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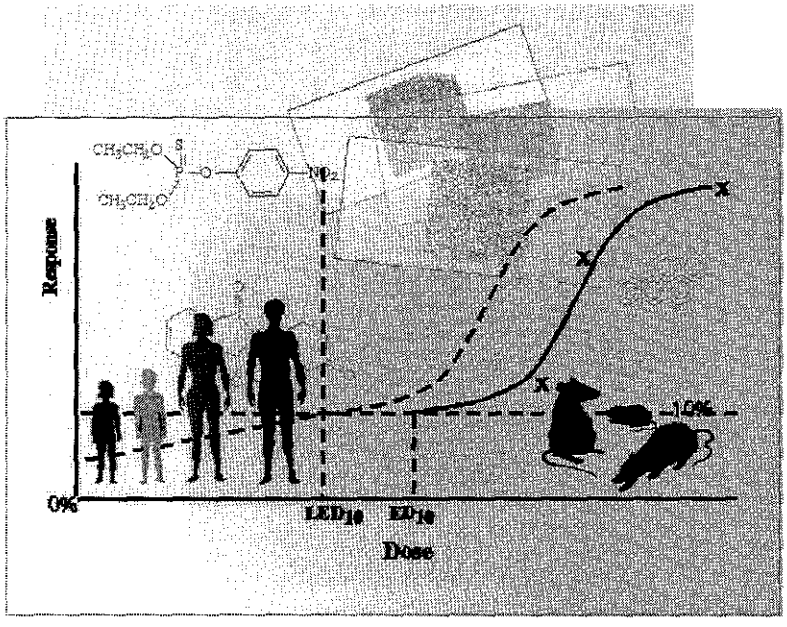
REVISED HUMAN HEALTH RISK ASSESSMENT

Etridiazole



U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509C)

Danette Drew, Risk Assessor
June 6, 2000

HUMAN HEALTH RISK ASSESSMENT

Etridiazole

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

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

Date: June 6, 2000

MEMORANDUM

SUBJECT: **Etridiazole (Terrazole®)**: HED **Revised** Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Chemical No. 084701. Reregistration Case No. 0009. Case #819299. Submission # S579038, DP Barcode D266264.

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Attached is the Health Effect Division's revised preliminary human health risk assessment for the fungicide etridiazole (Terrazole®). The registrant has submitted comments on the initial preliminary risk assessment (issued 1/3/00, DPBarcode D249681) which has been revised here to reflect those comments, where appropriate. The registrant's comments to the risk assessment as well as the Agency's subsequent responses are outlined point-by-point in the memorandum "Response to Registrant's 30-day Comments on Preliminary Risk Assessment for Terrazole", 4/26/00, R.Farrell. Minor corrections to errors were also made as a result of the Agency's meeting with Uniroyal on 5/25/00.

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1.0 EXECUTIVE SUMMARY

Etridiazole [5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole], the active ingredient in Terrazole®, is an organic, non-phytotoxic soil fungicide that is used to control various species of Pythium, Phytophthora, damp off, and root and stem rots. It is a reddish-brown liquid that is formulated as dusts (2.5% to 5% a.i.), granules (1.5% to 5% a.i.), wettable powders (35% a.i.), flowable concentrates (5.8% to 44.7% a.i.) and emulsifiable concentrates (4.3% to 44.3% a.i.). Tolerances are established for the residues of etridiazole and its monoacid metabolite [3-carboxy-5-ethoxy-1,2,4-thiadiazole] in or on the following raw agricultural commodities: avocados, corn, cottonseed, tomatoes, wheat, strawberries, meat, milk, poultry, and eggs (40CFR §180.370). Etridiazole is registered for use on ten crops as a seed treatment (barley, beans, corn, cotton, peanuts, peas, sorghum, soybeans, safflower, and wheat) and on cotton (as an at-planting soil treatment). Etridiazole is also applied to various ornamental plants and shrubs by horticultural nurseries, to interiorscapes, and on golf course fairways, tees, and greens. There are no registered homeowner uses. According to the Biological and Economic Analysis Division (BEAD), most etridiazole (~50%) is used on cotton at-planting, followed by nurseries (~25%) and on golf course turf (~5%).

Hazard Assessment

The toxicity data base for etridiazole contains several mammalian toxicity studies that do not meet the requirements of the Subdivision F guideline requirements for a food-use chemical (40 CFR Part 158.340). However, the Hazard Identification Assessment Review Committee (HIARC) evaluated the acceptable studies available in the data base and established an acute and a chronic reference dose (RfD) as well as doses and endpoints for short-, intermediate- and long-term dermal and inhalation exposure scenarios. The HIARC also evaluated available studies to determine if there is a special sensitivity for infants and children.

Etridiazole has a low order of acute toxicity via oral, dermal, or inhalation routes (Toxicity Category III or IV), produces mild irritation to the eyes (Toxicity Category III) and is a skin sensitizer.

Subchronic mammalian toxicity studies submitted to the Agency do not meet the Subdivision F guideline requirements for a food-use chemical (40 CFR Part 158.340) and therefore these studies were determined to be unacceptable for regulatory purposes.

Following chronic exposure in rats and dogs, the primary target for etridiazole toxicity is the liver. Systemic toxicities observed in the two-year rat carcinogenicity study include increased absolute and relative liver weights, hepatocytomegaly, spongiosis hepatis, clear, basophilic, and eosinophilic hepatocellular alterations, hepatic centrilobular pigmentation and cholangiectasis. Additional toxicities observed in this study were decreased body weight gains, renal tubule cell karyomegaly and testicular interstitial cell hyperplasia. In the two-year chronic toxicity study in dogs, systemic toxicity in both sexes manifested as increased serum aspartate aminotransferase

(SGOT) and serum alkaline phosphatase (ALK;SAP) activity, increased relative liver weights, liver pathology consistent with cholestatic hepatis, secondary bile nephrosis and increased prothrombin time.

There was no quantitative or qualitative evidence of increased susceptibility in the fetuses or the offspring of rats or rabbits following pre- and/or postnatal exposure to etridiazole. In the prenatal developmental toxicity studies in rats and rabbits and the multi-generation reproduction study in rats, any observed toxicity to the fetuses or offspring occurred at equivalent or higher doses than did toxicity to parental animals. Although the HIARC determined that the multi-generation reproduction study in rats was an unacceptable-guideline study and not adequate for regulatory purposes, the study results suggest that the observed offspring effects in this study occurred only at a treatment level which resulted in parental toxicity.

