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Fenarimol Summary Document: Registration Review

March 2007

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Docket Number: EPA-HQ-OPP-2006-0241
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Fenarimol Summary Document Registration Review: Initial Docket March 23, 2007

Approved By:

Debra Edwards 3/23/07

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I. PRELIMINARY WORK PLAN

Introduction:

The Food Quality Protection Act of 1996 amendments to the Federal Fungicide Insecticide and Rodenticide Act (FIFRA) mandated a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (the Agency) based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has begun to implement the new registration review program, and plans to review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state clearly what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

Anticipated Risk Assessment and Data Needs:

Ecological Risk:

- The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species assessment, for all fenarimol uses.
- The Agency anticipates needing the following data in order to complete these assessments:
    - Tier II seedling emergence and vegetative vigor plant studies
    - A toxicity study on a vascular aquatic plant species
- Additional information that will assist the Agency in refining the ecological risk assessment is described on pp. 23-24 of this document as part of the Ecological Risk Assessment Problem Formulation.

Human Health Risk:

- The Agency plans to assess aggregate risk from consumption of drinking water (turf scenario) and food, as well as aggregate risk to golfers from application to golf courses. These assessments will likely be completed as part of the risk assessment process for the pending use on hops.
- The Agency plans to conduct occupational risk assessments for all uses.

- No additional Human Health data are needed unless the Agency denies the waiver request currently in review for the 28-day inhalation toxicity study.
- Please refer to Section IV, Human Health Effects Scoping Document, for a detailed discussion of previous human health assessments.

Timeline:

EPA has created the following estimated timeline for the completion of the fenarimol registration review.

Activities	**Estimated Month/Year**
Phase 1: Opening the docket	
Open Public Comment Period for Fenarimol Docket	March 2007
Close Public Comment Period	June 2007
Phase 2: Case Development	
Develop Final Work Plan (FWP)	August 2007
Issue DCI	April 2008
Data Submission	April 2009
Preliminary Risk Assessment Completion	October 2010
Open Public Comment Period for Preliminary Risk Assessments	November 2010
Close Public Comment Period	January 2011
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	April 2011
Close Public Comment Period	June 2011
Final Decision and Begin Post-Decision Follow-up	September 2011
Total (years)	4.5

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the fenarimol case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Stakeholders are also specifically asked to provide information and data in the following areas:

1. Confirmation on the following label information.

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   a. sites of application
   b. formulations
   c. application methods and equipment
   d. maximum application rates
   e. frequency of application, application intervals, and maximum number of applications per season
   f. geographic limitations on use
2. Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses).
3. Use history.
4. Median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county.
5. Application timing (date of first application and application intervals) by use – national, state, and county.
6. Sub-county crop location data.
7. Usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals).
8. Directly acquired county-level usage data (not derived from state level data).
   a. maximum reported use rate (lbs. a.i./acre) from usage data – county
   b. percent crop treated – county
   c. median and 90th percentile number of applications – county
   d. total pounds per year – county
   e. the year the pesticide was last used in the county/sub-county area
   f. the years in which the pesticide was applied in the county/sub-county area
9. Typical application interval (days).
10. State or local use restrictions.
11. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
12. Monitoring data.
13. Environmental fate and toxicity data on the fenarimol degradate.
14. Fenarimol is not identified as a cause of impairment for any water body listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. However, the Agency invites submission of any other existing water quality data. To the extent possible, data elements outlined in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Water Quality & Impaired Water Body Data in OPP's Registration Review Risk Assessment & Management Process," should be provided. In order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments, see http://www.epa.gov/oppsrrd1/reregistration_review/water_quality.htm.

Next Steps:

After the comment period closes, the Agency will prepare a Final Work Plan for this pesticide.

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II. FACT SHEET

Background Information:

- Fenarimol Registration Review Case Number: 7001
- Fenarimol PC Code: 206600 CAS#: 60168-88-9
- Technical Registrant: Gowan Company
- One Technical product, five end-use products and one Special Local Need (SLN).
- First product registered in 1984.
- Not subject to reregistration; thus, no Reregistration Eligibility Decision (RED) is available.
- Tolerances were reassessed under FQPA in the Tolerance Reassessment Decision (TRED) completed in August 2002.
- Special Review and Reregistration Division (SRRD), Chemical Review Manager (CRM) Katherine St. Clair: stclair.katherine@epa.gov.
- Registration Division (RD) Contacts: Product Manager (PM): Mary Waller: waller.mary@epa.gov; Lana Coppolino: copplino.lana@epa.gov.

Use & Usage Information:

For additional details, please refer to the BEAD Appendix A document in the fenarimol docket.

- Fenarimol is a systemic foliar fungicide used on apples, bananas, cherries, filberts, grapes, pears, and pecans, and is also registered for use on ornamental plants, trees, and turf.
- Approximately 80,000 pounds of fenarimol are used annually.
- Fenarimol is used on less then 5% of the total crop treated for peaches and pears, on less than 10% of the crop treated for cherries and filberts, and on less than 25% of the crop treated for apples and grapes.
- Pests controlled include scab, powdery mildew, rusts, and leaf spot, by adversely affecting the formation of the fungal sterol ergosterol.
- Fenarimol is formulated as a flowable concentrate, granular, soluble concentrate/liquid, and emulsifiable concentrate.
- There are no residential uses, but there are turf uses on golf courses.
- Fenarimol may be applied by hand (for spot treatments), belly grinder, push-type spreader, or low- or high-volume ground sprayer.

Recent Actions:

- A new tolerance petition for hops is currently being evaluated by the Agency.
- A final rule for fenarimol was issued on 9/15/06 (71 FR 54423-54434), to revoke some tolerances, modify others, and establish new ones. In addition, the action revised the tolerance expression, which had been for parent fenarimol only in 180.421(a)(1), and for parent fenarimol plus various metabolites in 180.421(a)(2), by recodifying all tolerances

to 180.421(a), as parent fenarimol. This action resulted in a total of 25 established tolerances.

- A new tolerance was established for residues of fenarimol in or on filberts on 6/7/06 (71 FR 32841-32846).
- The TRED was issued on August 1, 2002, reassessing all 42 fenarimol tolerances (40CFR 180.421(a)(1) & (2)).

Ecological Risk Assessment Status:
Please refer to Section III of this document, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated ecological risk assessment needs. A summary follows:

- Based on preliminary exposure estimates and previous risk assessment endpoints, there are potential risks due to direct effects from acute exposure to listed aquatic invertebrates, listed and non-listed fish, aquatic-phase amphibians, aquatic plants, terrestrial plants, and listed and non-listed mammals from exposure to fenarimol at the maximum application rates. There is the potential for direct adverse effects to listed and non-listed fish, aquatic-phase amphibians, aquatic invertebrates, aquatic plants, terrestrial plants, and mammals from chronic exposure to fenarimol at the maximum application rates.
- The Agency plans to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all fenarimol uses.

Human Health Risk Assessment Status:
Please refer to Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. A summary follows:

Dietary (Food and Water):

- An acute dietary exposure assessment is not needed, because no toxicity endpoint from a single exposure to fenarimol has been identified.
- Based on highly refined analyses, chronic dietary (food only) risk from exposure to fenarimol is below the Agency's level of concern (LOC) for all U.S. populations (<1% of the chronic Population Adjusted Dose).
- The Agency plans to conduct a drinking water assessment for the existing turf uses. The Agency plans to conduct a chronic dietary (food + water) assessment. This assessment will then be used to assess aggregate (food + water) risk for fenarimol.

Residential:

- In the 2002 TRED, the registrants agreed to remove the residential turf uses of fenarimol from their labels. While there are still labels that have residential turf uses (1 technical label and 1 label that is not marketed), the registrants do not sell those products and thus

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have abided by the terms of the 2002 TRED. The Agency will work with the registrants to remove residential turf uses from all labels in the future.

- The Agency plans to conduct an aggregate assessment for golfers that include exposures from use on golf courses, food and water (turf scenario).

Occupational:

- In registration review, the Agency plans to conduct a comprehensive occupational assessment for all uses.

Data Call-In Status:

An outcome of the 2002 TRED was a generic data call-in (GDCI) that was issued in January 2004 for eighteen studies on fenarimol. Eleven of the studies have been submitted and are currently in review by the Agency. In addition,

- The following waiver request is in review:
  - 28-Day Inhalation Study waiver request (GLN 870.3465)
- The following study has been waived:
  - Developmental Neurotoxicity Study (GLN 870.6300)
- The following studies are outstanding and the first four will be useful for future drinking water assessment:
  - Photolysis of parent and degradates in water (GLN 835.2240)
  - Aerobic aquatic metabolism (GLN 835.4300)
  - Anaerobic aquatic metabolism (GLN 835.4400)
  - Terrestrial field dissipation (GLN 835.6100)
  - Storage stability (GLN 860.1380)

Tolerances:

- Please refer to the tolerance table and Codex MRL table on pp. 48-50 of this document.

Labels:

- A list of registration numbers is included below and the labels can be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home.

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Fenarimol Registration Numbers:

Registration #	Product Name	Company Name	Active Ingredient
10163-273	RUBIGAN E.C.	GOWAN CO	Fenarimol
10163-274	RUBIGAN A.S. TURF AND ORNAMENTAL	GOWAN CO	Fenarimol
10163-275	RUBIGAN A.S.	GOWAN CO	Fenarimol
10163-276	RUBIGAN TECHNICAL	GOWAN CO	Fenarimol
10163-290	RIVERDALE PATCHWORK	GOWAN CO	Fenarimol
10404-60	LESCO TWOSOME FLOWABLE FUNGICIDE	LESCO INC	Fenarimol
0010404-60	LESCO TWOSOME FLOWABLE FUNGICIDE	LESCO INC	Fenarimol

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III. ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION

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

March 26, 2007

PC Code: 206600
DP Barcode: D336002

MEMORANDUM

Subject: Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Fenarimol

To: Dirk Helder, Team Leader
Katherine StClair, Chemical Review Manager
Reregistration Branch 2
Special Review and Reregistration Division
Office of Pesticide Programs

From: Melissa Panger, Ph.D., Biologist
Greg Orrick, Environmental Scientist
Environmental Risk Branch 4
Environmental Fate and Effects Division
Office of Pesticide Programs

Through: Elizabeth Behl, Chief
Environmental Risk Branch 4
Environmental Fate and Effects Division
Office of Pesticide Programs

Attached is the preliminary problem formulation for the ecological risk assessment to be conducted as part of the Registration Review of the fungicide fenarimol.

