1	0.0009	0.099	0.01	0.5	3000
Children (1-6 years)	0.1	0.0021	0.098	0.01	0.5	3000

6. Residential (Homeowner) and Other Non-occupational Risk

Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Exposure from thiabendazole to adults and children can also occur from exposure to thiabendazole treated paints, carpets and textiles.

a. Residential Handler Risk

Table 7. Summary of Toxicological Endpoints and Other Factors Used in the Residential Risk Assessments for thiabendazole.

Assessment	Dose (mg/kg/day)	Endpoint	Study	Absorption factor
Short-term (dermal and inhalation)	NOAEL= 10 LOAEL= 40	Based on decreased fetal body weight	Oral Developmental Toxicity - Rat	60% -Dermal 100% - Inhalation
Intermediate- term dermal and inhalation	NOAEL=10 LOAEL= 40	Based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid	Fourteen Week Oral Toxicity (Feeding)	60% - Dermal 100%- Inhalation

Homeowner handler assessments are completed using a single scenario based on the use of short-sleeved shirts and short pants (i.e., common homeowner attire during the pesticide application season). In addition, only short-term exposures are assessed, as the Agency does not believe homeowners who apply paints that have been treated with thiabendazole will be exposed for more than seven days, see Table 7 and 8. Also, the Agency does not believe that homeowners exposed to thiabendazole treated carpets are at a risk since thiabendazole is applied to the backing of carpets during the manufacturing process and estimates are extremely

conservative. For homeowner handler exposure assessments, the Agency does not believe a tiered mitigation approach like that used for assessing occupational handler risk is appropriate. Homeowners often lack access to personal protective equipment (PPE) and also do not possess expertise in the proper use of PPE. Risk for this potentially exposed population is measured by a Margin of Exposure (MOE) which determines how close the residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

Due to thiabendazole's use profile, the Agency has concluded that there is a low potential for residential exposure. The low concentrations of thiabendazole incorporated in paints, adhesives, paper and carpet greatly reduces the potential for exposure.

Thiabendazole is used as a preservative in the backing of carpets and estimates used in the residential assessment overestimate actual exposure. In all cases, residential exposure is not expected to exceed occupational post-application exposure and therefore would not be expected to exceed the Agency's level of concern.

Table 8. Homeowner Uses: Risk Concerns*

Scenario	Acres	Rate	Short-Term MOE
Applying paints containing TBZ to surfaces, paintbrush	N/A	5 g/gal: 2gal/day	290

* Combined dermal & inhalation MOEs

b. Residential Post-application Risk

Thiabendazole can be used in carpets, paints, textiles and paper where exposure to adults and children may occur. Exposure may result from applying paint to homes, and sitting, laying or walking on carpets. As a result, both toddler, child, and adult risks were considered in the risk assessment. The calculated dermal and inhalation exposure was found to be within the following range: 100-1000 for adults, 59-590 for toddlers and 39-390 for infants.

7. Aggregate Risk

An aggregate risk assessment looks at the combined risk from exposure through both food, and drinking water, as well as from exposures to residential and other non-occupational sources (in this case, exposure to thiabendazole treated carpets and paints). Generally, all risks from these exposures must be less than 100% of the acute and chronic PADs to be considered acceptable to the Agency. For thiabendazole acute aggregate risk, chronic aggregate risk, short-term, intermediate-term and cancer aggregate assessments were completed. Results of the aggregate risk assessment are summarized here, and are discussed extensively in the document entitled, *"Thiabendazole and Thiabendazole salt: A revised HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document."* dated June 21, 2001."

a. Acute Aggregate Risk

The acute aggregate risk assessment considers a one-day oral exposure from food and water only. The estimated maximum peak concentrations of thiabendazole in surface water is 2.4 ppb which is below the Agency's DWLOC for all population subgroups. Therefore, acute aggregate risk estimates do not exceed the Agency's level of concern.

b. Short-term and Intermediate-term Aggregate Risk

Two short-term (1-7 days) and intermediate-term (1-6 months) exposure scenarios were identified for the adult populations: exposure to thiabendazole-treated carpet and paints treated with thiabendazole. These two scenarios were aggregated with the average dietary exposure since they can occur simultaneously. For infants and children, only the carpet exposure was aggregated with average dietary exposure. Estimated average concentrations of thiabendazole in surface and ground water are below the DWLOCs for thiabendazole in drinking water. Therefore, the Agency concludes with reasonable certainty that residues of thiabendazole in drinking water when considered with other sources of exposure would not result in unacceptable levels of aggregate exposure.

c. Chronic (Non-cancer) Aggregate Risk

The aggregate chronic dietary risk estimates include exposure to thiabendazole residues in food and water. No chronic residential use scenarios were identified (no contributions from paint residues were considered). Exposure from carpet may occur, however, this exposure is expected to dissipate over time. The aggregate chronic risk would be equal to or less than that calculated for short-term and intermediate-term aggregate risk. Exposure to combined residues of thiabendazole and its metabolites of toxicological concern based on a Tier 3 refinement using average residues from field trial and percent crop treated data represent 2% of the cPAD for the most highly exposed population subgroup (children 1-6 years of age and infants < 1 year). Exposure to all other sub-population groups represents 1% of the cPAD. The estimated average 56-day concentration of thiabendazole in surface water is 0.52 ppb. This estimated average is below the Agency's DWLOC for exposure to thiabendazole in drinking water. Therefore, chronic aggregate risk estimates do not exceed the Agency's level of concern.

d. Chronic (Cancer) Aggregate Risk

In accordance with the Cancer Assessment Review Committee, the Margin of Exposure (MOE) approach was used to assess cancer dietary risk. The results of the chronic (cancer) dietary assessment indicate an MOE of 13,000 for the general U.S. population, and is below the Agency's level of concern.

8. Occupational Risk Mitigation

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of thiabendazole include:

individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators. Risk for all of this potentially exposed population is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern. For occupational risk to thiabendazole, there are no long term or cancer exposure occupational scenarios.

9. Occupational Toxicity

The toxicity of thiabendazole is integral to assessing the occupational and residential risks. All risk calculations are based on the most current toxicity information available for thiabendazole, including a 21-day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for thiabendazole are listed below, in Table 9.

Table 9. Summary of Toxicological Endpoints and Other Factors Used in the Occupational Risk Assessments for thiabendazole.

Assessment	Dose (mg/kg/day)	Endpoint	Study	Absorption factor
Short-term dermal and inhalation	NOAEL = 10 LOAEL = 40	Based on decreased fetal body weights	Oral Developmental Toxicity - Rat	60% -Dermal 100%- Inhalation
Intermediate- term dermal and inhalation	NOAEL =10 LOAEL=40	Based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid	Fourteen Week Oral Toxicity (Feeding) Study	60%-Dermal 100%-Inhalation

Thiabendazole has low acute toxicity (Category III) and is neither irritating to the eyes or skin nor is a dermal sensitizer. Acute toxicity values are summarized below in Table 10.

Table 10. Acute Toxicity Profile for Occupational Exposure for Thiabendazole

Route of Exposure	Toxicity Category	MRID
Oral	III	41258201
Dermal	III	41258202
Inhalation	Waived	N/A
Eye Irritation	IV	40789806
Dermal Irritation	IV	40789807
Dermal Sensitizer	IV	40271701

a. Occupational Exposure

Chemical-specific exposure data were not available for thiabendazole. Baseline dermal and inhalation exposure assessments using PHED Version 1.1 surrogate data were use, see Table 11. For scenarios not covered by PHED, it was necessary to use data from studies found in the scientific literature so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments;

the application rates are derived directly from thiabendazole labels. The exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for thiabendazole, which is available in the public docket.

(1) Occupational Handler Risk

Occupational exposure scenarios include potential exposure to handler (mixers, loaders, applicators) during use or to persons entering treated sites after aplication is complete. thiabendazole is a fungicide formulated as a powder, dry flowable, or an emulsifiable concentrate. It is also used as a ready-to-use liquid for incorporation into paints, adhesives, textiles, and paper products. Field application of thiabendazole can be aerial (fixed wing or helicopter), ground boom, or by chemigation. Post-harvest application can be by dipping, spraying, or application during the waxing procedure for fruits and avocados. It can also be mixed with paints and adhesives or incorporated in the manufacture of textiles and carpeting.