Although there is no indication of neurotoxicity in any of the mammalian toxicity studies submitted, most of these studies are not adequate for regulatory purposes. Hence, there are insufficient data to assess the neurotoxic potential of etridiazole. The request for neurotoxicity studies (including a developmental neurotoxicity study in rats) is placed in reserve status pending submission and evaluation of a repeat multi-generation reproduction study in rats and a chronic toxicity study in dogs.

Etridiazole induced genotoxic responses in several mutagenicity assays and is considered a mutagen. Positive responses occurred in the gene mutation assay in *Salmonella typhimurium*, in the *in vitro* cytogenetics assay in Chinese hamster ovary cells and in the two *in vitro* sister chromatid exchange assays in Chinese hamster ovary cells.

Etridiazole is classified as a Group B2 chemical (probable human carcinogen) based on the occurrence of multiple tumor types in male and female rats (tumor sites noted were the liver, bile duct, mammary gland, thyroid, and testes), including the induction of a rare bile duct tumor (cholangiocarcinoma). A linear, low-dose approach (Q_1*) is used for human risk characterization. The most potent unit risk Q_1*, based on the thyroid follicular cell combined adenomas/carcinomas in male rats, is 3.33×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents [converted from animals to humans by use of the $(mg/kg\ body\ weight)^{3/4}$ interspecies scaling factor].

In 1999, the Hazard Identification Assessment Review Committee determined that the mouse carcinogenicity study was invalid; therefore, a new study in this species should be conducted. Although etridiazole was classified as a B2 carcinogen with a linear approach for carcinogenicity risk assessment, the Agency is requesting at this time a new carcinogenicity study in mice 1) because of the unacceptability and the uncertainties associated with the mouse study to satisfy the Subdivision Guideline F requirements; 2) in spite of the poor quality of this study, the presence of gross and histopathological lesions in the lungs indicates a concern for possible evidence of carcinogenicity in a different organ in a different species; and 3) it is possible that evidence of carcinogenicity could be demonstrated at lower doses (than that seen in rats) in this species which in turn may lead to a more potent Q1* and thus higher cancer risk estimates.

A FQPA Safety Factor is required for all population subgroups for etridiazole because of the lack of an acceptable multi-generation reproduction study in rats, which could identify potential reproductive effects to the parental animals or to the offspring following pre/post natal exposure to etridiazole. However, **the FQPA safety factor was reduced to 3x** because: (i) there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity studies in rats and rabbits (ii) although the multi-generation reproduction study in rats was determined to be an unacceptable-guideline study and not adequate for regulatory purposes by the HIARC, the study results suggest that the observed offspring effects in this study occurred only at a treatment level which resulted in parental toxicity and (iii) adequate data are available or conservative modeling assumptions are used to assess the potential for dietary (food and drinking water) exposure to infants and children.

An acute reference dose (RfD) was not determined for the general population because an appropriate endpoint attributable to a single exposure (dose) was not identified in oral toxicity studies (including the developmental toxicity studies in rats and rabbits). Therefore, an acute dietary risk assessment is not required for the general population.

However, an acute reference dose (aRfD) of 0.15 mg/kg/day was determined for the subpopulation group, females 13-50 years, based on the NOAEL of 15 mg/kg/day in the developmental toxicity study in rabbits and an uncertainty factor of 100 (10x for inter-species extrapolation and 10x for intra-species variation). The skeletal malformations/variations (missing sternebrae and tail defects) observed in the fetuses at 45 mg/kg/day are presumed to occur after a single exposure (dose) and therefore, the endpoint is appropriate for this risk assessment. As per the recommendation of the FQPA Safety Factor Committee (6/3/99), **the 3x FQPA Safety Factor is not applied to the population subgroup, females 13-50, for the estimation of acute dietary risk**. The Committee made this recommendation because no increased susceptibility was seen following *in utero* exposure, and in addition, the results of the multi-generation reproduction study may not provide an endpoint of concern (i.e., an *in utero* effect) that would be applicable to females of child-bearing age (13-50 years old).

As per current policy, a reference dose (RfD) modified by a FQPA safety factor is referred to as a population adjusted dose (PAD). Since the FQPA safety factor is not applicable to the acute RfD, **the acute RfD and the acute PAD are numerically equivalent for the subpopulation, females 13-50 years old.**

A chronic reference dose (RfD) of 0.016 mg/kg/day was established based on the NOAEL of 4.8 mg/kg/day from the two-year carcinogenicity study in rats and the application of an uncertainty factor of 300 (10x for intraspecies extrapolation, 10x for interspecies variation and 3x applied under FIFRA for the lack of an acceptable chronic study). The LOAEL in this study was 30.43 mg/kg/day based on increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in male rats. As per the recommendation of the FQPA Safety Factor Committee (6/3/99), the **3x FQPA safety factor is**

applied to chronic dietary risk assessment because uncertainty exists due to the lack of an acceptable multi-generation reproduction study in rats, which could identify potential toxicities following exposure to etridiazole in the offspring and/or the parental animals. Therefore, the **chronic population adjusted dose (cPAD) is 0.005 mg/kg/day.**

The HIARC identified doses and endpoints for short-, intermediate-, and long-term dermal and inhalation exposures. For short-term dermal exposure and risk assessments, the rabbit developmental NOAEL of 15 mg/kg/day was selected from the developmental toxicity study in rabbits. This dose and endpoint were selected because: 1) the developmental effects are considered short-term and thus are appropriate for this exposure period (i.e., 1-7 days) of concern, 2) the reproductive/fetal parameters are not evaluated in the dermal toxicity study and thus the consequences of these effects cannot be ascertained for the dermal route of exposure and 3) this endpoint will provide adequate protection for the subpopulation of females 13+ years old , i.e., pregnant workers (the population subgroup of concern is females of child-bearing age [13-50 years old]). In addition, the two 21-day dermal toxicity studies in rabbits were classified by the HIARC unacceptable because of major deficiencies.