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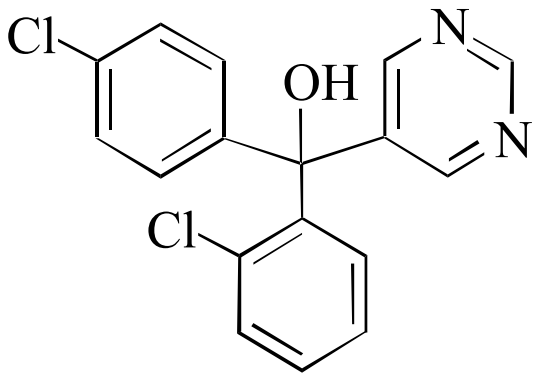
REGISTRATION REVIEW

ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION FOR:

FENARIMOL

alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol
CAS Registry Number: 60168-88-9
PC Code: 206600



Prepared by:

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STRESSOR SOURCE AND DISTRIBUTION

Fenarimol [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol] is a locally systemic foliar fungicide in the pyrimidine class of fungicides, which also includes dimethirimol, bupirimate, and ethirimol. It is the only member of this class currently registered for use in the U.S. Fenarimol is a demethylation inhibitor, which inhibits fungal growth by adversely affecting the formation of the fungal sterol ergosterol. Ergosterol is related to cholesterol and is needed for cell membrane formation. Fenarimol is used to control fungal diseases, such as rusts, molds, mildews, and scabs and is currently registered for use on apples, filberts, pears, pecans, cherries, grapes, ornamental plants, ornamental trees, and turf. It is generally applied in response to disease pressures, but may also be applied as a protectant.

Current formulations of fenarimol include Rubigan® E.C. (12.0% a.i.; EPA Reg. No. 10163-273), Rubigan® A.S. Turf and Ornamental (11.6% a.i.; EPA Reg. No. 10163-274), Rubigan® A.S. (11.6% a.i.; EPA Reg. No. 10163-275), Patchwork® (0.78% a.i., EPA Reg. No. 10163-290), and Twosome™ Flowable Fungicide (2.40% fenarimol a.i., 40.00% chlorothalonil a.i.; EPA Reg. No. 10404-60). Formulations include flowable (Rubigan® E.C., Rubigan® A.S. Turf and Ornamental, Rubigan® A.S., Twosome™ Flowable Fungicide) and granular (Patchwork®) end-use products. Fenarimol is typically applied by ground equipment, but application methods are not specified for the use of Rubigan® A.S. on grapes, Rubigan® A.S. Turf and Ornamental uses, Patchwork® uses, and Twosome™ Flowable Fungicide uses. Maximum seasonal rates for fenarimol are listed in **Appendix A**.

INTEGRATION OF AVAILABLE INFORMATION

The risk assessments that serve as the basis for this problem formulation include the following (for details, see **Appendix B**):

- Section 3 New Use (S3NU) Risk Assessment of proposed uses on turf and roses (Jan. 9, 1976)
- 19 Experimental Use Permit (EUP) Risk Assessments of uses on apples, grapes, turf, roses, pecans, and ornamentals from 1976 to 1984
- 12 S3NU Risk Assessments of proposed uses on turf, pecans, apples, grapes, pears, and cherries from 1983 to 1989
- 6 Section 18 Risk Assessments for uses on cherries, filberts, and hops from 1988 to 1999
- TRED Drinking Water Assessment (D282389+; Jul. 31, 2002)
- S3NU Risk Assessment (D240868+) of proposed uses on filberts and grapes east of the Rockies (Oct. 17, 2005)

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ECOLOGICAL EFFECTS

TOXICITY STUDIES

The available acute toxicity data on the active ingredient indicate that fenarimol is practically non-toxic to honey bees (LD_{50} >100 µg a.i./bee) and birds (northern bobwhite quail: LC_{50} >6125 mg a.i./kg diet); no more than slightly toxic to mammals (rat: LD_{50} > 599 mg a.i./kg-bw); moderately toxic to freshwater invertebrates (water flea: EC_{50} = 6.8 mg a.i./L); and highly toxic to freshwater fish (bluegill sunfish: LC_{50} = 0.9 mg a.i./L) on an acute exposure basis. In a 14-day toxicity study of green algae (*Selenastrum capricornutum*), cell count was the most sensitive indicator of fenarimol toxicity and resulted in a LOAEL of 0.43 mg a.i./L (NOAEL = 0.10 mg a.i./L) (MRID: 40777601)**.**

Chronic toxicity testing of technical grade fenarimol based on a fish early life-stage toxicity study with rainbow trout (*Oncorhynchus mykiss*) resulted in significant reduction in fish body size (length and weight) at 0.87 mg a.i./L (NOAEC = 0.43 mg a.i./L) (MRID: 129099). A life-cycle test of chronic toxicity effects of fenarimol to water fleas (*Daphnia magna*) resulted in a NOAEC of 0.113 mg a.i./L (MRID: 40283902).

Chronic toxicity testing on bobwhite quail and mallard ducks resulted in NOAECs at the highest concentrations tested: 300 mg a.i./kg diet and 250 mg a.i./kg diet, respectively (MRIDs: 402839-01 and 85066). Neither study identified any growth or reproductive effects at these concentrations, and, therefore, the actual concentration levels where growth or reproductive effects would be observed are likely higher.

Multi-generation studies in rats indicate that fenarimol causes reduced fertility and dystocia (difficult births) at levels as low as 1.2 mg/kg/day (NOAEL = 0.6 mg/kg/day-bw; NOEAC = 12.5 mg a.i./kg diet) (MRID: 45502302). Reproduction studies in mice (MRID: 45502307), guinea pigs (*Cavia* spp.) (MRID: 00126525, 00133474, and 00137159), and rabbits (*Oryctolagus cuniculus*) (MRID: 00084967) show that similar effects are found in mice, but are absent in guinea pigs and rabbits. Therefore, the reproductive effects were not seen in all mammal species tested.

Due to a lack of data, fenarimol toxicity to estuarine/marine animals, vascular aquatic plants, and terrestrial plants could not be determined.

INCIDENT REPORTS

A search of the EIIS (Environmental Incident Information System) database for ecological incidents (run on January 4, 2007) identified a total of three ecological incidents involving fenarimol; two involving terrestrial plants and one involving fish. The two plant incidents, both

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involving grapes, indicated that the damage to the plants reported in the incident was *possibly* related to fenarimol. The fish incident report, involving apple use, concluded that it was *unlikely* that fenarimol contributed to the fish kill. In all three incidents, the legality of the fenarimol use was undetermined, therefore, it is unclear if the incidents were due to misuse or to labeled use.

EXPOSURE CHARACTERISTICS

Fenarimol is soluble in water (13.7 mg/L at pH 7, 25°C), soluble in most organic solvents, has low vapor pressure (2.2×10^{-7} torr at 25°C), and has low potential to bioconcentrate in fish (BCF of 113X for whole fish). The compound is moderately mobile in soil, with a K_d of 1.5 to 11.9 and a K_{OC} of 400 to 1000. Compounds with K_d values less than five may present a ground water concern; therefore, fenarimol presents a ground water concern in some soils, especially those that are sandy and of low organic carbon content.

Fenarimol's major degradation pathway is photolysis in water ($t_{1/2}$ = 4-12 hours; MRID 248702, 46413701). The compound does not hydrolyze at environmental pHs (MRID 70426). Fenarimol is persistent to soil metabolism ($t_{1/2}$ = 3-5 years for aerobic degradation; no significant anaerobic degradation; MRID 248702) and slowly photolyzes on soil ($t_{1/2}$ = 130-269 days; MRID 45716302, 45716303). Field dissipation studies support the expected persistence of fenarimol in the field ($t_{1/2}$ = 64-892 days; MRID 248702, 251940). Therefore, fenarimol is expected to persist under most conditions in soil, ground water, and turbid surface water. Fenarimol in transparent surface water is expected to photolyze readily.

Fenarimol's sole identified major degradate is the photolysis product 4-chloro-2-(5-pyrimidyl)-2'-chlorobenzophenone. The MARC elected not to exclude this degradate in drinking water exposure assessment because of its potential to occur in surface water and the lack of data regarding its toxicity (DP Barcode 277692, Sep. 17, 2001). Its photolysis half-life in water appears to be twice that of fenarimol parent (MRID 129103). Because no submitted aqueous photolysis studies have reported a complete mass balance, there is uncertainty in the identity and rates of formation and decline of major degradates of fenarimol.

Over 80 minor photolysis products have been observed, most of which are chlorinated (MRID 70426). No information is available on the toxicity, fate, and/or transport properties of these or other possible degradates. Due to the substantial uncertainty in the identity, toxicity, fate, and transport of fenarimol's photodegradates, all of them were assumed to have similar toxicity to the parent compound in the Drinking Water Assessment for the TRED (D282389+; Jul. 31, 2002). This assumption of equivalent toxicity of fenarimol residues will continue to apply to current and future drinking water exposure and ecological risk assessments unless the toxicities of fenarimol's degradates are better understood.

A generic data call-in (GDCI) was issued in January 2004 as a result of the 2002 TRED for fenarimol. The registrant submitted some of the data requested and a waiver request (April 16,

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2004) for the GDCI. A response document prepared by EFED for the OPP rebuttal (May 22, 2006) indicated that the GDCI requests for aqueous photolysis, aerobic aquatic metabolism, anaerobic aquatic metabolism, and terrestrial field dissipation data are not waived. Submission of these GDCI data that remain requested may change current and future ecological risk conclusions, depending on the availability of toxicological data on identified degradates.

In conclusion, fenarimol residues present surface water and ground water concerns through runoff, spray drift, and leaching. Fenarimol's major degradation pathway is photolysis in water ($t_{1/2}$ = 4-12 hours). In turbid surface water and ground water, fenarimol will exist in the dissolved phase and bound to suspended particulates and sediment, and may persist with half-lives ranging from 3-5 years. The fate, transport, and toxicity properties of the major photodegradate, 4-chloro-2-(5-pyrimidyl)-2'-chlorobenzophenone, and the multiple minor photodegradates are unknown. Therefore, all residues of fenarimol are assumed to have similar toxicity to the parent compound.

CHARACTERISTICS OF ECOSYSTEMS POTENTIALLY AT RISK

For fenarimol and pesticides in general, the ecosystems at greatest risk are those in close proximity to the use areas. These would include orchards, vineyards, container- and field-grown ornamentals, golf courses, sod farms, other turf areas (*e.g.*, athletic fields), and water bodies directly adjacent to use sites that may receive chemical residues via drift, runoff, and/or discharged ground water. Within water bodies, the water column, sediments, and pore water are all compartments of concern. **Table 1** below summarizes the agricultural use sites that fenarimol is reported to be used on, the annual percent of crop treated (average and maximum) for each use, and average annual pounds of fenarimol applied for each use (OPP BEAD, 2006). Based on these estimates (which do not include all registered uses), the agricultural sites where the majority of fenarimol is used include apples, cherries, and grapes. Geographically, the majority of fenarimol use in agriculture occurs in the Northeast and Western U.S. (see **Fig. 1**).