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during ususal use patterns associated with thiabendazole. Based on the use patterns major exposure scenarios were identified for thiabendazole:

- planting potatoes
- observer on tractor planting potato seed pieces
- filling duster for potato seed treatment/cutting potato seed pieces
- manual seed treatment at farm
- commercial seed treatment
- mixing/loading for post harvest treatments
- exposure during post harvest handling of treated commodities
- applying paints containing thiabendazole to surfaces using a paintbrush
- applying paints containing thiabendazole to surfaces using an airless sprayer
- application to mushroom houses
- mixing/loading for mushroom houses
- post-application exposure to treated carpet, textiles, or paper
- tree injection

Table 11. Summary of Agricultural Risk Estimates for Short-term and Intermediate-term Exposure Scenarios

Exposure Scenario (Scenario #)	Baseline Daily Dose[a] (mg/kg/day)	Baseline MOEs[b]	Risk Mitigation Measures	
			Additional PPE[c]	
			Daily Dose[e] (mg/kg/day)	MOE[b]
Mixer/Loader Exposure and Dose Levels (includes Cutters for potato seed treatment)				
Filling duster for potato seed pieces, located outside facility (Rocky seed)	0.085	120	NA	NA
Filling duster for potato seed pieces, located outside facility (Clean seed)	0.045	222	NA	NA
Filling duster for potato seed pieces, located inside facility (Clean seed)	0.0078	1300	NA	NA
Cutting Potato Seed Pieces, Complete Operation Inside	0.0029	3400	NA	NA
Cutting Potato Seed Pieces, Cutter Inside and Duster Outside	0.00072	14000	NA	NA
Mixing/loading for post harvest treatment of commodities	0.011	910	NA	NA
Mixing/loading for mushroom treatment	0.030	333	0.0024	4200
Applicator Exposures and Dose Levels (includes Observer for Potato Treatment)				
Applying paints containing TBZ to surfaces, paintbrush	0.034	290	NA	NA
Applying paints containing TBZ to surfaces, airless sprayer	0.018	560	NA	NA
Planting potato seed pieces	0.0026	3800	NA	NA
Observer on tractor planting potatoes	0.0023	430	NA	NA
Manual seed treatment	0.18	56	NA	NA
Commercial seed treatment	No data[f]	No data[f]	No data[f]	No data[f]
Application to mushroom houses	0.13	77	0.089	112
Post Harvest and Post Application Exposures and Dose Levels				
Post harvest exposure during sorting/packing/culling	0.31	1600	NA	NA
Post application exposure to treated carpet, textiles, or paper - Adult	0.01-0.1[e]	100-1000	NA	NA
Post application exposure to treated carpet, textiles, or paper - Toddler	0.02-0.17	59-590	NA	NA
Post application exposure to treated carpet, textiles, or paper - Infant	0.03-0.26	39-390	NA	NA

a Baseline Daily Dose (mg/kg/day)=Baseline Daily Exposure (mg/day)/Body weight (70kg).
b Dermal MOE values calculated using the following equation: MOE = NOAEL (mg/kg/day), where dermal NOAEL=10.0mg/kg/day and an MOE of 100 is required.
c Additional PPE consists of a single layer of clothing and gloves
d Daily Dermal Dose (mg/kg/day) =[(Unit Dermal Exposure (mg/lb ai)* Max. App. Rate (lb ai/A) *Max. Treated)/Bod Weight (70kg)]
e Derived from a literature study.
f Exposure not expected to be as low as manual seed.

Exposure estimates derived in lieu of data are considered to be very conservative for the following reasons: (1) it was assumed that all of the thiabendazole on the treated surface could be transferred to the skin. The chemical is usually part of a wax matrix and quantitative transfer to the skin is unlikely; (2) the transfer coefficients for the hands were obtained from a field study in which contact with contaminated foliage was highly probable; a conveyor belt line would be unlikely to have such a high degree of contact (probably restricted to fingertips only). The MOE resulting from this scenario may be mitigated to a level of lesser concern by requiring additional PPE (double layer of clothing and chemical resistant gloves.) Provided that thiabendazole dermal exposures are mitigated for the above specified exposure scenario with PPE, MOEs for dermal/inhalation exposure/risk do not exceed the Agency's level of concern.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on thiabendazole labels range from 2 fluid ounces to 30 fluid ounces of active ingredient per acre in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight solid hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protective equipment (PPE) . The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest suite of protection is baseline. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation (PPE) are applied. If MOEs are still less than 100, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from thiabendazole activities include:

- Baseline PPE: Long-sleeved shirt and long pants, shoes and socks

  Label: "Wear protective clothing and rubber gloves when handling."

Short-term and Intermediate-term occupational scenarios have been presented for thiabendazole. Two short-term and intermediate-term scenarios require PPE to mitigate dermal risks from handling and/or applying thiabendazole-containing products. PPE is required to mitigate risk from dermal exposure during application in mushroom houses during the spawning stage. Also, manual seed treatment has been identified as an occupational use scenario with MOEs less than 100. The Agency believes that since this scenario is mostly non-existent, and has been replaced with commercial seed treatment practices this it should be removed from the label. The label language for manual seed treatment will be modified prohibiting its use.

One occupational scenario was not assessed by the Agency due to lack of TBZ-specific occupational data for this method of application: *Workers adding thiabendazole to paints and carpets*.

Nonetheless, the Agency has qualitatively considered whether exposure is likely and attempted to describe the level of risk from this scenario. For large paint operations, the addition of thiabendazole to paint is done by computerized mechanical equipment. Workers are only operating the computerized system and thiabendazole is added to the paint in an assembly line fashion. No exposure is expected during large operations. For small paint operations, thiabendazole is added to the paint can from water soluble bags. The paint is mixed in a kady mill mixer. Thiabendazole is added at the end of the mixing process. Based on the Agency's understanding of the smaller operations, workers are instructed to wear rubber aprons, gloves, goggles and a face shield. As such, the Agency does not have a risk concern for workers adding thiabendazole to paint.

b. Post-application Risk

Restricted-entry intervals (REIs) are calculated to determine the minimum length of time required following an application before workers are allowed to reenter a treated area. Entry restrictions are calculated to determine the minimum length of time required following an application before crop workers are allowed to reenter a treated area with or without the use of personal protective equipment to mitigate risks. REIs and entry restrictions are estimated in hours or days.

Currently, for thiabendazole, the labels state a restricted entry interval of 12 hours. Because thiabendazole is applied as a post-harvest dip for citrus, pome fruits, mango, bananas, papayas, and avocados, and used as a preservative in paints and adhesives, the Agency has concluded that there is a potential for occupational handler and post-application exposure risk. In the preliminary risk assessment, only one of four scenarios of post-application exposure resulted in an MOE that exceeded the Agency's level of concern: post-harvest exposure during sorting/packing/culling of fruit. Since the preliminary assessment, the Agency recalculated exposure numbers for this scenario based on transfer coefficiency information that was not available during the preliminary assessment. The newer data provided an MOE of 1600, well above the Agency's level of concern. Given the new MOE, no mitigation through the use of personal protective equipment will be necessary for this post-application scenario. Consequently, because the Agency does not believe there is significant risk for post-application exposures during sorting/packing/culling of fruit, the Agency believes that the minimum REI as established under EPA's Worker Protection Standards (WPS) for 12 hours, is sufficient to protect workers who may re-enter treated areas.

Occasionally, thiabendazole is applied as part of the manufacturing process for some paper products, canvas textiles, and incorporated into carpets. Again, the Agency has no data that addresses the potential exposure of these scenarios. Thiabendazole is applied during the manufacturing process. Carpet would most likely yield the highest exposure. The fungicide is applied via a trough during the manufacturing process to achieve a final level of 0.02-0.1% (paper), 0.05-0.3% (canvas), or 0.025-0.25% (nylon carpeting). These figures are based on a finished product weight. Since the Agency has no data that relates the weight of these products to the surface areas that would lead to potential exposure, scientific literature measuring exposures

of individuals performing activities on carpets following actuation of a total release fogger was used. The Agency acknowledges that extrapolation from this study is highly uncertain and requires several assumptions. For a thorough description of these assumptions and calculations see the document entitled, *"Revised Occupational and Residential Exposure Assessment and Recommendations for The Reregistration Eligibility Decision Document for Thiabendazole Incorporating Registrant and USDA Comments,"* dated September 14, 2000."

c. Human Incident Reports

The Agency has reviewed the OPP Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) databases for reported incident information for thiabendazole. Two of three reports in the Incident Data System on thiabendazole involve eye irritation. The Poison Control Center data for 1993-96 (400,000+ exposures to pesticides) contains nine exposures to thiabendazole (six adults, two children under 6, and one 6-19 year old). Only two of these exposures were reported to result in a minor medical outcome, 3 more were potentially minor or moderate but did not receive follow-up. Two had no symptoms and two had unrelated symptoms. Only two cases were seen in a health care facility and none was hospitalized. The California Department of Food and Agricultural data indicate that from 1982 through 1996, there were four cases of skin illness in packing/processing with thiabendazole.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For a detailed discussion of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division (EFED) chapter, dated February 4, 1999, available in the public docket, and on the internet at www.epa.gov/pesticides . EPA issued its preliminary environmental risk assessment for thiabendazole in February 1999. In response to comments and studies submitted to the Agency, the risk assessment was updated and refined.