Since no inhalation studies are available (with the exception of an acute inhalation toxicity study) in the etridiazole data base, the oral developmental NOAEL of 15 mg/kg/day was also selected and is considered appropriate for a short-term inhalation exposure (1 to 7 days) and risk assessment. This endpoint will provide adequate protection for the subpopulation of females 13-50 years old , i.e., pregnant workers (the population subgroup of concern is females of child-bearing age [13-50 years old]).

For intermediate- and long-term dermal and inhalation exposure risk assessments, the NOAEL of 4.8 mg/kg/day was selected from the two-year carcinogenicity study in rats and is considered appropriate for these exposure scenarios due to the lack of acceptable subchronic studies in the etridiazole data base. The developmental NOAEL (15 mg/kg/day) is not recommended for this time period since the lower NOAEL (4.8 mg/kg/day) in the two-year carcinogenicity study in rats is more protective for the intermediate-term dermal and inhalation exposure scenarios and risk assessments.

No dermal absorption study is available in the etridiazole toxicity data base. In addition, the dermal toxicity studies submitted to the Agency were evaluated and determined to be inadequate for regulatory purposes. Therefore, the default value of 100% dermal absorption equivalent to oral absorption was used in this risk assessment. Also, a default value of 100% was used for inhalation risk assessments.

A MOE of 100 (10x for interspecies extrapolation and 10x for intraspecies variation) is adequate for short- and intermediate-term dermal and inhalation occupational risk assessments. A MOE of 300 is required for long-term dermal and inhalation occupational risk assessments (10x for interspecies extrapolation, 10x for intraspecies variation and 3x under FIFRA for the lack of an acceptable chronic study).

Although there are no registered uses of etridiazole in or around the home, it is registered for use on golf courses. Hence, there is a potential for short-term non-occupational exposure to adults and children entering golf courses that have been treated with etridiazole. A risk assessment for this exposure scenario for the general population, including infants and children, was not conducted since the short-term dermal toxicological endpoint of concern was based on an *in utero* effect not applicable to these subgroups. A risk assessment was conducted for female golfers of child-bearing age (13-50 years old) using the developmental NOAEL of 15 mg/kg/day.

Dietary Exposure and Risk Estimates

Food

The residue chemistry database is adequate to support reregistration. Some confirmatory storage stability data are required. Based on plant and animal metabolism studies, the Metabolism Advisory Review Committee determined that the residues of concern are etradiazole and its monoacid metabolite (3-carboxy-5-ethoxy-1,2,4-thiadiazole). In the plant metabolism studies, no regulable residues were found in wheat grain, soybeans, or cottonseed at treatment rates up to 100x the maximum registered use rate. Although no parent was detected, the regulated monoacid metabolite was detectable in wheat forage and wheat straw (animal feed items) at a 10X treatment rate.

In the ruminant feeding study, at the feeding level of 3.4x the maximum theoretical dietary burden for dairy cattle, residues of etridiazole *per se* and the monoacid were non-detectable (each <0.05 ppm) in muscle, kidney, and liver. Residues of etridiazole *per se* in fat samples were non-detectable. Fat samples were not analyzed for the monoacid (residues of the metabolite were not expected in fat due to its solubility in water). Residues of etridiazole *per se* were non-detectable (<0.01 ppm) in milk samples with the exception of a few samples, at all dose levels, bearing trace amounts at 0.01 ppm. Residues of the monoacid were <0.05 ppm in milk samples. In the poultry feeding study, at the feeding level of 100x the maximum theoretical dietary burden for poultry, etridiazole *per se* and the monoacid were each <0.1 ppm (<LOQ) in meat, fat, skin, giblets (pooled liver, heart, and gizzard), and <0.01 and <0.05 ppm, respectively, in eggs (<LOQ). The available animal metabolism data indicate that a Category 6(a)3 [40CFR 180.6(a)3 "no reasonable expectation of finite residues"] situation exists with respect to residues of etridiazole in meat, poultry, poultry and meat by-products, fat, milk and eggs.

With the exception of tomatoes, all reassessed plant tolerances are based on the sum of the enforcement method limit of quantitation (LOQ) for etridiazole and its monoacid metabolite. Until such time as data are available to support foreign registrations for the use of etradiazole on tomatoes, this tolerance cannot be reassessed (the current tolerance for tomatoes is for those grown domestically. The registrant is no longer supporting etridiazole use on domestically grown tomatoes). The currently established meat/milk/poultry/egg tolerances have been recommended for revocation.

Acute and chronic (non-cancer and cancer) dietary exposure analyses for etridiazole were performed using the Dietary Exposure Evaluation Model (DEEM™). No Pesticide Data Program (PDP) or Food and Drug Administration (FDA) monitoring data were available and crop field trial data were not required for crops on which etridiazole is used as a seed treatment (D188371, P. Deschamp, 3/4/93). Field trial data were available only for cottonseed at a 6x application rate (in-furrow at-planting treatment). Residues of etridiazole were non-detectable (< LOQ) in the cottonseed field trial. For the acute analysis, tolerance level residues and 100% crop treated (CT) was assumed for all commodities (Tier 1) for the female (13-50 years) subgroups. For the chronic (non-cancer) analysis, tolerance level residues and 100% crop treated (CT) was assumed for all commodities (Tier 1) for the U.S. population and all population subgroups. These represent very conservative exposure analysis in that the Biological and Economic Analysis Division (BEAD) estimates that 1% or less of seeds are treated with etradiazole. Further, tolerances are based on the sum of method limits of quantitation (LOQ) for etridiazole regulable residues, not on measurable residues. Nonetheless, the acute and chronic (non-cancer) dietary risk estimates associated with the uses of etridiazole are below the Agency's level of concern. The acute dietary exposure estimates for female (13-50 years old) subpopulations (the only subgroup of concern for acute dietary exposure) at the 99.9th percentile exposure were all less than 4.6% of the aPAD. For the chronic (non-cancer) dietary exposure estimate, the most highly exposed population subgroup at the 95th percentile was children 1-6 years old at 31% of the cPAD.

For the cancer dietary exposure and risk assessment, a Tier 3 analysis was conducted. Residue levels of ½ the limit of quantitation (LOQ) and weighted average percent crop treated estimates were used for all commodities for the U.S. population. The cancer dietary risk estimate for the U.S. population is 1.6×10^{-7}, which is less than the level the Agency generally considers to be negligible for excess lifetime cancer risk.