Table 1. Screening Level Estimates of Agricultural Uses of Fenarimol (OPP BEAD, Feb. 14, 2006).

Crop	lbs a.i.	Percent Crop Treated	
		Avg.	Max.
Apples	10,000	20	20
Cherries	1,000	10	10
Grapes	10,000	15	25
Filberts	<500	10	10
Peaches	<500	<1	<2.5
Pears	<500	<1	5
Pomegranates*	<500		

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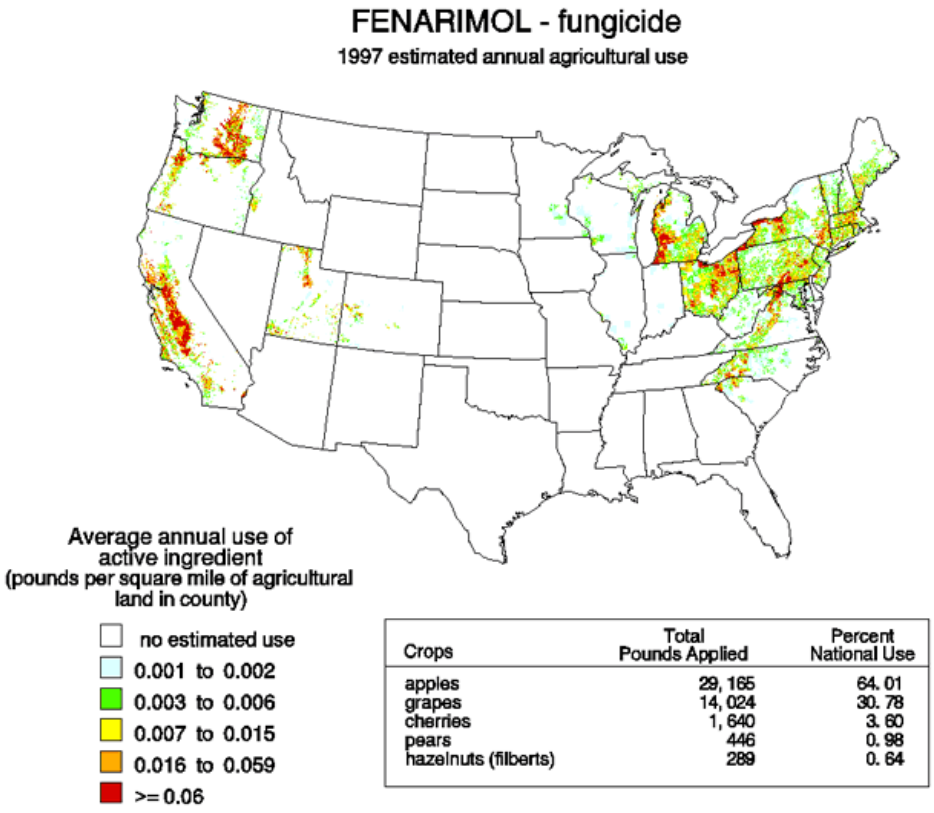
All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.
'<1' indicates less than 1 percent of crop is treated.
* California data only, but 95% or more of U.S. acres are in California



Crops	Total Pounds Applied	Percent National Use
apples	29, 165	64. 01
grapes	14, 024	30. 78
cherries	1, 640	3. 60
pears	446	0. 98
hazelnuts (filberts)	289	0. 64

FIGURE 1. This map shows the average annual pesticide use intensity expressed as average weight (in pounds) of fenarimol applied to each square mile of agricultural land in a county. The area of each map is based on state-level estimates of pesticide use rates for individual crops that were compiled by the National Center for Food and Agricultural Policy during 1995-1998 and on 1997 Census of Agriculture county crop acreage. The maps do not represent a specific year, but rather show typical use patterns over the four year period 1995 through 1998. Use intensity rates are expressed as the pounds applied per square mile of mapped agricultural land in a county. The area of mapped agricultural land for each county was obtained from an enhanced version of the 1992 USGS National Land Cover Data (NLCD). The map shows only agricultural uses.

Organisms of concern include birds, mammals, reptiles, fish, and terrestrial and aquatic invertebrates, plants, and amphibians. The assessment endpoints are intended to reflect population sustainability and community structure within ecosystems and hence relate back to ecosystems at risk. If risks are expected for given species/taxa based on the screening-level assessment, then risks might be expected to translate to higher levels of biological organization.

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ASSESSMENT ENDPOINTS

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (*i.e.*, a community of fish and aquatic invertebrates) and its attributes (*i.e.*, survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (*i.e.*, ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to a pesticide, such as fenarimol.

To estimate exposure concentrations, the ecological risk assessment considers an application(s) at the maximum application rate to use sites that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

CONCEPTUAL MODEL

The conceptual model used to depict the potential ecological risk associated with fenarimol assumes that as a fungicide, fenarimol is capable of affecting terrestrial and aquatic animals provided environmental concentrations are sufficiently elevated as a result of proposed label uses. However, through a preliminary iterative process of examining fate and effects data, the conceptual model, *i.e.*, the risk hypothesis, has been refined to reflect the exposure pathways and the organisms for which risk is most likely. Based on a preliminary risk screening and past assessments indicating that fenarimol is highly toxic to freshwater fish on an acute exposure basis and causes potential reproductive effects in mammals when chronically exposed, the hypothesis for the risks of fenarimol to non-target animals (depicted in **Fig. 2**) focuses on both aquatic and terrestrial environments. Therefore, exposure as a result of direct spray, spray drift, granules, and runoff will be considered. Risk to aquatic plants is also considered in this screening-level assessment. For terrestrial organisms, the major route of exposure considered is the dietary route; consumption of Patchwork® granules or food items such as plant leaves or

insects that have fenarimol residues as a result of spraying and drift. For aquatic animal species, the major routes of exposure are considered to be via the respiratory surface (gills) or the integument. Aquatic plants may be exposed via direct uptake and adsorption. Estimated exposure concentrations for all organisms are obtained through the use of several Agency exposure models.

RISK HYPOTHESIS

Risk hypotheses are specific assumptions about potential adverse effects (*i.e.*, changes in assessment endpoints) and may be evaluated on theory and logic, empirical data, mathematical models, or probability models (US EPA 2004). For this assessment, the risk is stressor-initiated, where the stressor is the release of fenarimol to the environment. The following risk hypothesis is presumed for this screening level assessment:

> *Based on the application methods, mode of action, and the sensitivity of non-target aquatic and terrestrial species, fenarimol has the potential to reduce survival, reproduction, and/or growth in terrestrial and aquatic organisms.*

In order for a chemical to pose an ecological risk, it must reach non-target organisms at concentrations found to cause adverse effects. The exposure pathway is the way by which a pesticide moves in the environment from the application site to non-target organisms. The assessment of ecological exposure pathways in this assessment includes an examination of the source and potential migration pathways for fenarimol, and the determination of potential exposure routes to non-target species.

Diagram

Application methods for the use of fenarimol involve foliar spray or granules using ground and potentially aerial (when not specified on the label) equipment. Ecological receptors that may potentially be exposed to fenarimol include terrestrial and semi-aquatic wildlife (*i.e.*, mammals, birds, amphibians, terrestrial invertebrates, and reptiles). In addition, aquatic receptors (*e.g.*, freshwater and estuarine/marine fish and invertebrates, amphibians, and aquatic plants) may also be exposed as a result of potential migration of fenarimol via spray drift and/or runoff from the site of application to various watersheds and other aquatic environments. These data form the basis for identifying potential endpoints, stressors, and ecological effects associated with fenarimol use (see **Fig. 2**).

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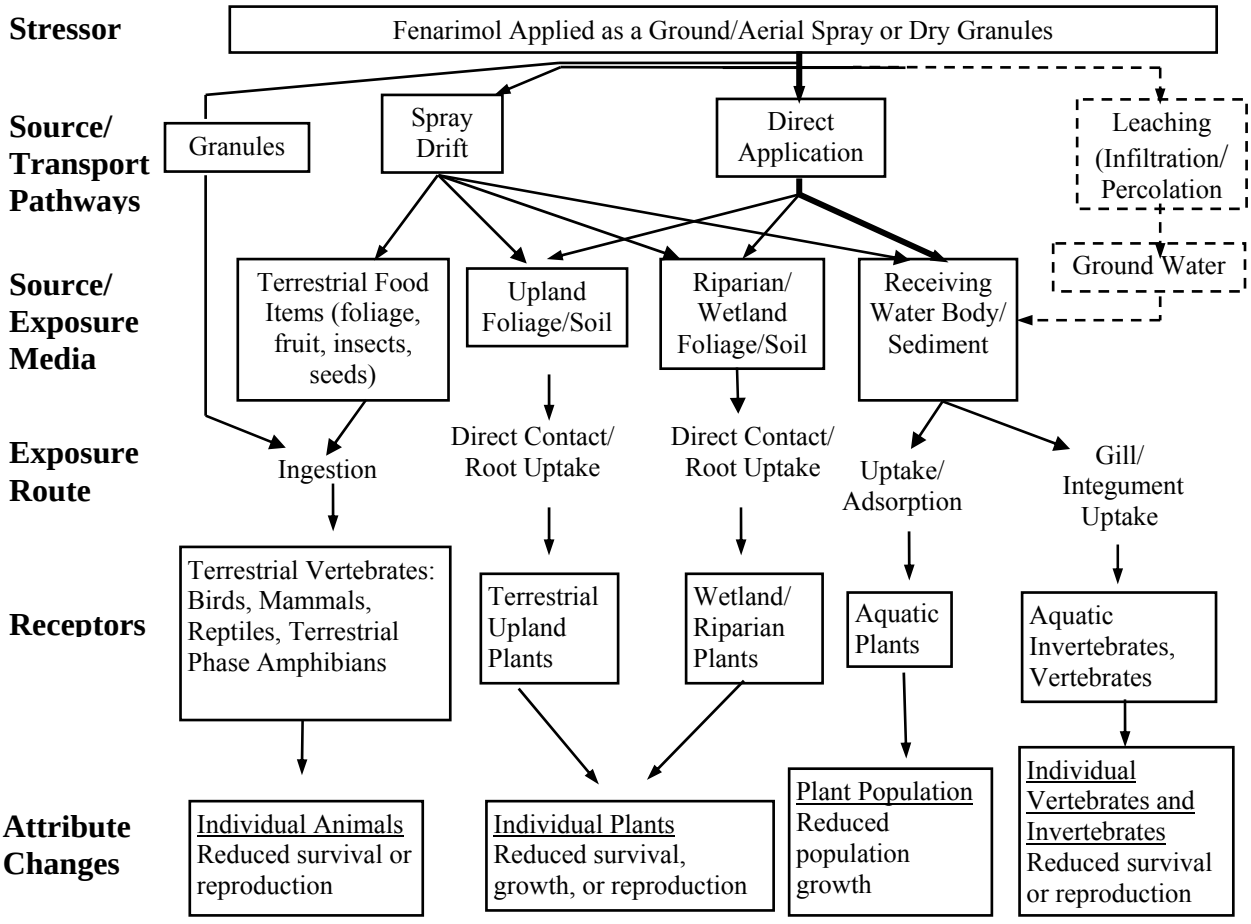

Figure 2. Conceptual model of the transport and effects of fenarimol in the environment.
*Dotted lines indicate that although this exposure route was considered, it was not thought to contribute significantly to the fate and transport of fenarimol.