1. Environmental Fate Characterization

a. Fate in Soil

Thiabendazole is quite stable to photolysis in soil and to hydrolysis. It does not metabolize significantly in soils, under aerobic and anaerobic conditions. Although it is shown to be quite persistent in the environment, the Agency believes that thiabendazole will strongly bind to soil due to its high soil/water partitioning coefficients, thus limiting the amount available for leaching into ground water and for runoff into surface water. Three degradates were identified in the aqueous photolysis study (benzimidazole-2-carboxamide as a major degradate; benzimidazole and benzimidazole-2-carboxylic acid as minor degradates), two minor degradates in the aerobic soil (bendimidazole) (see below). The only degradate that was analyzed for in the terrestrial dissipation studies is benzimidazole, since it is the major metabolite in a soil study (anaerobic soil metabolism). Test results showed that benzimidazole was not detected in any soil layers.

b. Fate in Water

Thiabendazole photodegrades in water. Thiabendazole, in aqueous pH 5 buffer solution exposed to xenon lamp for 96 hours at 25ºC, undergoes rapid photolytic degradation, with a half life of approximately 29 hours. Photodegradation involves primarily the structural alteration of the thiazole ring.

c. Persistence and Bioconcentration

Thiabendazole appears to be extremely persistent in the environment. Extrapolated half-lives ranged from 833-1100 days in cropped plots and from 1093-1444 days in bare-ground plots. There was some trace levels of parent thiabendazole (up to 0.033 ppm; detection limit 0.01 ppm) in the 6-12 inch soil depth in the study conducted on loamy sand soil cropped with wheat (Washington) and on sandy loam soil with studies in Illinois.

d. Mobility

Based on the organic carbon normalized Freundlich values and the McCall's Mobility Classification Scale, thiabendazole appears to have some mobility in sand (Koc=1104 mg/L), silt loam (Koc=1813 mg/L), and sandy loam (Koc=3993 mg/L), but shows no mobility in clay (Koc=22470 mg/L). The Freundlich adsorption coefficients (Kd's) are 2.76 mL/g in sand (0.25%OC), 15.97 mL/g in sandy loam (1.2%OC), 21.75 mL/g in silt loam (1.2%OC), and 269.6 mL/f in xlY (1.2%ox). The desorption coefficients are 8.15 mL/g in sand, 19.46 mg/L in sandy loam, 16.03 mg/L in silt loam, and 219.9 mL/g in 36 clay. No degradate was observed.

2. Drinking Water Assessment

Thiabendazole should be of minimal threat to drinking water resources, as most registered uses are indoors (i.e. use on mushrooms, and seeds) where leaching into ground water and runoff to surface water is not likely to occur. The Agency believes that thiabendazole use will not present any significant contamination to either surface water or ground water, and therefore, is not of concern.

3. Aquatic Exposure and Risk Assessment

The GENEEC program uses basic environmental fate values and pesticide label information to estimate the EECs in a one-hectare, two-meter deep pond following the planting of the treated seeds in a 10 ha field. The runoff event occurs two days after planting. GENEEC takes into account adsorption to the soil or sediment, degredation in soil before runoff, and degradation within the water body, then reports estimated concentrations of thiabendazole in surface water. It is not certain on how deep the seeds will be incorporated into the ground at planting. However, for this use, GENEEC assumes no seed incorporation and a maximum seed treatment rate of 3.6 oz ai/100lbs to derive a conservative estimation. The EECs also assume that thiabendazole is fully dissociated from the coats of the treated seeds after planting, and that there is no spray drift.

a. Risks to Fish and Aquatic Invertebrates

. The Agency compares risk quotients (RQs) to levels of concern (LOCs) to assess the potential for adverse acute and chronic effects to aquatic organisms. A presumption of risk occurs when an RQ equals or exceeds an LOC. The RQ is determined as follows:

RQ = EEC/toxicity value

For thiabendazole, the lowest LC_{50} (rainbow trout) is >0.1ppm but <1ppm, therefore thiabendazole has been categorized as highly toxic to freshwater fish. The LC_{50} for mysid shrimp, the most sensitive species, is in the range of 0.1 to 1ppm, therefore thiabendazole is categorized as highly toxic to estuarine/marine invertebrates on an acute basis. No acute or chronic LOC is exceeded for freshwater fish from a maximum seed treatment application on wheat. No acute or chronic LOC is exceeded for freshwater invertebrates from a maximum seed treatment application on wheat. The acute LOC is not exceeded for estuarine/marine fish from a maximum seed treatment application on wheat. Also, the acute LOC is not exceeded for estuarine/marine invertebrates from a maximum seed treatment application on wheat.

Table 12: Risk Quotients for Freshwater Fish*

Site	Appl. Rate (lb ai/A	Peak EEC (ppb)	56-Day Avg. ECC (ppb)	Acute RQ (EEC/LC_{50}	Chronic RQ (EEC/MATC)
Wheat Seed Treatment	0.2	2.4	1.6	0.004	0.13

* Based on Rainbow Trout LC_{50} of 560ppb and NOEC of 12 ppb.

Table 13: Risk Quotients for Aquatic Invertebrates*

Site	Appl. Rate	Initial EEC (ppb)	21-Day Avg. EEC (ppb)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC)
Wheat Seed treatment	0.2	2.4	2.0	0.003	0.05

* Based on Water Flea EC_{50} of 850 ppb and Chronic NOEC of 42 ppb.

b. Risk to Aquatic Plants

Aquatic plant testing is normally required for any pesticide that has outdoor, non-residential terrestrial uses that may move off-site by run-off and/or by drift. However, with thiabendazole, since the only outdoor use is as a seed treatment and minimal contamination of surface water is expected, aquatic plant testing is not required.

4. Terrestrial Exposure and Risk Assessment

Typically, birds and mammals can be exposed to pesticides applied as foliar sprays or granulars by a variety of routes, including ingestion, dermal contact, and inhalation. For thiabendazole, which is applied indoor as a seed treatment for wheat, exposure to wildlife is not relevant until treated seeds are planted back in the fields. Then, ingestion might become a route of exposure, as seed eating birds and small granivorous mammals uncover and consume the

treated seeds. It is uncertain how deep the seeds will be incorporated into the ground, however, if the seeds were planted deep into the ground, threat to wildlife would be insignificant. Applications to and treatment of mushrooms are also indoor uses, and therefore are of minimal danger to birds and mammals. Exposure of terrestrial wildlife from direct injection of thiabendazole and its salt into trees may occur but is also expected to be a minimal means of exposure.

a. Risks to Birds and Small Mammals

Thiabendazole is practically non-toxic to birds. (LD_{50}s exceed 2000 mg/kg). Acute risk for birds is not expected from the use of thiabendazole as a seed treatment for wheat or any other crop. Chronic risk for birds is not expected, and chronic exposure should be minimal from a seed-treatment use. In a chronic avian reproduction study it was indicated that chronic toxicity is not likely. In a small mammal study using rats (oral study), thiabendazole was practically non-toxic. LD_{50} values exceeded 2000 mg/kg. Avian reproduction studies on the northern bobwhite quail and mallard duck yielded results that show thiabendazole having no adverse effects on avian reproduction.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing thiabendazole as an active ingredient.

The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing thiabendazole. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of thiabendazole and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Based on a review of these data and public comments on the Agency's assessments for the active ingredient thiabendazole, EPA has sufficient information on the human health and ecological effects of thiabendazole to make decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that products containing thiabendazole are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V.

Based on its evaluation of thiabendazole, the Agency has determined that thiabendazole and thiabendazole salt products, labeled and used as specified in this document, would not present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of thiabendazole.

If all changes outlined in this document are incorporated into the labels, then all current risks for thiabendazole will be mitigated. Certain uses of the chemical do not present risks of concern; therefore, no label changes or amendments to the FIFRA registration are necessary at this time.

If the Agency determines that any of the determinations described in this RED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this RED.

B. Tolerance Reassessment

Based on the review of the generic data for thiabendazole, the Agency has sufficient information to reassess tolerances for thiabendazole. Specific findings are discussed in the following section. When making its reregistration decision, the Agency took into account all comments received during the public comment period. These comments in their entirety are available in the docket. A summary of the comments and the Agency response is noted in Appendix J.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with thiabendazole.

EPA has determined that risk from exposure to thiabendazole is within its own "risk cup." In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to thiabendazole "fit" within the individual risk cup. Therefore, the thiabendazole tolerances remain in effect and unchanged.

b. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for thiabendazole, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered all available information on the toxicity, use practices, and scenarios, and the environmental behavior of thiabendazole. The only residential exposure to thiabendazole would be through the use of thiabendazole treated paints and carpets. There are no other possible homeowner uses. Therefore, EPA has considered only acute, chronic (non-cancer), and chronic (cancer) exposures for dietary (food and drinking water) and short-term and intermediate non-occupational exposure in its aggregate risk.

Aggregate Dietary Risks: Acute and Chronic: Acute and chronic non-cancer dietary risks (food and water) are not of concern for any population subgroup, and no additional mitigation is necessary.

Short-term and Intermediate-term Aggregate Risks: Short-term and intermediate-term risks include exposure to food, water and short-term and intermediate-term non occupational risks. The two short-term and intermediate-term risks identified are not of concern to the Agency, and no mitigation is necessary.

c. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for thiabendazole, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of thiabendazole residues in this population subgroup.