Water

The Environmental Fate and Effects Division (EFED) provided a drinking water assessment for etridiazole. The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for etridiazole. Therefore, the Agency is presently relying on computer-generated estimated environmental concentrations (EECs). Tier 1 GEENEC estimated environmental concentrations (EECs) in surface water were estimated based on the application of etridiazole to cotton (1 in-furrow at-planting application at 0.38 ai/A), seed treatment (1 application at 0.001 lb ai/A) and application to golf course turf. The use on turf, which is limited to golf courses only, represents the most significant etridiazole use in terms of the potential to contaminate water. According to the registrant, the *recommended* application rate is 5.7 lb ai/A (the initial application at 3.8 lb ai/A, followed by a second application at 1.9 lb ai./A after 5-10 days). For the purpose of calculating GENEEC EECs for use in the human health risk assessment, EFED used a *typical* application rate of 7.6 lb ai/A (two applications at 3.8 lb ai/A at 10 day intervals). All EECs provided by EFED reflect parent-only (etridiazole) values and do not include the regulated monoacid

metabolite (3-carboxy-5-ethoxy-1,2,4-thiadiazole).

The Tier 2 (PRZM/EXAMS) model is not suitable for estimating EECs from pesticide use on turf. Therefore, a 36 year mean EEC is not available for etridiazole use on golf course turf. A Tier 2 (PRZM/EXAMS) 36 year mean surface water EEC was provided by EFED (D260263, R. Lee, 11/10/99) based on the application of etridiazole to cotton (one annual in-furrow application of 0.38 lb ai/A for 36 years).

EFED also provided a Tier 1 (SCIGROW) EEC for etridiazole in groundwater based on the *typical* application rate to golf courses. EFED did not provide a Tier 1 groundwater (SCIGROW) EEC for etridiazole use on cotton.

Groundwater EECs

Results from Tier 1 (SCIGROW) modeling, which represents an upper bound estimate of the concentration that might be found in groundwater from the typical use of etridiazole on golf courses, indicates that levels of etridiazole in groundwater are not likely to exceed 0.93 ppb.

Surface Water EECs

Results from Tier 1 (GENEEC) modeling, which represents upper bound estimates of the concentration that might be found in surface water from the typical use of etridiazole on golf course turf, indicates that levels of etridiazole in surface water are not likely to exceed 230 ppb for the peak (acute) and 57 ppb for the 56-day average EEC (170 ppb for the 56-day average divided by 3 as per HED SOP9.5). Further refinement of the surface water EECs from etridiazole use on golf courses is not possible as the Tier 2 models (PRZM and EXAMS) is not suitable for turf uses. Results from a Tier 2 (PRZM/EXAMS) modeling was performed for the multi-year use on cotton (one annual in-furrow application of 0.38 lb ai/A for 36 years, the only other non-seed treatment use of etridiazole) and indicated that etridiazole concentrations would not exceed 0.05 ppb for the 36 year mean (chronic- cancer).

Drinking Water Levels of Comparison

The surface water and groundwater estimates were used to compare to drinking water levels of comparison (DWLOCs) for aggregate risk assessments. The DWLOC represents how much of the acceptable exposure (i.e. the RfD or PAD) is available for exposure through drinking water.

The acute DWLOC for females (13-50 years) is 4300 ppb. The Tier 1 surface water EEC of 230 ppb and the Tier 1 groundwater EEC of 0.93 ppb are well below the DWLOC. Therefore, acute dietary exposure to drinking water does not exceed the Agency's level of concern.

The chronic DWLOCs for the U.S. population, non-nursing infants (< 1 year old), children (1-6 years old), females (13-19 years old), females (13-50), and males (13-19 years old) are 150, 40,

35, 130, 130, and 150 ppb, respectively. For ground water, the Tier 1 EEC of 0.93 ppb is less than the chronic (non-cancer) DWLOCs for all subpopulations. For surface water, the Tier 1 56-day average EEC of 57 ppb (based on golf course application) is less than the DWLOC for the U.S. population and female (13+ yrs) and male (13+ yrs) subgroups. The Tier 1 56-day surface water EEC of 57 ppb exceeds the DWLOC for non-nursing infants (< 1yr) and children 1-6 years old (40 and 35 ppb respectively). HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to chronic DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. The Tier 2 surface water EEC of 0.05 ppb (for 36 year use on cotton) does not exceed the DWLOCs for any subpopulation, including infants and children.

The chronic (cancer) DWLOC is 1 ppb for the U.S. population. For surface water, the Tier 1 chronic EEC of 57 ppb is greater than the cancer DWLOC for the U.S. population. HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to cancer DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. A Tier 2 (PRZM/EXAMS) surface water EEC was estimated for 36-year use on cotton. The Tier 2 surface water EEC of 0.05 ppb does not exceed the cancer DWLOC of 1 ppb. The Tier 1 groundwater EEC of 0.93 ppb does not exceed the cancer DWLOC of 1 ppb.

Occupational Exposure and Risk Assessment

Handler Risk Assessment:

No chemical-specific handler exposure data were submitted in support of the reregistration of etridiazole. Therefore, most of the mixer, loader, or applicator scenarios were evaluated for short- and intermediate term exposures and cancer risk using the Pesticide Handlers Exposure Database (PHED), Version 1.1. No PHED data exist for exposure during seed treatment, and there is little data in the literature. There is no data for powered blower application of granular product. Therefore, the Agency requested and received permission from Uniroyal to use a commercial seed treatment worker exposure study, which was submitted for reregistration of another chemical. In addition, a published occupational exposure study was used to assess on-farm seed treatment exposures. Numerous mixer/loader, applicator, and mixer/loader/applicator scenarios were evaluated.

Typical worker clothing is represented by the scenarios with a single layer of work clothes and chemical-resistant gloves. A margin of exposure (MOE) of 100 or greater for short- and intermediate-term occupational exposure does not exceed HED's level of concern. About one-quarter of the short- term (14 of 53) and 40% of intermediate-term (20 of 53) scenarios had MOEs that exceed HEDs level of concern (i.e., MOE < 100). An additional layer of clothing and respiratory protection had very little effect, effectively raising only one additional short-term MOE and two intermediate-term scenarios above the minimum MOE of 100.