ANALYSIS PLAN OPTIONS

In Registration Review, pesticide ecological risk assessments will follow the Agency's Guidelines for Ecological Risk Assessment, will be in compliance with the paper titled "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency" ("Overview Document") (January 2004), and will be done in accordance with Section 7 of the Endangered Species Act.

A review of previously completed screening level risk assessments indicate that screening level assessments of acute and chronic risk to non-target organisms has not been completed for all uses, most notably the uses with the highest potential application rates. Based on toxicity data and Risk Quotients (RQs) described in the assessment for eastern grapes and filberts (the most

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recent ecological assessment available), there are potential reproductive effects to mammals from chronic terrestrial exposure to fenarimol, when applied at the proposed label rates. The proposed application rates for filberts/grapes (0.21 lbs a.i./A/year) are considerably lower than the maximum application rates on the current labels for other tree fruit and nut crops, and for applications to turf (11 lbs a.i./A/year) and potentially ornamentals (max use rates could not be determined from information on the labels for this use). Furthermore, due to a lack of toxicity data, potential risks to estuarine/marine organisms, aquatic vascular plants, and terrestrial plants have not previously been assessed by the Agency.

Appendix B shows the current status of risk assessments for registered uses of fenarimol. In addition to conducting screening level assessments (and refined assessments, if necessary) for all fenarimol uses, other uncertainties and potential paths forward are described below.

- The available data for the assessment of acute and chronic risk to aquatic animals is currently limited to freshwater species (*i.e.*, no guideline toxicity data for estuarine/marine species are available for fenarimol). If no additional, acceptable toxicity data for estuarine/marine species are submitted by the registrant(s) or are located in the open literature, and in the absence of information that would suggest otherwise, we will assume that fenarimol is as toxic to estuarine/marine species as it is to freshwater organisms.

- No toxicity data are currently available for aquatic vascular plants or terrestrial plants. Although fenarimol is described as a fungicide and is used on a variety of dicots and monocots, risks to some plants are expected for the following reasons:

    a. One of the registered uses for fenarimol is annual bluegrass (*Poa annua*) management; an herbicidal use. The supplemental Rubigan A.S. label for *Poa annua* management (EPA reg. No. 10163-274) states:

    "Rubigan A.S. may exert a growth regulating effect in certain plants by reducing the biosynthesis of gibberellic acid. This effect is expressed as a reduction in internode elongation and suppression of overall plant growth. In the presence of sufficiently high rates of Rubigan A.S. or prolonged exposure, a species sensitive to this effect may be selectively suppressed."

    An additional statement on this label claims that "(a) single application of Rubigan A.S. in excess of 8.0 fluid ounces per 1000 square feet may inhibit the germination of creeping bentgrass for up to 30 days after application."

    b. There are two reported fenarimol ecological incidents involving terrestrial plants; both involving grape plants. Both incidents involved a mixture of several chemicals so it is difficult to ascertain if fenarimol was directly

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responsible for the plant damage, however, the incidents do indicate the possibility that acute exposure to fenarimol may damage non-target terrestrial plants.

c. Adverse effects (reduced cell count) are reported in green algae exposed to fenarimol at concentrations as low as 0.43 mg a.i./L (MRID: 40777601).

Because fenarimol is the only member of the pyrimidine class of fungicides currently registered in the U.S., there is no possibility of using submitted toxicity data from closely-related surrogate chemicals to fill in potential data gaps. Therefore, until additional data become available, risks to aquatic vascular plants and terrestrial plants (both Federally-listed and non-listed species) will be assumed in future fenarimol risk assessments.

- Due to the substantial uncertainty in the identity, toxicity, fate, and transport of fenarimol's photodegradates, all of them are assumed to have similar toxicity to the parent compound (see 'Exposure Characteristics' section above). This assumption of equivalent toxicity of fenarimol residues will continue to apply unless the toxicities of fenarimol's degradates are better understood.

- Maximum yearly application rates could not be determined based on information provided on the label for the following uses: filberts [Rubigan EC (Reg. No. OR-030037)], and ornamentals [Rubigan EC (Reg. No 10163-273), Rubigan AS Turf and Ornamental (Reg. No. 10163-274)]. Additionally, maximum rates per application could not be determined based on label information for use on ornamentals [Rubigan EC (Reg. No 10163-273), Rubigan AS Turf and Ornamental (Reg. No. 10163-274)]. The method of application was not specified on the following labels: Rubigan AS Turf and Ornamental (Reg. No. 10163-274), Rubigan AS (grape use; Reg. No. 10163-275), and Lesco Twosome Flowable Fungicide (Reg. No. 10404-60). In the absence of label clarifications, the following assumptions will be made in the ecological risk assessments for these uses:

  a. We will assume a maximum yearly application rate for filberts of 1.50 lbs a.i./acre (24 applications, 7-day application interval at the highest estimated application rate) and for ornamentals of 2.26 lbs a.i./acre (24 applications, 7-day application interval at the highest estimated application rate – see below).

  b. We will assume maximum rates per application for ornamentals of 100 gallons of tank mixture/acre (max of 0.094 lbs a.i./acre).

  c. We will assume aerial application for uses on turf, grapes, and field ornamentals where the method of application is not specified on the label.

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- The Lesco Twosome Flowable Fungicide label (Reg. No. 10404-60) recommends up to 5 applications at 14-day intervals of up to 7.8 fl oz product/1000 sq ft for turfgrass patch diseases in early spring (p. 4). This yields a maximum seasonal application rate of 3.30 lbs a.i./acre, which does not conform to the maximum seasonal application rate of 1.56 lbs a.i./acre (27.56 lbs total a.i./acre) reported on p. 5. In the absence of label clarifications, we will assume that applicators may follow either set of label directions.

Preliminary estimated environmental concentrations (EECs) were calculated for aquatic (using the GENEEC Model) and terrestrial (using the T-REX Model) exposure for various application rates (see **APPENDIX C** for details). The highest exposure estimates represent application to turf at an annual rate of 10.89 lbs a.i./acre (4 applications/year at 2.72 lbs a.i./acre).

Based on these preliminary exposure estimates, previous risk assessment endpoints, and the assumptions discussed above, there are potential risks (due to direct effects from acute exposure) to listed aquatic invertebrates, listed and non-listed fish, aquatic-phase amphibians, aquatic plants, terrestrial plants, and listed and non-listed mammals from fenarimol use at the maximum application rate(s). Direct adverse effects cannot be precluded for listed and non-listed fish, aquatic-phase amphibians, aquatic invertebrates, aquatic plants, terrestrial plants, and mammals from chronic exposure to fenarimol at the maximum application rate(s). The RQs for birds (and, thus, reptiles and terrestrial-phase amphibians) could not be calculated because no effects were seen at the highest concentrations tested. Therefore, risks to listed species in these taxa cannot be precluded at this time.

Because of the potential risk from direct effects to the listed and non-listed taxa described above, should exposure occur, listed species in all taxa may potentially be affected indirectly due to alterations in their habitat (*e.g.*, food sources, shelter, and areas to reproduce).

If the planned ecological risk assessment continues to indicate that fenarimol may potentially impact, either directly or indirectly, listed species or critical habitat, and therefore does not support a "not likely to adversely affect" determination, further refinements will be made. This will involve determining whether use of fenarimol "may affect" a particular listed species, and if so, whether it is "likely to adversely affect" the species, or in the case of designated critical habitat, whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat, and if so, whether the expected impacts are "likely to adversely affect" the critical habitat. The first step in the process is to improve the exposure estimates based on refining the geographic proximity of fenarimol's use and the listed species and/or critical habitat. If there is no geographic proximity, this information would support a determination that fenarimol use will have no effect on the species or critical habitat. If after conducting the first step of this analysis the Agency determines that geographic proximity exists, both potential direct effects and any potential indirect effects of the pesticide use will be

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examined. This process is consistent with the Agency's Overview Document. The Agency will consult as necessary with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (Services), consistent with the Services' regulations.

If the screening level risk assessment identifies potential concerns for indirect effects on listed species, the next step for EPA and the Services would be to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether fenarimol's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by fenarimol. Then EPA would determine whether the use of fenarimol overlaps the critical habitat or the occupied range of those listed species.

Anticipated Data Needs

The Agency has requested GDCI data, including acceptable aqueous photolysis, anaerobic aquatic metabolism, aerobic aquatic metabolism, and terrestrial field dissipation studies. Submission of these GDCI data has the potential to change current and future ecological risk conclusions, depending on the availability of toxicological data on identified degradates. EFED does not recommend requesting any additional environmental fate studies; however, EFED recommends requiring acceptable Tier II (because there are known phytotoxic effects) seedling emergence and vegetative vigor plant studies and a toxicity study on a vascular aquatic plant species.

The Agency will also conduct a search of the open literature to ensure that all best available science is utilized. The Agency uses the ECOTOX database as its mechanism for searching the open literature for ecological effects information. ECOTOX integrates three previously independent databases - AQUIRE, PHYTOTOX, and TERRETOX - into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife, respectively.