The FQPA Safety Factor was reduced to 1X based on the following factors: first, the toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. Second, the Agency believes that its exposure assessments will not underestimate the potential risk for infants and children from thiabendazole. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

d. Endocrine Disruptor Effects

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

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, thiabendazole may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

The Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's resides and "other substances that have a common mechanism of toxicity." The Agency is examining whether and to what extent benzimidazole fungicidal pesticides share a common mechanism of toxicity. Current information on the common mechanism of toxicity for benzimidazole fungicides is limited, and the Agency's understanding of this relationship needs to be further developed. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other benzimidazole fungicides or carcinogenic chemicals. Therefore, for the purposes of this risk assessment, the Agency has assumed that thiabendazole does not share a common mechanism of toxicity with other benzimidazole or carcinogenic chemicals.

D. Tolerances Summary

In the assessment, tolerances for residues of thiabendazole in/on plant commodities and mushrooms [40 CFR §180.242 (a)] are presently expressed as the combined residues of thiabendazole and 5-hydroxy-thiabendazole in animal commodities [40 CFR § 180.242 (b)]. For purposes of tolerance enforcement, thiabendazole residues of concern have been determined to include thiabendazole and its metabolite bendizmidazole (free and conjugated) in plant commodities. For animal commodities, thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole have been determined to be the residues of concern in animals. Accordingly, the tolerance definition for thiabendazole residues listed under 40 CFR 180/242 (a) will be amended to read as follows:

> Tolerances are established for the combined residues of thiabendazole [2-(4-thiazolyl) bendimidazole] and its metabolite benzimidazole (free and conjugated) in or on the following raw agricultural commodities:

In addition, the tolerance definition for thiabendazole residues in animal commodities listed under 40 CFR 180.242 (b) will be amended to read as follows:

> Tolerances are established for the combined residues of thiabendazole [2-(4-thiazolyl) benzimidazole] and its metabolite benzimidazole (free and conjugated) and benzimidazole in or on the following raw agricultural commodities.

1. Tolerances Listed Under 40 CFR § 180.242(a)

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for thiabendazole residues in/on apples, bananas, carrots, citrus fruits, mushrooms, papayas, pears and potatoes. Additional data are required for cantaloupe, sweet potato, wheat grain, wheat straw, soybean, and strawberry before the existing tolerances can be reassessed.

Based on the current use patterns and the available residue data, the established tolerances are adequate for thiabendazole residues in/on bananas, carrots, citrus fruits, mushrooms and potatoes. However, additional storage stability data are required to support the sweet potato field trial data. Available data indicate the established tolerance should be increased to 0.05 ppm on sweet potatoes.

2. Tolerances Listed Under 40 CFR § 180.242(a) to be Revoked

The tolerances for thiabendazole residues in banana pulp should be revoked since banana is not a regulated commodity. Tolerances should be revoked for thiabendazole residues in /on sugar beet RACs and processed fractions, grapes, rice RACs and processed fractions, and hubbard squash since uses on these crops are not being supported by the registrant, Syngenta. Tolerances for residues in dried citrus pulp, potato processing waste, and wheat milled fractions should all be revoked since thiabendazole residues do not concentrate in potato, wheat processed fractions, dried citrus pulp in excess of the tolerance on whole citrus fruits. Under the New Tolerance Section below, once a tolerance is established for residues in/on pome fruits, the separate tolerances on apples and pears should be revoked.

3. Tolerances Listed Under 40 CFR § 180.242(b)

Sufficient data are available to reassess tolerances for thiabendazole residues in animal commodities. Although benzimidazole, which is a residue of concern in animals, was not determined in the feeding studies, data from the animal metabolism studies will be used to calculate residue levels of benzimidazole in animal commodities for purposes of tolerance reassessment and risk assessment. In addition, data from the ruminant feeding study were used to reassess tolerances in hogs.

The tolerances for meat of cattle, hogs, horses, goats, and sheep will be retained at 0.1 ppm to harmonize with Codex. Based on the aforementioned data, tolerances for thiabendazole residues in meat by products of cattle, horses, goats, and sheep should be increased to 0.4 ppm and that the tolerance for residues in hog, meat by products should be increased to 0.3 ppm. The tolerance for thiabendazole residues in milk should be decreased to 0.1 ppm based on the data as well.

4. Tolerances listed under 40 CFR § 180.242(b) to be Revoked

Based upon the maximum dietary burden for poultry (0.16 ppm) and data from the poultry feeding study, tolerances for residues in poultry meat, meat by products, and eggs should be revoked. In addition, based on the maximum dietary burden for beef cattle (37.6 ppm) and swine (5.1 ppm) and the data from the ruminant feeding study, tolerances for residues in fat of cattle, hogs, hoses, goats, and sheep should be revoked.

5. New Tolerances to Be Established under 40 CFR § 180.242 (a)

New tolerances are needed for thiabendazole residues in/on wet apple pomace (12.0 ppm), citrus oil (15.0 ppm), pome fruits (5.0 ppm based on group crop), and wheat forage and hay. At the present time, sufficient data are only available to determine appropriate tolerances for residues in wet apple pomace and citrus oil. Residue data are required before an appropriate tolerance can be determined for residues in/on wheat forage and hay. A summary of thiabendazole tolerance reassessments is presented in Table 14.

Table 14. Tolerance Reassessment for Thiabendazole

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR § 180.242 (a)			
Apples (post-h)	10.0	Revoke	Concomitant with establishing a 5.0 ppm tolerance on Pome fruits, the tolerance on apples should be revoked
Avocados	10.0	10	Registrant is supporting avocado for import only. *Avocado*
Banana (pre&post-h)	3.0	3.0	*Banana*
Banana, pulp	0.4	Revoke	Banana pulp is not a regulated commodity of banana.
Banana, pulp (post-h)	0.4		
Beans, dry	0.1	0.1	Numerous SLNs registered. *Beans, dry*
Beets, sugar, pulp, dehydrated	3.5	Revoke	Technical Registrant is not supporting use.
Beets, sugar, pulp, dried	3.5	Revoke	Technical Registrant is not supporting use.
Beets, sugar, tops	10.0	Revoke	
Beet, sugar, without tops	0.25	Revoke	
Cantaloupes (post-h)	15.0	TBD	Registrant is supporting cantaloupe for import only.
Carrots (post-h)	10.0	10.0	*Carrot*

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment/ *[Correct Commodity Definition]*
Citrus fruits (post-h)	10.0	10.0	*Fruit, citrus, group*
Citrus, pulp, dried (post-h)	35.0	Revoke	Data indicate that thiabendazole residues do not concentrate in dried pulp in excess of the 10 ppm tolerance established in/on whole fruit.
Grapes	10.0	Revoke	No registered uses on grapes
Lentils	0.1	Revoke	Temporary tolerance expired 10/31/98
Mangos	10.0	10.0	Registrant is supporting mango for import only. *Mangos*
Mushrooms	40.0	TBD	*Mushroom*
Papayas (post-h)	5.0	5.0	Registrant is supporting papaya for import only. *Papaya*
Pears (post-h)	10.0	Revoke	Concomitant with establishing a 5.0 ppm tolerance on Pome fruits, the tolerance on pears should be revoked.
Potatoes (pre-&post-h)	10.0	10.0	*Potato*
Potatoes, processing waste (pre-&post-h)	30.0	Revoke	Data indicate that thiabendazole residues do not concentrate in potato processed commodities.
Rice, rough	3.0	Revoke	Technical Registrant is not supporting this use.
Rice, straw	10.0	Revoke	
Rice, hulls	8.0	Revoke	
Soybeans	0.1	TBD	Registrant is supporting seed treatment only. *Soybean, seed*
Squash, hubbard	1.0	Revoke	No registered uses on squash.
Strawberries	5.0	TBD	Registrant is supporting strawberry for import only. *Strawberry*
Sweet potatoes (post-h to SP intended only for use as seed)	0.02	0.05	Residue data support a higher tolerance. *Sweet potato, roots*
Wheat, grain	1.0	TBD	Residue data support a lower tolerance.
Wheat, straw	1.0	TBD	Residue data support a lower tolerance
Wheat, milled fractions (excluding flour)	3.0	Revoke	Data indicate that thiabendazole residues do not concentrate in wheat processed commodities
Tolerances listed under 40 CFR § 180.242 (b):			
Cattle, meat	0.1	0.1	A category 40 CFR180.6(a)(3)[1] situation exists for the potential of thiabendazole resiudes in meat and fat of livestock.*
Cattle, fat	0.1	Revoke	
Cattle, meat byproduct	0.1	0.4	Residue data indicate that the tolerance should be increased. *Cattle, meat by products*