Nearly all scenarios for which engineering controls were feasible had MOEs of 100 or greater when controls were added. The one exception is mixing and applying wettable powder to turf via groundboom at the highest application rate, for an intermediate-term exposure, which had a MOE of 71. The engineering control that was applicable to most scenarios was a water soluble bag (WSB) for the wettable powder. Currently, the WSB is not available for etridiazole. Also, seven short-term and nine intermediate-term exposure scenarios that are common in nursery and turf work, had MOEs less than 100 and there were no feasible engineering controls. An enclosed system for handling and loading granular products would be desirable to reduce handler exposure, but is also not available at this time. The hand-held application methods have no known engineering controls, but some may be replaced by use of chemigation. As these values are based on chemical surrogate data with lower vapor pressures, the effect of adding respiratory protection would probably be greater than indicated, but the baseline inhalation exposure would also be greater. Double-layer clothing, or coveralls over work clothes, and respirators also add the risk of heat stress and decrease range of motion, visibility, and communication. Therefore engineering controls are preferred to additional personal protective equipment (PPE). There were no data for granular application by powered dust blower.

Worker cancer risks were estimated for private and commercial handlers using *typical* application rates. Baseline (no glove, single layer of clothing) cancer risks exceeded 10^{-4} in one-third (10 of 34) of private and one-half of commercial (15 of 34) applicators. Cancer risks exceeded 1.0×10^{-4} for one-quarter (9 of 34) of "private" or non-commercial applicator exposure scenarios, where workers wore a single layer of clothing and chemical-resistant gloves. For commercial applicators wearing the same protective equipment, one third (12 of 34) had cancer risks greater than 1.0×10^{-4}. By using additional PPE and/or engineering controls, about two-thirds of the handler scenarios cancer risks were reduced below 1.0×10^{-4}, except for those application methods which had no known method of engineering control (six scenarios) or no data (3 scenarios). Again, most of these were the scenarios involving application of granular products to turf and soil, discussed above.

Occupational Post-Application Risk Assessment

The registrant submitted studies of residues on turf, transfer of residues, and a post-application study of greenhouse workers using treated potting soil. The turf residue transfer study was found to be adequate for assessment of golf course workers.

None of the MOEs for post-application worker scenarios exceeded the Agency's levels of concern. Greenhouse or nursery workers are expected to be exposed to the post-application residues of potting soil on a regular basis (potentially more than six months per year), for an estimated 4 hours per day. The MOE required for long-term exposure is 300. The 12-hour re-entry dose for potting soil handling from the submitted study was used to estimate an MOE of 900 for intermediate or long-term exposures (wearing a single layer of clothing but no gloves), and a cancer risk of 2.9×10^{-5}. Different levels of contact with treated turf were estimated, using tractor mowing to represent the lower, and hand mowing the higher range of exposure. These exposure

MOEs ranged from 650 to 1300. The lifetime cancer risk for mowing is estimated at 2.0×10^{-5} to 4.0×10^{-5}, based on the turf residue data. Risks for handling pre-treated seed while planting cotton were estimated using PHED surrogate data. Short-term MOEs were between 48,000 and 60,000 and intermediate-term MOEs between 18,000 and 22,000. Estimated cancer risks for private farmers handling and planting treated cotton seed were between 6.8×10^{-8} and 8.4×10^{-8}. Commercial planters handling treated cotton seed (20 days per year) have an estimated cancer risk of 2.0×10^{-7} to 2.4×10^{-7}, depending on the amount of pesticide applied.

Incident Reports:

Relatively few incidents of illness have been reported due to etridiazole. However, at least two incidents were reported in California citing specific health effects from contact with recently treated soil. In 1997 an incident involving a greenhouse worker experiencing symptoms after potting soil, and on another occasion, a worker handled soil that was treated with etridiazole and experienced eye and skin illness for two years. Detailed descriptions of 10 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) were reviewed and in one case, etridiazole was judged to be responsible for the health effects. A total of 30 unintentional exposures were reported to the Toxic Exposure Surveillance System from 1993 through 1996. All thirty cases involved adults and older children ages six to nineteen, nine of which had a minor outcome, two with moderate outcome, and none that were considered life-threatening.

Occupational Exposure Concerns:

There is a data gap for all seed handling activities, and the studies used for this assessment were considered limited, not compliant with study guidelines, not chemical-specific, and should be interpreted together with default scenarios for range-finding purposes. The risk assessments for soil-incorporated liquids and granules were also based on surrogate data from groundboom operations, and may be considered conservative estimates. There are virtually no applicable data (beyond the studies cited) on the use of dust formulations in occupational settings. Therefore, data are required for both commercial and on-farm settings. There are no data for engineering controls, such as closed systems, for granular formulations. Caution should be used in interpreting the scenarios that used default data, given the high vapor pressure of etridiazole, and inhalation exposure may be underestimated. Product labeling should be upgraded to comply with 42 CFR Part 84 and 29 CFR 134, particularly to require the use of organic vapor filtering respirators during mixing and loading, due to the high vapor pressure (1.1×10^{-2} mm Hg) of etridiazole. Current labeling requires a dust/mist filtering respirator for mixing and loading products containing higher concentrations (i.e. greater than 10%) of active ingredient.

Non-Occupational Risk Assessment

Although there are no registered homeowner uses of etridiazole, it is registered for use on golf courses. Therefore, there is a potential for short-term non-occupational exposure to adults and children entering golf courses that have been treated with etridiazole. A risk assessment for this

exposure scenario for the general population, including infants and children, was not conducted since the short-term dermal toxicological endpoint of concern was based on an *in utero* effect not applicable to these subgroups. An appropriate endpoint applicable to the general population, including infants and children, was not available. A risk assessment was conducted for female golfers of child-bearing age (13-50 years old) using the developmental NOAEL of 15 mg/kg/day. Because the FQPA Safety Factor Committee determined that the 3x FQPA safety factor does not apply to the acute dietary risk assessment, it is also not applicable to the short-term dermal risk assessment as both assessments are based on the same toxicity endpoint (developmental NOAEL). Therefore, an MOE of 100 or greater is adequate for female golfers 13-50 years old. The dermal exposure estimate for female golfers was based on a turf transferable residue study as opposed to using default residential SOP assumptions. For female golfers (13+ years old), the short-term non-occupational MOE of 17,000 does not exceed the Agency's level of concern.

Cancer risk estimates were determined for all adult golfers. The exposure estimate was derived from the turf transferable residue study data and assumed a four hour exposure occurring 18 times a year. The estimated cancer risk for adult golfers is 8.9×10^{-7} .