Other Information Needs

There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is very much interested in obtaining the following information:

1. confirmation on the following label information
    a. sites of application

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   b. formulations
   c. application methods and equipment
   d. maximum application rates
   e. annual frequency of application, date of initial application per year, application intervals, and maximum number of applications per year
   f. geographic limitations on use
2. use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses)
3. use history
4. median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county
5. application timing (date of first application and application intervals) by use – national, state, and county
6. sub-county crop location data
7. usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals)
8. directly acquired county-level usage data (not derived from state level data)
   g. maximum reported use rate (lbs. a.i./acre) from usage data – county
   h. percent crop treated – county
   i. median and 90th percentile number of applications – county
   j. total pounds per year – county
   k. the year the pesticide was last used in the county/sub-county area
   l. the years in which the pesticide was applied in the county/sub-county area
9. typical application interval (days)
10. state or local use restrictions
11. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
12. monitoring data
13. environmental fate and toxicity data on the fenarimol degradates

The analysis plan will be revisited and may be revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

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APPENDIX A: Current Fenarimol Registrations and Uses

FENARIMOL REGISTRATIONS:

FORMULATION	EPA REG. NO.	% ACTIVE	METHODS OF APPLICATION	USE RESTRICTIONS
RIVERDALE PATCHWORK	10163-290	0.78%	Granular	
RUBIGAN E.C.	10163-273 OR-030037	12%	Ground	- Apply with ground equipment only. - Do not apply through any type of irrigation system.
RUBIGAN A.S.	10163-275	11.6%	Ground	- Apply with ground equipment only. - Do not apply through any type of irrigation system.
RUBIGAN A.S. TURF AND ORNAMENTAL	10163-274	11.6%	NR	- Do not apply through any type of irrigation system
LESCO TWOSOME FLOWABLE FUNGICIDE	10404-60	2.4%	NR	- Use of this product on home lawns is prohibited. - Do not apply through any type of irrigation system.

FENARIMOL USES:

USE	FORM.	MAX APPL. RATE	MAX APPL. INTERVAL	MAX APPL. RATE/ SEASON	MAX NO. OF APPL./ SEASON
Apples	Rubigan EC Rubigan AS	0.094 lbs a.i./A	7	0.656 lbs a.i./A	NR
Filberts	Rubigan EC	0.0625 lbs a.i./A	7	NR	NR
Pears	Rubigan EC Rubigan AS	0.094 lbs a.i./A	7	0.656 lbs a.i./A	NR
Pecans	Rubigan EC Rubigan AS	0.094 lbs a.i./A	7	0.656 lbs a.i./A	NR
Cherries	Rubigan EC	0.094 lbs a.i./A	7 (E) 14 (W)	0.469 lbs a.i./A (E) 0.375 lbs a.i./A (W)	NR
Grapes	Rubigan EC Rubigan AS	0.049 lbs a.i./A	14	0.148 lbs a.i./A 0.164 lbs a.i./A	NR
Roses (Field Grown)	Rubigan EC	0.094 lbs a.i./100 gal tank mix (… insure thorough wetting of all plant surfaces)	7	NR	NR
	Lesco Twosome Flowable	0.066 lbs a.i./A	7	2.19 lbs a.i./A	NR

USE	FORM.	MAX APPL. RATE	MAX APPL. INTERVAL	MAX APPL. RATE/ SEASON	MAX NO. OF APPL./ SEASON
Ornamentals (Field or Container Grown) (ajuga, begonia, calendula, chrysanthemum, dahlia, delphinium, hydrangea, phlox, sweet pea, verbena, zinnia)	Rubigan EC Rubigan AS Turf and Ornamental	0.039 lbs a.i./100 gal tank mix (… insure thorough wetting of all plant surfaces)	10	NR	NR
Ornamentals (Field or Container Grown) (crepe myrtle, euonymus, photinia) (and roses for Rubigan AS)	Rubigan EC Rubigan AS Turf and Ornamental	0.078 lbs a.i./100 gal tank mix (… insure thorough wetting of all plant surfaces)	10	NR	NR
Landscape Ornamentals	Lesco Twosome Flowable	0.093 lbs a.i./A	7	2.18 lbs a.i./A	NR
Ornamentals (crabapple and Hawthorn)	Rubigan AS Turf and Ornamental	0.094 lbs a.i./100 gal tank mix (… insure thorough wetting of all plant surfaces)	7	NR	NR
Ornamental Dogwwod	Rubigan AS Turf and Ornamental	0.0625 lbs a.i./100 gal tank mix (… insure thorough wetting of all plant surfaces)	14	NR	NR
Pachysandra	Lesco Twosome Flowable	0.186 lbs a.i./A	7	2.18 lbs a.i./A	NR
Conifers	Lesco Twosome Flowable	0.372 lbs a.i./A	21	0.991 lbs a.i./A	NR
Turf (general)	Lesco Twosome Flowable	0.678 lbs a.i./A 0.492 lbs a.i./A	7	3.30 lbs a.i./A	1 (at this rate) NR
	Rubigan AS Turf and Ornamental	2.72 lbs a.i./A	7	10.89 lbs a.i./A	12

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USE	FORM.	MAX APPL. RATE	MAX APPL. INTERVAL	MAX APPL. RATE/ SEASON	MAX NO. OF APPL./ SEASON
Turf (golf courses – greens)	Lesco Twosome Flowable	0.678 lbs a.i./A 0.438 lbs a.i./A	14 (initial appl.) 7	4.38 lbs a.i./A	NR
	Rubigan AS*	2.04 lbs a.i./A 1.36 lbs a.i./A	14	4.08 lbs a.i./A	2 3
	Rubigan AS Turf and Ornamental	2.72 lbs a.i./A	7	10.89 lbs a.i./A	12
Turf (golf courses – tees)	Lesco Twosome Flowable	0.678 lbs a.i./A 0.438 lbs a.i./A	14 (initial appl.) 7	3.12 lbs a.i./A	NR
	Rubigan AS*	2.04 lbs a.i./A 1.36 lbs a.i./A	14	4.08 lbs a.i./A	2 3
	Rubigan AS Turf and Ornamental	2.72 lbs a.i./A	7	10.89 lbs a.i./A	12
Turf (golf courses – fairways)	Lesco Twosome Flowable	0.678 lbs a.i./A 0.438 lbs a.i./A	7	1.56 lbs a.i./A	1 (at this rate) NR
	Rubigan AS Turf and Ornamental	2.72 lbs a.i./A	7	10.89 lbs a.i./A	12

NR = Not reported on the label
(E) = East of the Rockies
(W) = West of the Rockies
* *Poa annua* management for overseeded Bermudagrass

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APPENDIX B: Past Ecological Risk Assessments for Fenarimol

DOCUMENT DATE	TYPE OF REGISTRATION/ ASSESSMENT	USE(S)	POTENTIAL RISK IDENTIFIED	SUMMARIZED ECOLOGICAL CONCLUSIONS
1/9/1976	S3NU	Turf Roses	No	Use areas are of little value to nontarget organisms except earthworms. No objections, but request submission of earthworm or soil biota data.
1/29/1976	EUP	Grapes	No	(No objections to the proposed EUP.)
1/30/1976	EUP	Apples Grapes	No	(No objections to the proposed EUP.)
12/21/1981	EUP	Apples Grapes	No	Assessor anticipates no unreasonable adverse effects to non-target fish or wildlife from the use of Rubigan EC in the proposed EUP program (no RQs provided).
1/28/1982	EUP	Apples Grapes	No	(Concur with granting of EUP.)
8/25/1982	EUP	Apples Grapes	No	Assessor anticipates no unreasonable hazards to non-target fish or wildlife
9/15/1982	EUP	Apples Grapes	No	(Concur with granting of EUP.)
9/16/1982	EUP	Apples Grapes	No	(Refer to 9-15-82 EUP evaluation.)
2/3/1983	S3NU	Turf	No	Significant acute effects to non-target populations are not expected. Chronic effects cannot be addressed. Stock Island Snail and Mohave Chub are noted as listed species of concern.
2/4/1983	S3NU	Turf	No	(Addendum to adjust EEC to 30 ppb)
2/25/1983	S3NU	Turf	No	(Unknown)
3/7/1983	EUP	Turf	No	Concur with extension of EUP.
4/6/1983	EUP	Roses	No	Significant hazards to wildlife populations are not anticipated under the EUP extension.
4/14/1983	EUP	Grapes	No	Significant hazards to wildlife populations are not anticipated under the EUP extension.

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DOCUMENT DATE	TYPE OF REGISTRATION/ ASSESSMENT	USE(S)	POTENTIAL RISK IDENTIFIED	SUMMARIZED ECOLOGICAL CONCLUSIONS
4/18/1983	EUP	Roses	No	(Concur with extension of EUP.)
5/27/1983	RTC-EUP	Turf	No	(Data are insufficient for human exposure assessment and do not address 2-25-83 review of original March 1982 submission.)
6/6/1983	EUP	Grapes	No	(Concur with extension of EUP.)
6/22/1983	Memo	Turf	No	Accept new fish LC_{50} results.
10/6/1983	EUP	Pecans	No	No significant adverse effects are anticipated due to limited acreage of use. 25 listed species identified as species of concern.
11/30/1983	EUP	Apples Grapes	No	(Concur with extension of EUP.)
11/30/1983	EUP	Pecans	No	(Concur with extension of EUP.)
2/16/1984	EUP	Turf	No	No significant adverse effects are anticipated due to limited acreage of use. 3 listed species identified as species of concern.
2/17/1984	EUP	Ornamentals	No	No significant adverse effects are anticipated due to limited acreage of use and low application rates.
3/15/1984	EUP	Ornamentals	No	(No objection to 1-year extension.)
3/15/1984	EUP	Turf	No	(No objection to 1-year extension.)
8/23/1984	S3NU	Pecans	No	No significant acute hazards to birds or aquatic biota are expected. The risk assessment is incomplete without chronic bird and aquatic invertebrate data.
10/5/1984	S3NU	Apples	No	Provides minimal acute hazards to nontarget organisms. The risk assessment is incomplete without chronic bird data.
12/13/1984	S3NU	Grapes	No	Unable to complete the risk assessment without avian reproduction and acute honeybee studies.
1/3/1986	S3NU	Apples Pecans	No	The risk assessment is incomplete without chronic bird and aquatic invertebrate data.
6/20/1986	S3NU	Apples	No	Apple use addition to Rubigan EC for ornamentals will not result in

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DOCUMENT DATE	TYPE OF REGISTRATION/ ASSESSMENT	USE(S)	POTENTIAL RISK IDENTIFIED	SUMMARIZED ECOLOGICAL CONCLUSIONS
				additional environmental hazards.
10/20/1987	S3NU	Pears	No	(Cannot concur without long-term soil dissipation and laboratory volatility studies.)
10/20/1987	S3NU	Apples Pecans Grapes	No	(The assessor concurs with Rubigan EC use on grapes, but cannot concur with the registration of Rubigan A.S. on apples, grapes, and pecans because of fate data gaps. Cannot concur with deletion of max. application rate.)
11/2/1987	S3NU	Apples Pecans Grapes Pears	No	Significant acute hazards to terrestrial populations are not expected, nor are acute or chronic hazards to aquatic organisms. Tier I algae study is requested.
3/17/1988	RTC	Grapes	No	(Response to 10-20-87 comments: The Terrestrial Field Dissipation study is waived, but the lab volatility study is still requested.)
5/4/1988	S18	Cherries	No	Not likely to pose a hazard to nontarget organisms.
5/12/1988	S18	Cherries	No	(No review needed for ground water concerns.)
5/24/1988	S3NU	Cherries	No	No additional environmental hazards. (Concur with proposed use.)
8/12/1988	RTC	Grapes	No	(Response to 10-20-87 comments: All data requirements for the registration of Rubigan A.S. for apples, pears, pecans, and grapes have been satisfied (both studies waived).)
12/14/1988	S3NU	Apples Pecans	No	No adverse impacts to nontarget organisms are expected (response to submission of requested studies).
2/21/1989	S3NU	Cherries	No	No risk to nontarget animals. Cannot assess risk to plants without a Tier I aquatic plant toxicity test.
5/3/1989	S18	Cherries	No	No hazard to nontarget organisms.
4/15/1992	S18	Filberts	No	Not expected to result in adverse effects to nontarget organisms.