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment/ *[Correct Commodity Definition]*
Milk	0.4	0.1	Tolerance should be lowered based on data from ruminant feeding study
Hog, meat	0.1	0.1	A category 40CFR180.6(a)(3)[1] situation exists for the potential of thiabendazole residues in meat and fat of livestock
Hog, fat	0.1	Revoke	
Hog, meat byproduct	0.1	0.3	Residue data indicate that the tolerance should be increased. *Hog, meat byproducts*
Horse, meat	0.1	0.1	A category 40 CFR180.6(a)(3)[1] situation exists for the potential of thiabendazole residues in meat and fat of livestock.
Horse, fat	0.1	Revoke	
Horse, meat byproduct	0.1	0.4	Residue data indicate that the tolerance should be increased. *Horse, meat byproducts*
Goat, meat	0.1	0.1	A category 40CFR180.6(a)(3)[1] situation exists for the potential of thiabendazole residues in meat and fat of livestock.*
Goat, fat	0.1	Revoke	
Goat, meat byproduct	0.1	0.4	Residue data indicate that the tolerance should be increased. *Goat, meat byproducts*.
Sheep, meat	0.1	0.1	A category 40 CFR180.6(a)(3)[1] situation exists for the potential of thiabendazole residues in meat and fat of livestock.
Sheep, fat	0.1	Revoke	
Sheep, meat byproduct	0.1	0.4	Residue data indicate that the tolerance should be increased. *Sheep, meat byproducts*
Poultry, meat byproduct, and meat	0.1	Revoke	A category 40 CFR180.6(a)(3) situation exists for the potential of thiabendazole residues in poultry commodities.
Eggs	0.1		
Tolerances Needed Under 40 CFR § 180.242(a)			
Apple, wet pomace	None	12.0	Based on a 3.5x concentration factor for wet apple pomace and HAFT residues of 3.4 ppm in/on apples
Citrus, oil	None	15.0	Based on an average 2.4x concentration factor for citrus oil and HAFT residues of 5.2ppm in/on citrus fruits
Fruit, pome, group	None	5.0	Residue data support establishing a 5.0 ppm tolerance on pome fruits; the separate tolerances on apples and pears should be revoked
Wheat, forage and Wheat, hay	None	TBD	Data are required on thiabendazole residues in/on wheat forage and hay.

* Tolerances in meat of cattle, goats, hogs, horses, and sheep are being retained to harmonize with Codex.

TBD To be determined

1 Based on animal metabolism studies (i.e. exaggerated feeding studies) these tolerances can be recommended for revocation because they are no longer needed. When EPA establishes tolerances for residues in or on raw agricultural commodities, consideration must be given to the possible residues of those pesticides in meat, milk, poultry, and/or eggs produced by animals that are fed agricultural products containing pesticide residues.40CFR180.6(a)(3).

6. Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiabendazole in/on various fruit, vegetable and animal commodities. Codex MRLs for thiabendazole are currently expressed in terms of the parent for plant commodities and in terms of the sum of parent and 5-hydroxy-thiabendazole for animal commodities. Once the tolerance expressions for U.S. tolerances are modified to include residues of benzimidazole, the U.S. tolerance definition will no longer be compatible with Codex. The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

(I) Once the U.S. tolerance definition is changed to include benzimidazole, the definitions of the U.S. tolerances and Codex MRLs will be incompatible.

(II) The MRLs for banana, cereal grain, citrus fruits and milk are the only MRLs that are numerically equivalent to the reassessed U.S. tolerances.

7. Residue Analytical Methods

Adequate analytical methods are available for data collection and enforcing tolerances of thiabendazole residues as currently defined. The Pesticide Analytical Manual (PAM) Vol. II which lists several methods for determining residues of thiabendazole *per se* in or no plant commodities and one method for determining residues of thiabendazole and 5-hydroxy-thiabendazole in milk.

The registrant has proposed new HPLC/flouorometric detection methods for determining residues of benzimidazole (free and conjugated) in/on plant commodities and residues of thiabendazole, 5-hydroxy-thiabendazole (free and conjugated), and benzimidazole in animal commodities. These methods are similar to the current enforcement methods. However, the new methods employ additional clean-up procedures and utilize HPLC/fluorescence detection for separating and quantifying residues.

E. Human Health Risk Mitigation

The following is a summary of the rationale for managing risks associated with the current use of thiabendazole. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Dietary Risk Mitigation

a. Acute Dietary (Food)

The acute dietary risk for thiabendazole is below the Agency's level of concern for the U.S. general population and all population subgroups, including infants and children at the 99.9th percentile. The most highly exposed subgroup is children 1-6 years of age with 77% of the acute

Population Adjusted Dose (aPAD) occupied. The preliminary dietary risk assessment for thiabendazole indicated that the acute dietary risk was above the Agency's level of concern for children 1-6 years old (aPAD 117%). Mushroom overspray application was driving the risk. Since that time, the registrant, Syngenta, has canceled the overspray mushroom application of thiabendazole which has reduced the aPAD to 77%. Given this amendment, the acute dietary risk is no longer of concern to the Agency, and no mitigation is necessary.

b. Chronic (Non-cancer) Dietary (Food)

Chronic (non-cancer) dietary risk is also not of concern. Chronic (non-cancer) dietary risk for the most exposed population subgroups, all infants (<1 year) and children 1-6 years of age, is 2% of the chronic Population Adjusted Dose (cPAD). These risks are not of concern; therefore, no mitigation measures are necessary to address chronic dietary risk from food.

c. Chronic (cancer) Dietary

In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment, the Cancer Assessment Review Committee has classified thiabendazole as "likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormonal balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance." Thus, after carefully weighing expected exposure authorized under EPA label requirements, current registered use patterns and allowed dietary exposure from imported crops for thiabendazole are not likely to cause cancer. This classification was derived by the oral route. An MOE approach was used and is supported by the weight-of-the-evidence that suggests that thiabendazole may interfere with thyroid-pituitary homeostasis. The study evaluated was a 106-week chronic toxicity/carcinogenicity study in Sprague-Dawley rats. Male rats had significant increasing trends for thyroid follicular cell adenomas and combined adenomas/carcinomas, and significant comparisons of the dose group and the control group (90mg/kg/day). There were also significant differences in the pair-wise comparisons of the 30mg/kg/day) dose group for thyroid follicular cell adenomas. In light of the systemic effects observed, dosing was considered adequate for assessing the carcinogenic potential of thiabendazole in rats. The Cancer Assessment Review Committee concluded that thiabendazole was carcinogenic in male and female rats at high doses because treatment related increased incidence of thyroid follicular cell adenomas was noted at high-dose male rats and mid-dose male rats, and high-dose female rats. Thyroid tumors were considered to be treatment related due to the progressive nature of the tumor and evidence of dose response. The weight-of-the-evidence indicates that thiabendazole may interfere with thyroid-pituitary homeostasis at high doses. The Agency concluded that the thyroid tumors in male and female rats were treatment related.

Thyroid cancer is a rare condition in the United States, occurring with an incidence of about 4% per year of the population (based on 1997 statistics). The incidence is predominant in older persons. In children it occurs at a rate of 1 per million. Therefore, it does not appear that the young have a propensity for thyroid cancer. The basic elements of thyroid function and hormone homeostasis are the same in children and adults. In the case of thiabendazole, the oral

perinatal and prenatal studies revealed no evidence of increased susceptibility of rat, rabbit or mouse fetuses to *in utero* exposure. Therefore, based on the mode of action of thiabendazole, children are not expected to be more susceptible than adults. The mode of action of thiabendazole in animals, to the extent that it is applicable to humans, appears equally applicable to human subpopulations. Therefore, children are not expected to be more susceptible to thiabendazole-induced thyroid effects than adults. In conclusion, after careful examination of the data, and expected exposure authorized under EPA label requirements and imported food, current registered use patterns for thiabendazole are not likely to cause cancer.

d. Dietary (Drinking Water)

Model estimates (EECs) of potential drinking water exposure from ground water sources do not exceed the acute or chronic (non-cancer and cancer) DWLOC values, and therefore, are not of concern. Potential drinking water exposure does not exceed acute or chronic (non-cancer or cancer) DWLOC values, and is therefore not of concern to the Agency. No mitigation measures are necessary to address drinking water dietary concerns.

2. Non-occupational Risk Mitigation

a. Non-occupational Non-cancer

The only non-occupational exposure expected to occur may include short-term application of thiabendazole-treated paints by adults and exposure to thiabendazole-treated carpets by children and infants. There are no exposure data for thiabendazole for these use patterns. Therefore, the Agency used either surrogate data from the scientific literature, PHED and/or modeling techniques for all of the exposure scenarios. Use information, for this reason, should be considered to be very conservative. For all exposure scenarios: it was assumed that all of the thiabendazole on the treated surface could be transferred to the skin. The chemical is part of a wax matrix and quantitative transfer to the skin is unlikely. In addition, with thiabendazole-treated paints, the material is dispensed from either a hand-operated pump or in the form of a pouch, and is mixed during formulation of the paint. The scenario is closed and is expected to yield no appreciable post application exposures. The carpet exposure estimates were taken from a spray study, and not a product that was treated during manufacture. MOEs for exposure to thiabendazole-treated paints ranged from 290-560. The target MOE is 100 for all occupational exposure scenarios. Since the MOEs (290-560) for exposure to thiabendazole-treated paints are higher than the target MOE of 100 (an MOE of 100 or greater indicates a level in the acceptable range for exposure) this risk is not of concern to the Agency, and no mitigation is necessary. With carpet exposure, the MOEs range from 100-1000 for adults; 59-590 for toddlers; and 39-390 for infants. Since the exposure estimates were derived from a surrogate surface spray study (thiabendazole is treated to the backs of carpets), and estimates assume that ALL residues on the surface of the material are available for transfer; and because residues measured were surface only, the Agency believes that use information should be considered extremely conservative. Therefore, the Agency believes that the risks are an overestimation and no mitigation is necessary.

b. Non-occupational Cancer

The Agency did not identify any non-occupational cancer risk scenarios and therefore, no mitigation is necessary.