Aggregate Exposure and Risk Estimates

Acute Aggregate Exposure and Risk Estimates

The acute aggregate risk estimate includes acute dietary (food and water) exposures only.

Acute aggregate risk estimates from aggregate exposure to etridiazole in food and water do not exceed the Agency's level of concern. For the Tier 1 acute dietary exposure analysis, tolerance level residues were used and 100% crop treated was assumed for all commodities. For all female (13-50 yrs) subgroups (the population of concern), less than 4.6% of the aPAD is occupied by dietary (food) exposure. Thus, the acute dietary (food) risk associated with etridiazole uses is below the Agency's level of concern. The acute DWLOC for females is 4300 ppb. The Tier 1 surface water EEC of 230 ppb and the Tier 1 groundwater EEC of 0.93 ppb are well below the DWLOC. Therefore, HED concludes with reasonable certainty that acute aggregate exposure to etridiazole does not exceed the Agency's level of concern.

Short-Term Aggregate Exposure and Risk Estimates

The short-term (non-cancer) aggregate risk estimate includes chronic dietary (food and water) and short-term non-occupational (golf course) exposures only. There are no homeowner uses for etridiazole. **Aggregate short- term risk estimates do not exceed the Agency's level of concern.** In aggregating short-term risk, HED considered background chronic dietary food exposure and short-term dermal exposures (golf course scenario) along with potential drinking water exposures. The short-term food MOE is 7.5×10^{3}. The short -term non-occupational (golfer) MOE is 1.7×10^{4}. The total short-term food and non-occupational aggregate MOE value for females (13+yrs) is 5.2×10^{3} . This MOE is much greater than the acceptable short-term MOE of 100. For surface

water and groundwater, the estimated average concentrations of etridiazole (57 ppb and 0.93 ppb, respectively) are less than the DWLOC of 4300 ppb (for females 13-50 years). Therefore, short-term aggregate exposure for females of child-bearing age (13-50 years) to etridiazole does not exceed the Agency's level of concern.

An aggregate short-term risk assessment for the general population, including infants and children, was not conducted since the short-term dermal toxicological endpoint was based on an *in utero* effect and is not applicable to these populations.

Intermediate-Term Aggregate Exposure and Risk Estimates

Since recreational, non-occupational activities on golf courses are considered short-term exposures and no residential (homeowner) exposure scenarios exist, an intermediate-term aggregate risk assessment is not required.

Chronic (Non-Cancer) Aggregate Exposure and Risk Estimates

The chronic aggregate risk estimate includes chronic dietary (food and water) exposures only. There are no homeowner uses for etridiazole.

Chronic (non-cancer) aggregate risk estimates from aggregate exposure to etridiazole in food and water exceed the Agency's level of concern for infants and children. The chronic (non-cancer) dietary (food) risk associated with the registered uses of etridiazole is below the Agency's level of concern. When tolerance level residues and 100% crop treated was assumed in the chronic (non-cancer) dietary analysis (Tier 1), the highest percent of cPAD occupied for all subgroups was 31% for children (1-6 years). For ground water, the Tier 1 EEC of 0.93 ppb is less than the DWLOCs for all population subgroups. For surface water, the Tier 1 EEC of 57 ppb is less than the DWLOC for the U.S. population and female (13-19 yrs, and 13-50 yrs) and male (13-19 yrs) subgroups. The Tier 1 chronic surface water EEC of 57 ppb exceeded the DWLOC for non-nursing infants (< 1yr) and children 1-6 years old (40 and 35 ppb respectively). HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to chronic DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. The Tier 2 surface water EEC of 0.05 ppb (for 36 year use on cotton) does not exceed the DWLOCs for any subpopulation, including infants and children.

In accordance with OPP policy (S. Johnson, 11/17/97) if the EECs exceed the DWLOCs, water monitoring data are necessary to refine the drinking water exposure estimate. SRRD and EFED should determine the nature and extent of the water monitoring data required.

Cancer Aggregate Exposure and Risk Estimates

The cancer aggregate risk estimate includes chronic dietary (food and water) and non-occupational (golf course) exposures only. There are no homeowner uses for etridiazole.

Cancer aggregate exposure and risk estimates for non-golfers (general popultion) and adult golfers exceed the Agency's level of concern. The estimated non-occupational cancer risk for adult golfers is **8.9 x 10^{-7}**. When a refined Tier 3 (½ LOQ residue levels and estimated percent crop treated information) dietary exposure analysis is performed, the carcinogenic dietary risk estimate for etridiazole is **1.6 x 10^{-7}** for the general U.S. population (estimated dietary exposure is 0.000005 mg/kg/day). **The cancer dietary (food) risk estimate associated with the proposed uses of etridiazole does not exceed the Agency's level of concern**. The cancer DWLOC for the US population is 1 ppb. Using a Tier 1 screening level model (GENEEC) for turf, the estimated levels of etridiazole in surface water is 57 ppb (56 day average). The Tier 1 surface water EEC exceeds the cancer DWLOC. HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to cancer DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. Using a Tier 2 screening level model (PRZM/EXAMS) for 36 year use on cotton, the estimated level of etridiazole in surface water is 0.05 ppb. The Tier 1 groundwater (SCIGROW) EEC is 0.93 ppb. **The Tier 2 surface water EEC (cotton) and Tier 1 groundwater EEC do not exceed the cancer DWLOC.**

In accordance with OPP policy (S. Johnson, 11/17/97) if the EECs exceed the DWLOCs, water monitoring data are necessary to refine the drinking water exposure estimate. SRRD and EFED should determine the nature and extent of the water monitoring data required.

Reassessment of Tolerances

Tolerances Listed Under 40 CFR §180.370:

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for etridiazole residues in/on undelinted cottonseed. Based upon the current use patterns and the available residue data, the established tolerances for etridiazole residues in/on undelinted cottonseed can be lowered to 0.1 ppm.

Sufficient data are also available to reassess the tolerances for residues in/on corn and wheat commodities. The tolerances for residues of etridiazole in/on corn and wheat grain at 0.05 ppm should be reassessed at 0.1 ppm. The available residue data support the tolerances at 0.1 ppm for residues in/on corn forage and fodder and wheat forage and straw.