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DOCUMENT DATE	TYPE OF REGISTRATION/ ASSESSMENT	USE(S)	POTENTIAL RISK IDENTIFIED	SUMMARIZED ECOLOGICAL CONCLUSIONS
3/1/1995	S18	Filberts	No	Minimal adverse effects are expected to nontarget organisms including three listed bird species.
10/7/1997	S18	Hops	No	No risks. No plant data. (No RQs for mammals calculated.)
2/11/1999	S18	Filberts	Yes	No risks to freshwater fish, invertebrates, or birds. Chronic risk to mammals identified. Same conclusions for listed species.
10/17/2005	S3NU	Grapes Filberts	Yes	Chronic risk to mammals identified. Unable to assess risk to estuarine/marine organisms and terrestrial plants due to lack of data.

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APPENDIX C: Preliminary EECs and RQs for Aquatic and Terrestrial Organisms

Table 1. Agency Levels of Concern (LOCs).

Risk Presumption	Taxa	LOC
Acute Risk	Birds, mammals, aquatic animals	0.5
	Plants	1
Acute Restricted Use	Birds, mammals	0.2
	Aquatic animals	0.1
Acute Endangered Species	Birds, mammals	0.1
	Aquatic animals	0.05
	Plants	1
Chronic Risk	Birds, mammals, aquatic animals	1

Table 2. Preliminary Tier I Aquatic Estimated Environmental Concentrations (EEC) of Fenarimol, reported in µg/L (Calculated using GENEEC).

Use pattern	EPA Reg. No.	Max. Annual App. Rate (lbs a.i./acre)	Peak EEC	Max. 4-day Mean EEC	Max. 21-day Mean EEC	Max. 60-day Mean EEC	Max. 90-day Mean EEC
Turf	10163-274	10.89	460	459	454	444	436
Turf	10404-60	3.30	139	139	137	134	132
Ornamentals	10163-273, 10163-274	2.26	94.5	94.3	93.3	91.2	89.6
Ornamentals	10404-60	2.18	91.9	91.7	90.8	88.7	87.2
Turf	10404-60	1.56	65.9	65.8	65.1	63.6	62.5
Filberts	OR-030037	1.50	62.3	62.1	61.5	60.1	59.0
Apples, pecans, pears	10163-273, 10163-275	0.656	27.4	27.4	27.1	26.5	26.0

Table 3. Summary of Preliminary Risk Quotient Calculations for Aquatic Organisms for Various Fenarimol Application Rates.

Use pattern	EPA Reg. No.	Max. Annual App. Rate (lbs a.i./acre)	RQ		
			Aquatic Invertebrate	Fish	Non-Vascular Aquatic Plant
Turf	10163-274	10.89	0.07	0.511	1.07
Turf	10404-60	3.30	0.02	0.154	0.32
Ornamentals	10163-273, 10163-274	2.26	0.014	0.105	0.22

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Table 4. Summary of Preliminary Risk Quotient Calculations for Mammals Based on Upper Bound Kenega EECs (Calculated Using T-REX 1.3.1, and the Highest Registered Application Rate – 2.27 lb a.i./acre, 4 applications, 7-day application interval).

Table a. Upper 90th Percentile Kenega, Acute Mammalian Dietary Based Risk Quotients

	EECs and RQs							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
LC50 (ppm)	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
1	2147	1789	984	820	1207	1006	134	112

Size class not used for dietary risk quotients

Table b. Upper 90th Percentile Kenega, Chronic Mammalian Dietary Based Risk Quotients

NOAEC (ppm)	EECs and RQs							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
13	2147	172	984	79	1207	97	134	11

Size class not used for dietary risk quotients

Table c. Upper 90th Percentile Kenega, Chronic Mammalian Dose-Based Risk Quotients

Size Class (grams)	Adjusted NOAEL	EECs and RQs									
		Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
		EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15	1.32	2047	1552	938	711	1151	873	128	97	28	22
35	1.07	1414	1326	648	608	796	746	88	83	20	18
1000	0.46	328	711	150	326	184	400	21	44	5	10

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Docket Number: EPA-HQ-OPP-2006-0241
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IV. HUMAN HEALTH EFFECTS SCOPING DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

March 21, 2007

SUBJECT: **Fenarimol** (PC 206600) Scoping Document in Support of Registration Review, DP# 336007

FROM: Danette Drew, Senior Scientist
Reregistration Branch 3
Health Effects Division (7509P)
Office of Pesticide Programs

THRU: Catherine Eiden, Branch Chief
Reregistration Branch 3
Health Effects Division (7509P)
Office of Pesticide Programs

TO: Katherine St. Clair, Chemical Review Manager
Reregistration Branch 2
Special Review and Reregistration Division (7508P)
Office of Pesticide Programs

Attached is a human health risk assessment status update for the fungicide fenarimol, which is beginning the Registration Review process. EPA's Health Effects Division (HED) has considered recent fenarimol risk assessments, updates to toxicity, exposure and usage databases, and changes in science policy in its review. HED has determined that recent risk assessments meet current standards for science and that toxicity and exposure databases for fenarimol are substantially complete. However, Ecological Fate and Effects Division (EFED) is revising its estimated environmental concentrations (EECs) in drinking water sources based on maximum label application rates for fenarimol use on turf. Once EFED has finalized its revised drinking water assessment, HED will determine if revisions to the aggregate risk assessments are necessary for combined dietary exposures to fenarimol through food and drinking water.

Revisions to the dietary assessments may necessitate revisions to assessments aggregating dietary and residential exposures for adults and children potentially exposed to fenarimol through residential uses listed on the current labels. The occupational exposure risk assessments will be revisited under Registration Review for all currently registered uses of fenarimol, using current policies and procedures. Sufficient data are available to perform the human health risk assessments for fenarimol.

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Registration Review – Fenarimol (PC 206600)

Human Health Risk Assessment Status

Introduction

The HED Fenarimol Registration Review Team has evaluated the status of the human health assessments for the fungicide fenarimol to determine whether sufficient data are available and whether a new human health risk assessment is needed to support Registration Review. The primary sources for the status update were the most recent human health risk assessment (September 2002), the Tolerance Reassessment Eligibility Decision (TRED) (August 2002), Agency memorandum, *Fenarimol: Re-evaluation of the FQPA Safety Factor*, (April 2006), and an OPPIN bibliography of submitted studies (MRIDs). Memoranda regarding the proposed new use of fenarimol on hops were also considered (August 2006, November 2006). A screening Google Scholar search and a Science Direct search indicated recently published toxicity studies for fenarimol that may or may not be relevant to human health risk assessment. A more comprehensive literature search and evaluation of relevant data will be performed under the Registration Review process for fenarimol. Incident databases were also reviewed.

Fenarimol is a systemic foliar fungicide (pyrimidine class) used for control of such pests as scab, powdery mildew, rusts, and leaf spot. Fenarimol is currently registered for use on the following fruit and nut crops: apples, cherries, filberts, grapes, pears, and pecans. Fenarimol is used on imported bananas. It is also registered for use on ornamental plants, trees, grasses, and turf. A section 3 registration for use on hops is undergoing EPA review.

Hazard Characterization and Toxicology

The toxicity database for fenarimol is substantially complete for the purpose of assessing human health risks.

The liver is the most evident target organ for toxicity, aside from the effects of fenarimol on aromatase. Liver toxicity was manifested by liver weight increases and the presence of "fatty

liver" in rats. In dogs, liver weight was increased and there were also increases in serum enzymes indicative of liver toxicity. The data base for carcinogenicity is considered complete. Fenarimol has been classified as not likely to be a human carcinogen (Group E). The mutagenicity/genetic toxicity data base is considered complete and indicates no mutagenicity concern.

The data base for prenatal developmental and reproductive toxicity is considered complete. The developmental and reproductive toxicity studies showed no evidence of increased sensitivity or susceptibility of young rats or rabbits following pre- or postnatal exposure to fenarimol.

In a July 2002 report of the HED Hazard Identification Assessment Review Committee (HIARC), it was concluded that a 3X FQPA safety factor be retained because of the potential of fenarimol to affect the hormone system during reproductive development and the need to better characterize its endocrine effects. This concern was based on the observation from an *in vitro* study that fenarimol inhibited aromatase (an enzyme complex responsible for estrogen biosynthesis that converts androgens into estrogens, and thus aromatase inhibition would result in attenuate estradiol levels) and its affect on fertility in males and dystocia in females. The HIARC concluded that a special developmental toxicity study to assess for potential hormonal effects elicited by aromatase inhibition was required for fenarimol and a FQPA safety factor of 3X (for database uncertainty)was required.

The previous fenarimol risk assessment (September 2002) identified three data needs: a primary dermal irritation study, a 28-day inhalation study, and a special developmental toxicity study. HED has subsequently received the following two toxicological submissions:

1) data intended to support a waiver request for an inhalation study (based on atomization droplet size spectra for fenarimol).

According to the September 2002 assessment, it was agreed that the registrant may submit a waiver for the 28-day inhalation study. It was stated that "this waiver must contain sufficient data on the particle size of the sprays and other preparations that may result in inhalation exposure. It also must contain sufficient other information regarding the potential inhalation exposure such as duration of exposure in terms of hours per day, per week, etc." The submitted waiver request will be reviewed under the Registration Review process. Since the last risk assessment on fenarimol, HED has implemented an inhalation toxicity study waiver policy. In addition to evaluating droplet size, fenarimol will be evaluated for other criteria for a waiver such as degree of inhalation toxicity (fenarimol is Category III in an acute inhalation study) and whether calculated inhalation MOEs are greater than 1000 (based on oral toxicity data) for all inhalation scenarios.