3. Aggregate Risk Mitigation

a. Acute Aggregate Risk

Estimated acute risk for thiabendazole for food is 77% of the aPAD for children 1-6 years of age, and surface and ground water acute EECs are below the DWLOC for all population subgroups. Thus, acute risk from food and water is not of concern and no mitigation is necessary.

b. Short-term and Intermediate-term Aggregate Risk

Two short-term and intermediate-term exposure scenarios were identified for the adult populations: exposure to thiabendazole-treated carpet and thiabendazole-treated paints. These two scenarios were aggregated with the average dietary exposure since they can occur simultaneously. Estimated average concentrations of thiabendazole in surface and ground water are below the DWLOCs for thiabendazole in drinking water. Thus, short-term and intermediate-term aggregate risk is not of concern and no mitigation is necessary.

c. Chronic (Non-cancer) Aggregate Risk

Chronic (non-cancer) aggregate risk for thiabendazole includes only food and water exposures. Estimated risks from food for the most highly exposed subgroup, children 1-6 years old, indicate that 2% of the cPAD is occupied by dietary (food) exposure and that surface and ground water EECs are below the chronic DWLOC for this population subgroup. Therefore, chronic (non-cancer) aggregate risks are not of concern, and no mitigation is necessary.

d. Chronic Cancer Aggregate Risk

In accordance with the Cancer Assessment Review Committee, the Margin of Exposure (MOE) approach was used to assess cancer dietary risk. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) were used in the assessment. The results of the chronic (cancer) dietary assessment indicate an MOE of 13,000 for the general U.S. population, with the deletion of the mushroom overspray use. A MOE of 13,000 means that potential exposures to humans is 13,000 times less than the exposure to rats at which no adverse effects were observed. The MOE is based on the results observed in a rat study where thiabendazole was shown to induce thyroid tumors in male rats and also based on mechanistic studies showing disturbance of the thyroid-pituitary homeostasis. Rats have also demonstrated an increased sensitivity compared to humans to thyroid induced tumors which adds an even greater comfort level to the significance of the calculated MOE. Children are not expected to be more susceptible to thiabendazole-induced thyroid effects than adults.

4. Occupational Risk Mitigation

a. Handler Exposure

There are potential occupational exposures to pesticide handlers via the dermal and inhalation routes when applying thiabendazole. Scenarios assessed and corresponding risk estimates are shown in Table 11. The footnotes indicate the level of protection (PPE) needed to bring the risk estimate to a level that is not of concern (MOE greater than 100). Currently, for thiabendazole, the labels state a restricted entry interval (REI) of 12 hours. The Agency does not believe there is significant potential for post-application exposure to thiabendazole based on application methods, timing and frequency. Therefore, the minimum Restricted Entry Interval (REI) as established under EPA's Worker Protection Standards (WPS) for 12 hours, is sufficient to protect workers who may re-enter treated areas.

(1) Spray Application to Mushroom Houses

Spray application to mushroom houses is identified as an occupational use with MOEs greater than 100. However, Syngenta has voluntarily canceled the overspray application of thiabendazole on mushrooms as of *October 10, 2001* in order to mitigate dietary risks to children 1-6 years of age. Although this eliminated the acute dietary risk concern, there still exists an occupational concern for the applicators. Therefore, the label language will be changed to specify chemical resistant gloves be worn while applying thiabendazole to mushroom houses during spawning only. No further mitigation is necessary.

(2) Manual Seed Treatment

Manual seed treatment has been identified as an occupational use with MOEs less than 100. However, manual seed treatment is virtually non-existent in current occupational operations. The Agency believes that since this scenario is mostly non-existent, and has been replaced with commercial seed treatment practices that it should be removed from the label. The label language will be modified prohibiting manual seed treatment.

(3) Post-Harvest Sorter/Packers/Culling of Fruit

The Agency recalculated exposure numbers for workers sorting/packing/culling fruit after harvest based on new transfer coefficiency information that was not available at the time of the preliminary risk assessment. The new data provided an MOE of 1600, well above the Agency's level of concern and therefore no additional risk mitigation is necessary for this scenario.

One occupational scenario was not assessed by the Agency due to lack of thiabendazole-specific occupational data: *Workers adding thiabendazole to paints and carpets*. For large paint operations, the addition of thiabendazole to paint is done by computerized mechanical equipment. Occupational workers are only operating a computerized system and thiabendazole is added to the paint in an assembly line fashion. No exposure is expected during this occupational scenario.

For small paint operations, thiabendazole is added to the paint from water soluble bags. The paint is mixed in a kady mill mixer. Thiabendazole is added at the end of the mixing process. The Agency has qualitatively considered whether exposure is likely and attempted to describe the level of risk from this scenario. Based on the Agency's understanding of the smaller operations, workers are instructed to wear rubber aprons, gloves, goggles and a face shield. Given the low toxicity of thiabendazole, and the small amounts used in paints, the Agency does not have a risk concern for workers adding thiabendazole to paints when the aforementioned personal protective equipment is used.

5. Environmental Risk Mitigation

Given that the currently registered use patterns (i.e. post-harvest uses and seed treatment) result in low exposures and the relatively low toxicity of thiabendazole, no environmental mitigation is necessary.

F. Other Label Statements

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing thiabendazole. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future *Federal Register* notice. The Agency is not requiring label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV and V, which include, among other things, submission of the following:

A. For thiabendazole technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

(2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

(1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Lorilyn M. Montford at (703) 308-8170 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
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Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Lorilyn M. Montford
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient thiabendazole, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

(2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

(3) five copies of the draft label incorporating all label amendments outlined in Table 11 of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-31);

(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

(6) the product-specific data responding to the PDCI.

Please contact Moana Appleyard at (703) 308-8175 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (PDCI/PRB)
Moana Appleyard
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Moana Appleyard
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of thiabendazole for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

(1) *In vitro* mammalian gene mutation(870.5300)
(2) *In vitro* chromosome aberration assay (870.5975)
(3) Chemical Identity: Revised CSF (830.1550)
(4) UV/visible absorption (GLN 830.7050)
(5) Multiresidue method testing (GLN 860.1360)
(6) Additional storage stability data for sweet potatoes (GLN 860.1380)
(7) Additional residue data for benzimidazole (free and conjugated in/on cantaloupe and strawberry for foliar application. (GLN 860.1500)
(8) Residue data on wheat, dry beans (if registrant intends to support), and soybeans (GLN 860.1500)
(9) Processing study for the processed fractions of soybeans (GLN 860.1520)

A draft copy of the generic data call-in (DCI), outlining specific data requirements, accompanies this RED.

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling should bear the labeling contained in Table 11 at the end of this section.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study master record identification (MRID) numbers should be cited according to the instructions in the requirement status and registrants response form provided for each product.

A draft copy of the product-specific data call-in (PDCI), outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 15 at the end of this section.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell thiabendazole products bearing old labels/labeling for 12 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

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

Table 15: Summary of Labeling Changes for Thiabendazole

Description	Amended Labeling Language	Placement on Label
Manufacturing-use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into fungicides for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements under the subheading Environmental Hazards
End-use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] (All Formulations)	"Personal Protective Equipment (PPE) "Mixers, loaders, applicators, and other handlers must wear: * long sleeve shirt and long pants * shoes, plus socks" "In addition to the above, handlers making applications to mushroom houses using hand held sprayers must wear chemical resistant gloves." (The glove statement is only required for products labeled for use on mushrooms)	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements (For All Products)	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	"Users should wash hands before eating, drinking, chewing gum, tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls
Environmental Hazards	"Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste."	Precautionary Statements under Environmental Hazards
Restricted Entry Interval (For products which include use on mushrooms)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry PPE Established by the RED. (For products which include use on mushrooms)	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical -resistant gloves made of any waterproof material."	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box.
Other Risk Mitigation Restrictions	Remove all manual seed treatment uses, and include the following statement: " Manual seed treatments are prohibited."	Directions for Use

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

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represent actions that the Registrant should take to amend their labels or product registrations.

IV. Appendicies

This Reregistration Eligibility Decision document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding federal holidays, from 8:30 am to 4:00 pm.

The docket initially contained preliminary risk assessments and related documents as of August 1, 2001. Sixty days later the public comment period closed. The EPA then considered comments, revised the risk assessment, and prepared the formal "Response to Comments" document and the revised risk assessment.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.epa.gov/pesticides/reregistration.