The tolerance for avocados and strawberries should be revoked as the registrant is no longer supporting those crops. Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown outside of the United States in order to reassess a tolerance for tomatoes.

Data indicate that a Category 6(a)(3) {40CFR 180.6(a)3 "no reasonable expectation of finite residues"} situation exists with respect to residues of etridiazole and the monoacid metabolite in

meat, meat by-products (mbyp), fat, and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, mbyp, and eggs. Therefore, at this time, tolerances for etridiazole in animal commodities will be revoked. However, once the outstanding storage stability data on the monoacid metabolite is submitted and reviewed, the 6(a)3 status may be reevaluated. Additionally, if the current etridiazole use patterns change, it will be necessary to reevaluate the 6(a)3 status.

Tolerances Needed Under 40 CFR §180.370:

New tolerances are needed for etridiazole residues in/on the following raw agricultural commodities: cotton gin byproducts, peanut nutmeat and hay, sorghum grain and forage, barley grain and hay, and safflower seed. The available residue data indicate that tolerances for residues of etridiazole should be established on these commodities at 0.1 ppm.

In addition, new tolerances are needed for etridiazole residues in/on the following crop group: legume vegetables (succulent or dried) crop group and foliage of legume vegetables, each at 0.1 ppm.

Data Requirements

There are data gaps for etridiazole with regard to the standard Subdivision F Guideline requirements for a food-use chemical (40 CFR Part 158.340). The HIARC has recommended submission of a multi-generation reproduction study (protocol to include early thyroid measurements; pre-mating, adults and pups) due to the concern for potential endocrine disruption. In addition, a chronic toxicity study in dogs and a carcinogenicity study in mice, that meet the current guidelines, are required. Pending submission and evaluation of these chronic studies, additional studies (i.e., delayed neurotoxicity study in the hen, acute neurotoxicity study, subchronic neurotoxicity study and/or developmental neurotoxicity study) may be required.

There is a data gap for all seed handling activities, and the studies used for this assessment were considered limited, not compliant with study guidelines, not chemical-specific, and should be interpreted together with default scenarios for range-finding purposes. There are virtually no applicable data (beyond the studies cited) on the use of dust formulations in occupational settings. Therefore data are required for both commercial and on-farm settings. Caution should be used in interpreting the scenarios that used default data, given the high vapor pressure of etridiazole, and inhalation exposure may be underestimated. Product labeling should be upgraded to comply with 42 CFR Part 84 and 29 CFR 134, particularly to require the use of organic vapor filtering respirators during mixing and loading, due to the high vapor pressure (1.1×10^{-2} mm Hg) of etridiazole. Current labeling requires a dust/mist filtering respirator for mixing and loading products containing higher concentrations (i.e. greater than 10%) of active ingredient.

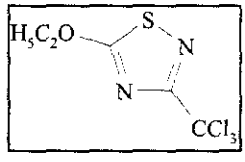
The requirements for storage stability data on animal commodities are not satisfied for the purposes of reregistration. Data are required depicting the storage stability of the monoacid metabolite stored frozen in animal commodities for up to 2 years. Samples from the poultry and ruminant feeding studies were stored frozen for ~6 weeks and 2 years, respectively, prior to analysis for residues of the monoacid.

All pertinent product chemistry data requirements are satisfied for the Uniroyal 98.6% T/TGAI, except additional data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Agency has no objections to the reregistration of etridiazole with respect to product chemistry data requirements.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

Description of Chemical

Etridiazole [5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole] is a soil fungicide and nitrification inhibitor used at planting (in furrow soil treatment) for cotton and for seed treatments of barley, beans, corn, cotton, peanuts, peas, safflower, sorghum, soybeans, and wheat. Etridiazole is also used on turf (golf courses) and ornamentals (greenhouse and nurseries).



Empirical Formula:	$C_5H_5Cl_3N_2OS$
Molecular Weight:	247.5
CAS Registry No.:	2593-15-9
PC Code:	084701

Etridiazole is a reddish-brown liquid with a boiling point of 95 C at 1 mm Hg, specific gravity of 1.5, octanol/water partition coefficient (K_{ow}) of 2.344×10^3, and vapor pressure of 1.1×10^{-2} mm Hg at 25 C. Etridiazole is practically insoluble in water (~100 ppm at 25 C), and is soluble in

acetone, carbon tetrachloride, ethanol, ether, and xylene. Etridiazole hydrolyzes with acids and bases.

Manufacturing-Use Product

A search of the Reference Files System (REFS) conducted 4/21/99 identified a single etridiazole manufacturing-use product (MP) registered under PC Code 084701: the Uniroyal Chemical Company, Inc. 98.6% technical product (T; EPA Reg. No. 400-413). Only the 98.6% T is subject to a reregistration eligibility decision.

Regulatory Background

The Terrazole Guidance Document dated 9/80 required additional product chemistry data concerning explodability and miscibility (OPPTS 830.6316 and 6319); however, the Terrazole (SRR) Reregistration Standard dated 3/30/89 required that all updated product chemistry data be submitted in support of the reregistration of etridiazole. Data evaluated under the Guidance Document and submitted in response to the Guidance Document requirements were re-evaluated/reviewed under the SRR.

The current status of the product chemistry data requirements for the etridiazole T/TGAI is presented in the attached data summary Table A1 (Appendix A). Refer to this table for a listing of the outstanding product chemistry data requirements.

All pertinent product chemistry data requirements are satisfied for the Uniroyal 98.6% T/TGAI, except additional data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table, and either certifies that the suppliers of beginning materials and the manufacturing process have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Agency has no objections to the reregistration of etridiazole with respect to product chemistry data requirements.

3.0 HAZARD CHARACTERIZATION

3.1 HAZARD PROFILE

Etridiazole has a low order of acute toxicity via oral, dermal, or inhalation routes (Toxicity Category III or IV), produces mild irritation to the eyes (Toxicity Category III) and it is a skin sensitizer in the Beuhler dermal sensitization assay.

Subchronic mammalian toxicity studies submitted to the Agency do not meet the current Subdivision F guideline requirements for a food-use chemical (40 CFR Part 158.340) and

therefore these studies were determined to be unacceptable for regulatory purposes. Hence, subchronic toxicity studies were not used in this risk assessment.