2) data intended to support a waiver request for a special developmental toxicity study.

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The Agency is no longer requiring a special developmental toxicity study for fenarimol as there are adequate data evaluating the potential endocrine effects of fenarimol during reproduction and development in the young animal (Swartz, March 2007). Fenarimol has been evaluated in two new special studies: a pubertal female assay and an uterotrophic assay. The pubertal female assay involves the use of rats to screen for estrogenic and thyroid activity in females during sexual maturation, and examines abnormalities associated with sex organs and puberty markers, as well as thyroid tissue. The uterotrophic assay involves the use of female rats to screen for estrogenic effects. In this *in vivo* assay, uterine weight changes are measured in ovariectomised or immature female rats.

No adverse effects were found in the female pubertal assay when rats were treated at 50 and 250 mg/kg/day for 21 days, except for a decrease in T4 and an increase in circulating TSH levels. In the uterotrophic assay, a dose of 200 mg/kg/day results in a significant increase of uterine weights which were accompanied by an increase in serum FSH levels and a decrease in serum T3 levels. The uterotrophic response and the effects found on thyroid hormone levels are found at much higher doses than the regulatory endpoints (selected for current fenarimol risk assessment) based on the rat multi-generation study where fenarimol reduced fertility of males at 1.2 mg/kg/day with a NOAEL of 0.6 mg/kg/day.

The new special studies (the pubertal and uterotrophic assays), along with the existing standard 2-generation rat reproductive study, provide an adequate characterization of the reproductive, developmental and endocrine effects of fenarimol. With these new data, there is greater confidence in the current NOAEL of 0.6 mg/kg/day, and the 3X FQPA safety factor for residual concerns regarding endocrine effects should be reduced to 1X.

Dietary (food only) Exposure

With respect to the assessment of dietary risks, the dietary exposure database is complete. There are adequate residue data reflecting the use of all existing formulations on representative commodities. HED identified a reference dose for chronic exposure (cRfD) of 0.006 mg/kg/day from the multi-generation reproduction study based on a no observed adverse effect level (NOAEL) of 0.6 mg/kg/day (LOAEL of 1.2 mg/kg/day based on decreased litter size), and a 10X uncertainty factor for interspecies extrapolation and a 10X uncertainty factor for intraspecies variation. HED calculated a chronic Population Adjusted Dose (cPAD) of 0.002 mg/kg/day. The cPAD is the RfD divided by the FQPA safety factor (3X). Chronic dietary exposure estimates greater than 100% of the cPAD would exceed HED's level of concern. Chronic dietary (food only) risk estimates were less than 1% of the cPAD for all populations using a refined exposure assessment (monitoring and field trial data, percent crop treated information, and processing factors). The reduction in the FQPA safety factor from 3X to 1X would result in a cPAD of 0.006 mg/kg/day and resulting chronic dietary risk estimates would remain below the level of concern, thus a revised chronic dietary (food only) risk assessment is not warranted.

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No acute dietary assessment is required as no suitable single dose effect on which to base an acute dietary assessment was identified in the toxicity database.

Residential Exposure

According to a previous human health risk assessment (June 2002), potential residential (non-occupational) exposures were anticipated as a result of applications of fenarimol to residential lawns (and turf) by homeowners and by professional lawn care operators. Risks were estimated for both residential handler exposures (adults) and residential postapplication exposures (adults and toddlers). Residential exposure was of concern for adults and toddlers for several exposure scenarios as a result of application of fenarimol to residential turf. See Table 1 below for the summary of scenarios and risk estimates.

Even with the FQPA safety factor for residual uncertainties regarding endocrine effects reduced to 1X, the level of concern (Margin of Exposure or MOE) for short-term residential exposures remains 1000 because of the application of an uncertainty factor of 10X for lack of a NOAEL in the critical study on which the endpoint for short-term risk assessments is based. The MOE for intermediate-term residential exposures remains 100. As such, several scenarios of concern remain. These MOEs are in brackets in Table 1 below.

The Special Review and Reregistration Division (SRRD) subsequently informed HED that the registrant had agreed to amend their product labels to prohibit residential use and handling (i.e. mixing, loading or applying) of fenarimol in residential settings in order to mitigate these exposures. Applications to turf would be limited to golf courses, and stadium fields or professional athletic fields only. Therefore, residential handler and residential postapplication exposure scenarios should no longer exist. Only non-occupational postapplication exposures of adult golfers remain to be evaluated. Based upon the slow dissipation rate of fenarimol and the possibility of multiple applications to turf, intermediate-term exposures of adult golfers would be possible. However, according to the September 2002 assessment, HED had been informed by SRRD that the registrant had agreed to amend their product labels to extend the re-application interval to turf to 30 days, thereby eliminating any potential intermediate-term residential exposures. Therefore, the only non-occupational postapplication exposure scenario remaining to be evaluated would be *short-term* dermal exposure to adult golfers.

Therefore, in the September 2002 human health risk assessment, only short-term dermal exposure to adult golfers was assessed. Resulting risk estimates were not of concern for adult golfers (MOE of 14,000 vs. a level of concern at 1000). The short-term assessment for golfers need not be revised under Registration Review.

HED notes that some current fenarimol product labels still list turf uses other than golf courses such as “parks, athletic fields, commercial and residential areas” (EPA Reg No. 10163-274; March 4, 2003) and “parks, athletic fields, sod farms, and similar commercial and residential

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areas" (EPA Reg No.10163-290; September 19, 2003). Additionally, labels for Reg. Nos. 10163-274, 10163-290, and 10404-60 still specify re-treatment intervals of less than 30 days. HED will evaluate these uses to determine if the potential for non-occupational (residential) exposures exist and will revisit, where necessary, any non-occupational risk assessments.

Table 1. Summary of Residential Exposure Scenarios and Risk Estimates

Exposure Scenario	Route of Exposure	Population	ST MOE	IT MOE
Residential Handlers (Mixers/Loaders/Applicators) Exposures				
Applying Granular Product by Hand Application	Dermal	Adult	1600	N/A
Loading/Applying Granular for Belly Grinder Application	Dermal	Adult	[280]	N/A
Loading/Applying Granular for Push-type Spreader Application	Dermal	Adult	45,000	N/A
Applying Granular Product by Hand Application	Inhalation	Adult	71,000	N/A
Loading/Applying Granular for Belly Grinder Application	Inhalation	Adult	25,000	N/A
Loading/Applying Granular for Push-type Spreader Application	Inhalation	Adult	1.7E+6	N/A
Combined Residential Handlers Exposures				
Applying Granular Product by Hand Application	Dermal & Inhalation	Adult	1500	N/A
Loading/Applying Granular for Belly Grinder Application	Dermal & Inhalation	Adult	[280]	N/A
Loading/Applying Granular for Push-type Spreader Application	Dermal & Inhalation	Adult	44,000	N/A
Postapplication Exposures				
High Contact Activities - e.g. Working	Dermal	Adult	[950]	1400
High Contact Activities - e.g. Playing	Dermal	Toddler	[660]	1000
Low Contact Activity - Mowing	Dermal	Adult	27,000	21,000
Low Contact Activity - Golfing	Dermal	Adult	14,000	10,000
Hand to Mouth Activity	Oral	Toddler	[860]	[78]

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Exposure Scenario	Route of Exposure	Population	ST MOE	IT MOE
Incidental Turf grass Mouthing	Oral	Toddler	3400	320
Incidental Ingestion of Soil	Oral	Toddler	2.6E+5	2.4E+4
Ingestion of Fenarimol Product Granules	Oral	Toddler	[220]	N/A
Combined Post application Exposures				
All Incidental Oral Non-Dietary (except granular ingestion)	Oral	Toddler	[690]	[62]
Dermal & All Incidental Oral Non-Dietary (except granular ingestion)	Oral & Dermal	Toddler	[340]	[58]
Residential Handler (Belly Grinder Spreader) & High Contact Post-Application Activities	Dermal	Adult	[214]	N/A

Aggregate

Drinking water risks were last assessed using the Drinking Water Level of Comparison (DWLOC) approach. In the 2002 risk assessment, surface water EECs (84 ppb; provided by the Ecological Fate and Effects Division/EFED 2002) exceeded the chronic DWLOCs for all populations (70 ppb for US population, 60 ppb for females 13-50 years old, and 20 ppb for infants and children). The 84 ppb value included all residential uses and the golf course use of fenarimol. However, the 2002 TRED indicated that with the residential uses removed from the labels, a correction factor of .31 can be applied to the 84 ppb surface water number to account for the use of fenarimol only on tees, greens, and fairways on golf courses. This reduced the chronic EEC to 26 ppb which still somewhat exceeded the chronic DWLOC of 20 ppb for infants and children (the most sensitive population subgroups).

With the 3X FQPA safety factor for residual concerns regarding endocrine effects reduced to 1X, the chronic DWLOCs for all populations, including infants and children, would be well above the 26 ppb surface water EEC (210 ppb for US population, 180 ppb for females, and 60 ppb for infants/children). That said, it should be noted that EFED is revising its EECs based on maximum label application rates for use on turf (the previous EFED assessment did not use the maximum allowed seasonal rate). Also since there are labeled turf uses other than golf courses, such as parks, athletic fields, commercial and residential areas, the .31 correction factor may no longer be applicable. Once EFED has finalized its revised drinking water assessment, HED will determine if potential fenarimol exposures through drinking water are significant enough to warrant a revised dietary assessment.

In the September 2002 human health risk assessment, short-term dermal postapplication exposures for adult golfers were combined with average dietary (food & water) exposures in a

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short-term aggregate risk assessment and did not result in risk estimates above the Agency's level of concern.

Once EFED has finalized its revised drinking water assessment, HED will determine if a revised short-term aggregate assessment is necessary for adult golfers for combined exposures to fenarimol. A revised chronic dietary (food plus water) aggregate assessment may also be needed for all populations. Aggregate (dietary plus residential) assessments may also need to be performed for adults and children potentially exposed to fenarimol through residential uses listed on the current labels. [The toxicity endpoints and doses for use in the risk assessment are summarized in Appendix I.]

Occupational Exposure

Fenarimol was registered after 1984 and was not subject to the reregistration requirements of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) of 1988. The 2002 fenarimol assessment only addressed the human health risks required for reassessment of tolerances under the FQPA and did not require an occupational risk assessment. As such, a recent comprehensive occupational exposure assessment has not been performed for the all the currently registered uses of fenarimol using the most current standards and policies. Under Registration Review, the occupational exposure assessments will be revisited using the current policies for the use scenarios listed in Table 2. There are sufficient data available to perform an occupational exposure risk assessment. [The toxicity endpoints and doses for use in the occupational risk assessment are summarized in Appendix I.]