Appendix A. Thiabendazole Table of Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Use Limitations
Apples				
Post-Harvest Dip, Spray, Mist	42.3% [100-889]	16 fluid oz. per 100 gallons water	Subsequent dosing allowed	-Treat apples only before or after storage
Post-Harvest Wax Spray	.20% [2792-36	1 Gallon of coating per 10,000 Apples	One application per crop	-Do not contaminate water food or feed by storage or disposal
Post-Harvest Wax Spray; Spray	.20% [5202-17]	1 Gallon of coating per 8,000 to 10,000 lbs. of fruit	One application per crop	-Do not contaminate water, food or feed by storage or disposal
Post-Harvest Spray, Floodwater	98.5% [5202-23]	One Unit per 82.5 gallons water	One application per crop	-Do not contaminate water, food or feed by storage or disposal
Post-Harvest Spray, Flood, Wax, Drench or Slurry	98.5% [5202-26]	One Unit (594 grams) per 53 Gallons water	One application per crop	-Do not contaminate water, food or feed by storage or disposal
Post-Harvest Spray, Dip	98.5% [43410-7]	couldn't read label	One application per crop	-Do not contaminate water, food or feed by storage or disposal
Post-Harvest Mist, Drench, Spray	98.5%WP [43410-33]			
Pears				
Post-Harvest Dip, Spray, Mist	42.3% [100-889]	16 fluid oz. per 100 gallons water	Subsequent dosing allowed	Treat pears only once
Post-Harvest Spray	98.5% [5202-17]	1 Gallon of coating per 8,000 to 10,000 lbs. of fruit	One application per crop	-Do not contaminate water, food or feed by storage or disposal
Post-Harvest Mist, Drench, Spray	98.5% WP [43410-33]			
Post-Harvest Spray, Floodwater	98.5% WP [5202-23]	One Unit per 82.5 gallons water	One application per crop	-Do not contaminate water, food, feed by storage or disposal
Post-Harvest Spray, Flood, Drench or Slurry	98.5% [5202-26]	One Unit (594 grams) per 53 gallons of water	One application per crop	

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Use Limitations
Citrus				
Post-Harvest Dip	.10% [2792-35]	1 Gallon per 8 lbs. citrus	One application	
Post-Harvest Spray	98.5% WP [2792-50]	577 grams (1 bag) per 55 gallons of ready-to-use wax formulation	One application	
Post-Harvest Spray, Flood,	98.5% WP [5202-23]	One unit per 82.5 gallons of water	One application	
Post-Harvest Spray, Flood	98.5% EC [5202-24]	One unit per 55 gallons of wax	One application	
Post-Harvest Spray, Flood, Drench Slurry	98.5% FC [5202-26]	One unit (594 grams) per 53 gallons of water	One application	
Post-Harvest Spray	5.0% SC [8764-12]	One gallons per 250 gallons of water		-Do not contaminate food, feed by storage or disposal
Post-Harvest Spray-brush Applicator	.1% RTU [8764-40]	One gallon per 10,000 obs. of fruit	One application	
Post-Harvest Dip, Spray	98.5% SC [8764-50	15.2 oz. per 580 Gallons of water	One application	
Post-Harvest Spray, Dip	98.5% WP [43410-7]			
Post-Harvest Mist, Drench, Spray	98.5% WP [43410-33]			
Bananas				
Post-Harvest Spray, Floodwater	98.5% WP [5202-23]	One unit per 82.5 gallons of water	One application	
Post-Harvest Spray, Flood, Drench, Slurry	98.5% FC 5202-26]	One unit (594 grams) per 53 gallons of water	One application	

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Use Limitations
Post-Harvest Spray	5.0% FC [8764-12]	One gallon per 250 gallons of water	One application	-Do not contaminate food or feed by storage or disposal
Post-Harvest Dip, Spray	98.5% SC [8764-50]	15.2 oz. per 580 gallons of water	One application	
Post-Harvest Spray, Dip	98.5% WP [43410-7]			
Post-Harvest Mist, Drench, Spray	98.5% WP [43410-33]			
Carrots				
Post-Harvest Dip, Spray, Mist	42.3% FC [100-889]	41Fluid oz. per 100 gallons of water	Subsequent Dosing	
Post-Harvest Dip	98.5% RTU [2792-50]	577 grams (one bag) per 100 gallons of water		
Mushrooms				
During Spawning Only Spray	42.3% FC [100-889]	20 Fluid oz. per 1000 sq. ft.	Subsequent dosing allowed	-Do not apply 12 hours prior to harvest
Potatoes				
Tubers Post-Harvest Mist, Dip, Spray	42.3% FC [100-889]	0.42 Fluid oz. per gallon of water per 2,000 tubers	Subsequent dosing allowed	-Do not treat potatoes after cutting
Post-Harvest Mist, Drench, Spray	98.5% WP [43410-33]			
Post-Harvest Mist	98.5% WP [2792-50]	5.67 grams/2000 tubers in sufficient water		
Potato and Sweet Potato Seed Pieces				
Pre-Harvest Dip, Spray, Mist	42.3% FC [100-889]	8 Fluid oz. per 7.5 gallons of water	One application	-Do not use treated roots for food or feed
Pre-Harvest Dust	.5% D [2935-417]	1 lb. of dust to 100 lbs of cut potato seed pieces	One application	-Do not apply to water or to areas where surface water is present

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate	Maximum Number of Applications	Use Limitations
Pre-Harvest Spray, Dip	98.5% [43410-7]			
Seed Soybean, Wheat				
Spray mist or Slurry	30% FC [100-890]	2.0 - 4.0 Fluid oz. per equal amounts of water per bushel	One application	-Do not use for food, feed or oil purposes
Slurry Seed Treatment by machine	2.5% RTU [400-438]	3 Fluid oz. per 100 lbs. of seed	One application	
Slurry treatment by machine	2.7% FC [400-439]	2.5 - 4.0 Fluid oz. per 100 lbs of seed	One application	
Ready-To-Use	.54% FC [2935-497]	3 Fluid oz. per bushel	One application	
Slurry Treatment	1.0% FC [7501-131]	4 Fluid oz. per 100 lbs. seed	One application	
Ready Mix or Slurry Treatment	30% FC [7501-134]	4 Fluid oz. per equal amounts of water	One application	
Slurry Treatment, Mist	.34% RTU [7501-135]	6.6 Fluid oz. per bushel	One application	
Slurry Treatment, Mist	1.5% FC [7501-166]	5 Fluid oz. per 100 lbs. seed	One application	
Ornamental Bulbs and Corms				
Post-Harvest Dip, Spray, Mist	42.3% FC [100-889]	30 Fluid oz. per 100 gallons of water	One application	
Paint, (Interior and Exterior), Wallpaper, Adhesives, Nylon Carpeting, Textiles				
Conventional Blending Methods	98.5% WP [43410-33]			
Conventional Blending	50% RTU [47332-7]	One Syringe per one gallon paint		
Conventional Blending	50% SC [62366-1]	10 grams (1pouch) to 1 gallon of paint or adhesive		

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	Old Guideline Number			
830.1550	61-1	Chemical Identity and Composition	ABCKMO	**Data Gap**, 00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204, 44724601
830.1600	61-2A	Start. Mat. & Mnfg. Process	ABCKMO	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204
830.1620	61-2B	Description of Production Process	ABCKMO	00029108, 00047895, 00047980, 00051865, 00125601,40835501, 41258204
830.1670	61-2B	Formation of Impurities	ABCKMO	00029108, 00047895, 00047980, 00051865, 00125601, 40835501, 41258204
830.1700	62-1	Preliminary Analysis	ABCKMO	41083501, 41473301, 44724602
830.1750	62-2	Certification of limits	ABCKMO	41083501, 41473301
830.1800	62-3	Analytical Method	ABCKMO	41083501
830.6302	63-2	Color	ABCKMO	40789801
830.6303	63-3	Physical State	ABCKMO	40789801
830.6304	63-4	Odor	ABCKMO	40789801
830.6313	63-13	Stability to normal and elevated temperatures, metals, and ions	ABCKMO	41025001, 43172801
830.7000	63-12	pH of Water Solutions	ABCKMO	40789801
830.7050	None	UV/Visable Light	ABCKMO	Data Gap
830.7200	63-5	Melting Point	ABCKMO	40789801
830.7300	63-7	Density	ABCKMO	40789801
830.7840 830.7860	63-8	Solubility	ABCKMO	40947301
830.7950	63-9	Vapor Pressure	ABCKMO	40789801
830.7370	63-10	Dissociation Constant	ABCKMO	40947302
830.7550	63-11	Octanol/Water Partition Coefficient	ABCKMO	40789801
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	ABCKMO	41025002, 232421
850.2200	71-2A	Avian Dietary Toxicity - Quail	ABCKMO	41025003, 232421
850.2200	71-2B	Avian Dietary Toxicity - Duck	ABCK	41025004
850.2400	71-3	Wild Mammal Toxicity	ABCK	41258201, 100853