The Registration Division performed an assessment of short-term exposure and risk to occupational pesticide handlers (mixers, loaders, applicators) and to agricultural workers (post application) for the proposed use of fenarimol on hops (August 2006). Risk estimates were below the level concern.

Table 2. Occupational Exposure Scenarios for Fenarimol Uses

EPA Reg Number/Product Name	Crops	Application Rate lb ai/A or lb ai/gal	Handler Assessment Required?	Application Method	Post application exposure Required ?
10404-60/ Twosome	Turf	0.66 lb ai/A	Yes	Ground Boom, High pressure handwand, Back pack sprayer	Yes
10163-274 and 10163-275 Rubigan A.S Includes the supplemental	Turf	2lbs ai/A	Yes	Ground Boom, High pressure handwand, Back pack sprayer	Yes
	Apple	0.1 lb ai/A		Air blast Sprayer	
	Pear	0.1 lb ai/A			
	Pecans	0.1 lb ai/A			

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	Grapes	0.05 lb ai/A			
10163-273/ Rubigan includes a SLN (OR 030037)	Hazelnut	0.0625 lb ai/A	Yes	Air blast sprayer	Yes
	Apple	0.1 lb ai/A	Yes	Air blast sprayer	
	Pears	0.1 lb ai/A			
	Grapes	0.05 lb ai/A			
	Cherries	0.1 lb ai/A			
	Ornamental	0.0008 lb ai/gal		Low pressure hand wand, Back pack sprayer	
10163-290/Riverdale/Patch work	Turf	2.7 lb ai A	Yes	Granular spreader	Yes

Other Issues:

Residue Chemistry and Product Chemistry Data

Storage stability data for livestock commodities were required to support the storage durations used in the livestock feeding studies. A 2006 study has been submitted and is currently under review.

Additional product chemistry data were required concerning enforcement analytical methods, stability, storage stability, pH, UV/Visible absorption, density, octanol/water partition coefficient, and solubility (OPPTS 830.1800, 6313, 6317, 7000, 7050, 7300, 7550, and 7840) of the T/TGAI. Product chemistry data have been submitted and are currently under review.

Tolerances

A final rule for fenarimol was issued September 15, 2006 (71-54423-54434) wherein 40 CFR Part 180 section 180.421 is amended by revising paragraph (a) to read as follows:

Sec. 180.421 Fenarimol; tolerances for residues.

(a) General. Tolerances are established for residues of the fungicide fenarimol, alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	0.1
Apple, wet pomace	0.3
Banana	0.25
Cattle, fat	0.01
Cattle, kidney	0.01
Cattle, meat	0.01

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Cattle, meat byproducts, except kidney.....0.05
Cherry, sweet.....1.0
Cherry, tart.....1.0
Goat, fat.....0.01
Goat, kidney.....0.01
Goat, meat.....0.01
Goat, meat byproducts, except kidney..... 0.05
Grape..... 0.1
Hazelnut.....0.02
Horse, fat..... 0.01
Horse, kidney.....0.01
Horse, meat.....0.01
Horse, meat byproducts, except kidney..... 0.05
Pear.....0.1
Pecan.....0.02
Sheep, fat..... 0.01
Sheep, kidney.....0.01
Sheep, meat.....0.01
Sheep, meat byproducts, except kidney..... 0.05

Additionally, the time-limited tolerances for filberts (hazelnuts) and hops expired 12/31/98. The 2002 risk assessment recommended that the established time-limited tolerances for hops and filberts should be revoked. However, a permanent tolerance (0.02ppm) was added for residues of fenarimol on filberts on 6/7/06 (71 FR 32841-32846). Filberts were included in the 2002 dietary risk assessment.

Field trial data were submitted to support a Section 3 registration on hops. The Registration Division has recommended, based on residue chemistry considerations, that the requested tolerance of 1.2 ppm be established for the residues of fenarimol, *per se* in/on hops (November 2006).

Harmonization Issues

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of fenarimol in/on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of fenarimol *per se* and are presented in the table below. Except for cattle liver, cherries, and pecans, the U.S. tolerances and Codex MRLs are not in harmony with respect to numerical levels.
Currently there are no MRLs for Canada.

Mexican MRLs exist for fenarimol on apple (0.1 ppm), pear (0.1 ppm), pecan (0.1 ppm), filbert (0.02 ppm), cherry (1 ppm), and grape (0.1 ppm) (source: http://www.fas.usda.gov/htp/MRL.asp). Except for pecan, these numerical levels are consistent with the corresponding US tolerances.

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Table 3. Codex MRLs and applicable U.S. tolerances for fenarimol. Recommendations are based on conclusions following reassessment of U.S. tolerances.

Codex		Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL [1] (mg/kg)		
Apple pomace, dry	5	wet apple pomace = 0.3	Dry apple pomace is no longer considered a significant livestock feed item.
Artichoke globe	0.1	--	
Banana	0.2	0.25	
Cattle kidney	0.02 (*)	0.01 (*)	
Cattle liver	0.05	Revoked	covered by tolerance for meat byproducts
Cattle meat	0.02 (*)	0.01 (*)	
Cherries	1	1	
Dried grapes (currants, raisins and sultanas)	0.2	Revoked	
Grapes	0.3	0.1	
Hops, dry	5	1.2	proposed
Melons, except watermelon	0.05	--	
Peach	0.5	--	
Pecan	0.02 (*)	0.02 (*)	
Peppers, sweet	0.5	--	
Pome fruits	0.3	apple/pear = 0.1	
Strawberry	1	--	

*Residues at or below limit of detection

Incident Reports

An updated fenarimol incident report was prepared January 2007.There were few reports of ill effects from exposure to fenarimol in the available databases. There were a total of 26 poisoning cases reported between 1993 and 2003 which may have been associated with exposure to fenarimol. Reported symptoms included skin rashes, swelling, upper respiratory irritation, chest pain, and in a case of ingestion, vomiting. Out of the 20 cases reported to the Poison Control Center, none reported a serious or even a moderate outcome.

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CONCLUSION: HED has determined that recent risk assessments meet current standards for science and that toxicity and exposure databases for fenarimol are substantially complete. However, EFED is revising its EECs in drinking water sources based on maximum label application rates for fenarimol use on turf. Once EFED has finalized its revised drinking water assessment, HED will determine if a revised aggregate assessment is necessary for adult golfers for combined exposures to fenarimol. A chronic dietary (food plus water) aggregate assessment may also be needed for all populations. Aggregate (dietary plus residential) assessments may also need to be performed for adults and children potentially exposed to fenarimol through residential uses listed on the current labels. The occupational exposure risk assessments will be revisited under Registration Review for all currently registered uses of fenarimol, using the current policies and procedures. Sufficient data are available to perform the human health risk assessments for fenarimol.

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Referenced Memoranda

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Fenarimol, August 1, 2002, L. Rossi.

Fenarimol. Updated HED Human Health Assessment for the Tolerance Reassessment Eligibility Decision (TRED) Document DP# 285162. September 3, 2002, B. O'Keefe.

Report of the HED Hazard Identification Assessment Review Committee, July 29, 2002; TXR No. 0050977.

Fenarimol: Re-evaluation of the FQPA Safety Factor, DP#331611, March 12, 2007, C. Swartz.

FENARIMOL: Human Nondietary Exposure/Risk Assessment for the Use of Fenarimol on Hops, DP # 330744, August 24, 2006, M. Dow.

Fenarimol. Section 3 Registration on Hops. Summary of Analytical Chemistry and Residue Data. Petition Number 6E7074, DP # 331894, November 15, 2006, D. Rate.

Updated Drinking Water Assessment to Support TRED for Fenarimol, N. Birchfield, 7/31/02.

Fenarimol. Revised HED Human Health Assessment for the Tolerance Reassessment Eligibility Decision (TRED) Document, DP # 283429, June 7, 2002, B. O'Keefe.

Review of Fenarimol Incident Reports, DP# 336006, January 25, 2007, M. Hawkins and H. Allender.

APPENDIX I

Summary of Toxicological Doses and Endpoints for Fenarimol for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	N/A	N/A	N/A	No appropriate hazard was identified for single dose risk assessment.
Chronic Dietary (All Populations)	NOAEL= 0.6 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=1X	Chronic RfD =0.006 mg/kg/day cPAD =0.006 mg/kg/day	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Incidental Oral Short-Term (1-30 days)	LOAEL= 35 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=10X (UF_L)	Residential LOC for MOE 1000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects.
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= 0.6 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=1X	Residential LOC for MOE=100	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Dermal Short-Term (1-30 days)	LOAEL= 35 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=10X (UF_L)	Residential LOC for MOE 1000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects.
Dermal Intermediate-Term (1-6 months)	NOAEL= 0.6 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=1X	Residential LOC for MOE=100	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Inhalation Short- Term (1-30 days)	LOAEL= 35 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=10X (UF_L)	Residential LOC for MOE 1000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects.
Inhalation Intermediate-Term (1-6 months)	NOAEL= 0.6 mg/kg/day	UF_A=10X UF_H=10X FQPA SF=1X	Residential LOC for MOE=100	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable. For extrapolation

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from an oral study for dermal risk assessment, a 5% dermal absorption factor should be used. For extrapolation from an oral study for inhalation risk assessment, a 100% inhalation factor should be used.

Summary of Toxicological Doses and Endpoints for Fenarimol for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1-30 days)	LOAEL= 35 mg/kg/day 5% DA	UF_A=10X UF_H=10X UF_L=10X	Occupational LOC for MOE = 1000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects.
Dermal Intermediate-Term (1-6 months)	NOAEL= 0.6 mg/kg/day 5% DA	UF_A=10X UF_H=10X	Occupational LOC for MOE = 100	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Inhalation Short-Term (1-30 days)	LOAEL= 35 mg/kg/day 100% IA	UF_A=10X UF_H=10X UF_L=10X	Occupational LOC for MOE = 1000	Special Reproduction Study (Rat) LOAEL = 35 mg/kg/day based on decreased fertility and dystocia, an indication of hormonal effects.
Inhalation Intermediate-term (1-6 months)	NOAEL= 0.6 mg/kg/day 100% IA	UF_A=10X UF_H=10X	Occupational LOC for MOE = 100	Rat reproduction LOAEL = 1.2 mg/kg/day Based on decreased liveborn litter size.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. MOE = margin of exposure. LOC = level of concern. N/A = not applicable. For extrapolation from an oral study for dermal risk assessment, a 5% dermal absorption factor should be used. For extrapolation from an oral study for inhalation risk assessment, a 100% inhalation factor should be used.

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V. GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area

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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
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
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

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