REQUIREMENT			USE PATTERN	CITATION(S)
850.2300	71-4A	Avian Reproduction - Quail	ABCK	235974
850.2300	71-4B	Avian Reproduction - Duck	ABCK	235974
850.1075	72-1A	Fish Toxicity Bluegill	ABCK	42477701, 41025006, 227331, 42508901
850.1075	72-1C	Fish Toxicity Rainbow Trout	ABCKMO	41025005, 227331,
850.1010	72-2A	Invertebrate Toxicity	ABCKMO	41709401, 232421
	TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity-Rat	ABCKMO	41258201
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	ABCKMO	41258202
870.2400	81-4	Primary Eye Irritation-Rabbit	ABCKMO	40789806
870.2500	81-5	Primary Skin Irritation	ABCKMO	40789807
870.2600	81-6	Dermal Sensitization	ABCKMO	40271701
870.3100	82-1A	90-Day Feeding - Rodent	ABCKMO	42942801, 42942802
870.5300	84-2A	Gene Mutation (Ames Test)	ABCKMO	**Data Gap**
870.5375	84-2B	Structural Chromosomal Aberration	ABCKMO	**Data Gap**
	ENVIRONMENTAL FATE			
835.2120	161-1	Hydrolysis	ABCK	41265301
835.2240	161-2	Photodegradation - Water	ABC	43328305
835.2410	161-3	Photodegradation - Soil	ABC	41397301, 41397302
835.4100	162-1	Aerobic Soil Metabolism	ABCK	41791201
835.4200	162-2	Anaerobic Soil Metabolism	ABC	41559601
835.4400	162-3	Anaerobic Aquatic Metabolism	ABC	41559601
835.1240	163-1	Leaching/Adsorption/Desorption	ABCK	41170102
835.6100	164-1	Terrestrial Field Dissipation	ABCK	43187201, 43187202, 43187203
	RESIDUE CHEMISTRY			
860.1300	171-4A	Nature of the Residue - Plants	ABK	41872901, 41872902, 41872903
860.1300	171-4B	Nature of the Residue - Livestock	AB	42011701, 42057901
860.1340	171-4C	Residue Analytical Methods - Plant	ABK	42718401, 43328301, 43328302, 4332803, 43328307, 43547601, 43721902, 43721903, 43721904
860.1340	171-4C	Residue Analytical Methods - Animals	ABK	00123329, 40271706, 40271707, 40789815, 40789817, 40789818, 43251501, 43251503, 43251504
860.1360	171-4M	Multi residue Method	ABCK	**Data Gap**
860.1380	171-4E	Storage Stability	ABK	**Data Gap**, 40271706, 40271707, 40789816, 40789817, 40789818, 42515802, 42568001, 42718401, 42868701, 43251502, 43251505, 43531001, 43547601

REQUIREMENT			USE PATTERN	CITATION(S)
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry and Eggs	AB	
		Meat, Meat-by-products, and fat of cattle, goats, hogs, horses, and sheep		40789817
		Milk		40789817
		Meat and Meat-by-products of poultry		00123329
		Eggs		00123329
860.1500	171-4K	Crop Field Trials	ABK	**Data Gap**
		Cantaloupe		
		Strawberry		
		Wheat		
		Dry Beans		
		Soybeans		
860.1500	171-4K	Crop Field Trials	ABK	
		Carrots		00123302, 00123303
		Potato		42660302, 43531002, 43547601
		Sweet Potato		42660301, 43531002, 43547601
		Citrus Fruits Group		42568001, 43328306, 43328307, 43721904
		Apples		42515802, 43721903
		Pears		42515801, 43721903
		Wheat, grain		42718401, 43328301, 43328302
		Wheat, straw		42718401, 43328301, 43328302
		Bananas		42868701, 43721901, 43721902
		Mushrooms		42598901, 43531001
		Papayas		00071747, 00071748, 00071749, 00071750, 00123334, 00123335
		Tobacco		42905201
860.1520	171-4L	Processed Food/Feed	AB	
		Soybeans		**Data Gap**
		Apple		42515802, 43721903
860.1520	171-4L	Processed Food/Feed	AB	
		Citrus, dried pulp		42568001, 43328306
		Potato, processing waste		42660302, 43531002
		Wheat, milled fractions (Flour)		42718401
860.1850	165-1	Confined Rotational Crop	AB	43187201, 43187202, 43187203, 42367801

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 1, 2001. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on October 1, 2001.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/op

These documents include:

HED Documents:

1. Shallal, Suhair (USEPA/OPPTS/HED) Memo to Beth Edwards of SRRD on the thiabendazole Responses to Registrant's Error Corrections and Comments. August 8, 2000.

2. Shallal, Suhair (USEPA/OPPTS/HED) Memo to Beth Edwards of SRRD on Thiabendazole and Thiabendazole Salt, HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. May 1, 2000.

3. Jaquith, David (USEPA/OPPTS/HED) Memo to Suhair Shallal on the Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Thiabendazole. March 14, 2000.

4. Diwan, Sanjivani (USEPA/OPPTS/HED) Memo to David Nixon of HED on the Thiabendazole Report of the Cancer Assessment Review Committee. February 24, 2000.

5. Shallal, Suhair (USEPA/OPPTS/HED) Memo to Beth Edwards of SRRD on the Revised HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. September 28, 2000.

6. Morton, Thurston (USEPA/OPPTS/HED) Memo to Suhair Shallal of HED on Thiabendazole. Revised Acute and Chronic (Non-cancer and Cancer) Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment. September 7, 2000

7. Morton, Thurston (USEPA/OPPTS/OPP/HED) Memo to Suhair Shallal of HED on the Thiabendazole Revised Acute and Chronic (Non-cancer and Cancer) dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment. December 8, 1999.

8. Morton, Thurston (USEPA/OPPTS/OPP/HED) Memo to William Sproat of SRRD on Thiabendazole. Product and Residue Chemistry Chapters for the Thiabendazole Reregistration Eligibility Decision (RED). December 8, 1999.

9. Nixon, David (USEPA/OPPTS/OPP/HED) Memo to Suhair Shallal of HED on Thiabendazole. The HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED). October 12, 1999.

10. Morton, Thurston (USEPA/OPPTS/OPP/HED) Memo to Beth Edwards/William Sproat on Thiabendazole. Anticipated Residue Assessment for the HED Risk Assessment. October 7, 1999.

11. Guant, Patricia (USEPA/OPPTS/OPP/HED) Memo to Suhair Shallal of HED on Thiabendazole-Report of the Hazard Identification Assessment Review. July 21, 1999.

12. Shallal, Suhair (USEPA/OPPTS/OPP/HED) Memo to Lorilyn Montford. A Revised HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. June 21, 2001.

13. Hummel, Sue (USEPA/OPPTS/OPP/HED) Memo to Beth Edwards. Thiabendazole: Product and Residue Chemistry Chapters for the Thiabendazole R.E.D. December 8, 1999.

EFED Documents:

1. Nguyen, Thuy (USEPA/OPPTS/OPP/EFED) Memo to Beth Edwards of SRRD on EFED Reregistration Eligibility Document for Thiabendazole. February 4, 1999.

Other Related Documents:

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

    b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date

from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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Appendix E. Generic Data Call-In

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix F. Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

Appendix G. EPA'S Batching of Thiabendazole Products for Meeting Acute Toxicity Data Requirements For Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Thiabendazole** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirty nine products were found which contain **Thiabendazole** as the active ingredient. These products have been placed into four batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	100-963	99.5
	1706-196	98.5
	2792-50	98.5
	2792-71	98.5
	5202-23	98.5
	5202-24	98.5
	5202-26	98.5
	8764-50	98.5
	43410-7	98.5
	43410-33	98.5
	64864-47	98.5

Batch 2	EPA Reg. No.	% Active Ingredient
	1706-190	50.0
	1706-207	50.0
	47332-7	50.0
	62366-1	50.0

Batch 3	EPA Reg. No.	% Active Ingredient
	100-890	30.0
	7501-134	30.0
Batch 4	EPA Reg. No.	% Active Ingredient
	2935-417	0.5
	34704-206	0.5

No Batch	EPA Reg. No.	% Active Ingredient
	100-889	42.30
	400-438	Thiabendazole: 2.50 Carboxin: 27.80 Imazalil: 2.00
	400-439	Thiabendazole: 2.70 Carboxin: 32.60
	1381-162	Thiabendazole: 0.35 Thiram: 12.62
	1381-163	Thiabendazole: 0.33 Thiram: 11.64
	1381-169	Thiabendazole: 2.00 Maneb: 50.00
	1706-221	25.00
	1706-222	50.00
	2792-35	Thiabendazole: 0.10
	2792-36	0.20
	2935-497	Thiabendazole: 0.54 Lindane: 10.30 Maneb: 13.60
	2935-498	Thiabendazole: 1.00 Lindane: 18.75 Maneb: 25.00
	5202-17	Thiabendazole: 0.20
	7501-131	Thiabendazole: 1.00 Captan: 20.25 PCNB: 8.40
	7501-135	Thiabendazole: 0.34 Thiram: 12.60
	7501-166	Thiabendazole: 1.50 Carboxin: 16.70 Imazalil: 1.20
	8764-12	5.00
	8764-40	0.10
	64864-44	3.00

No Batch	EPA Reg. No.	% Active Ingredient
	64864-46	0.10

Appendix I. List of Available Related Documents and Electronically Available Forms

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product_	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf

8570-30	Pesticide Registration Maintenance Fee Filing_	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

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

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

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

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

a. Registration Division Personnel Contact List
B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
C. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' website.

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

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

The telephone number for NTIS is (703) 605-6000.

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

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: http://npic.orst.edu..

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the

applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.