Following chronic exposure in rats, the primary target for etridiazole toxicity is the liver. At 640 ppm (30.43 mg/kg/day in males, 38.45 mg/kg/day in females), systemic toxicities observed in the 2-year rat carcinogenicity study included decreased body weight gain in females, increased absolute and relative liver weight in males, hepatocytomegaly in males, spongiosis hepatis in males, clear, basophilic, and eosinophilic hepatocellular alterations in both sexes, hepatic centrilobular pigmentation in females, cholangiectasis in females, renal tubule cell karyomegaly in males and females and testicular interstial cell hyperplasia in males. In the two year, non guideline chronic toxicity study with dogs, systemic toxicities in both sexes manifested as increased serum aspartate transferase (SGOT) and serum alkaline phosphatase (ALK;SAP) activity, increased relative liver weights, liver pathology consistent with cholestatic hepatis with secondary bile nephrosis and increased prothrombin time at a dose level of 25 mg/kg/day.

In accordance with the Agency's Proposed Guideline for Carcinogen Risk Assessment (April 11, 1993), the HED Cancer Peer Review Committee (CPRC) classified etridiazole as a Group B2 carcinogen (Probable Human Carcinogen). This classification is based on the following factors: (i) occurrence of multiple tumor types in male and female rats (tumor sites noted were the liver, bile duct, mammary gland, thyroid, and testes) including the induction of a rare bile duct tumor (cholangiocarcinoma), and (ii) non-neoplastic lesions observed in similar target organs that lend support to the association of etridiazole exposure with the induction of tumors; increased absolute and relative liver weight (males), hepatocytomegaly (males); clear, basophilic, and eosinophilic cellular alterations (males and females); cholangiectasis (females); centrilobular pigmentation (females); spongiosis hepatis of the liver (males); and testicular interstial cell hyperplasia (males) and (iii) positive mutagenicity data. The carcinogenicity study in mice was determined to be unacceptable and not adequate for assessment of the carcinogenic potential of etridiazole in this species.

For the purpose of human risk characterization, the CPRC concluded that a low dose extrapolation model (Q_1*) be applied to the experimental animal tumor data. A quantification of risk was recommended for each sex using all tumor bearing animals with tumor types that are statistically significant for that sex. In addition, a separate risk quantification was performed on the rare bile duct tumor, cholangiocarcinoma, for each sex. The estimates of unit risk , Q_1*, were obtained by application of the Multi-Stage model, Tox_Risk program, Version 3.5, K. Crump, 1994 (Memorandum: L. Brunsman, 2/10/99). Following these calculations, the most potent unit risk Q_1*, based on the occurrence of thyroid follicular cell combined adenomas/carcinomas in male rats, is **3.33×10^{-2} (mg/kg/day)$^{-1}$** in human equivalents [converted from animals to humans by use of the (mg/kg body weight)$^{3/4}$ cross species scaling factor].

There was no quantitative or qualitative evidence of increased susceptibility in rats or rabbits following pre- and/or postnatal exposure to etridiazole. In the developmental toxicity study in rats, reduced fetal body weights and late resorptions at 75 mg/kg/day occurred in the presence of maternal toxicity (increased mortality, decreased absolute body weights and body weight gains and anogenital matting at dose levels of 30 mg/kg/day). In the prenatal developmental toxicity study in rabbits, both fetal and maternal toxicity were observed at the LOAEL of 45 mg/kg/day. At this dose, increased mortality and body weight decreases were observed in maternal animals and fetal toxicity consisted of reduced fetal body weights, decreased viability and an increase in the incidence of skeletal malformations/variations.

In the multi-generation reproduction study in rats, offspring toxicity (reduced fetal body weights) were observed only at a dose (32 mg/kg/day) which resulted in evidence of parental toxicity (reduced parental body weights). However, the HIARC determined that this study is unacceptable and not adequate for regulatory purposes.

Although mammalian neurotoxicity studies for etridiazole have not been conducted, these special neurotoxicity studies (i.e., delayed neurotoxicity in the hen, acute neurotoxicity, subchronic neurotoxicity and/or developmental neurotoxicity) are not required at the present time because there is no evidence of neurotoxicity in the available guideline toxicity studies. The request for neurotoxicity studies, specifically, a developmental neurotoxicity study in the rat, is placed in reserve status pending submission and evaluation of a new multi-generation reproduction study in rats and a chronic toxicity in dogs.

Etridiazole induced positive responses in both the absence and presence of S9 metabolic activation in the sister chromatid exchange assays in Chinese hamster ovary cells and in one *in vitro* cytogenetic chromosomal aberration assay in Chinese hamster ovary cells. In the absence of S9 metabolic activation, etridiazole induced reverse gene mutations in *Salmonella typhimurium*. There was, however, no evidence of a positive effect in an *in vivo* cytogenetics micronucleus assay in mice and in a second *in vitro* cytogenetics chromosomal aberration assay in Chinese hamster ovary cells. Based on the positive mutagenic and genotoxic responses observed in the mutagenicity battery, etridiazole is considered a mutagen.

Analysis of whole body elimination in male and female rats indicated that etridiazole is rapidly absorbed and peak elimination occurs within 48 hours of dosing. The metabolite profile in urine was similar between sexes and among the four dose groups; metabolites were identified as etridiazole carboxylic acid, ethyl (aminocarbonyl) carbamate, N-carboxy oxamic acid and N-acetyl cysteinyl conjugate of etridiazole.

No dermal absorption study is available in the etridiazole toxicity data base. In addition, the dermal toxicity studies submitted to the Agency were evaluated and determined to be inadequate

for regulatory purposes. Therefore, the default value of 100% dermal absorption was used in this risk assessment.

There are several data gaps for the standard Subdivision F Guideline requirements for a food-use chemical (40 CFR Part 158.340); a multi-generation reproduction study in rats (protocol to include early thyroid measurements; pre-mating, adults and pups), a chronic toxicity study in dogs (that meets the chronic toxicity test guidelines), and a carcinogenicity study in mice. In addition, there is insufficient data to assess the neurotoxic potential of etridiazole. However, the request for additional studies (i.e., delayed neurotoxicity study in the hen, acute neurotoxicity study, subchronic neurotoxicity study and/or developmental neurotoxicity study) is placed in reserve status pending submission and evaluation of a repeat multi-generation reproduction study in rats and a chronic toxicity study in dogs.

Tables 1 and 2 summarize the acute, subchronic and chronic toxicity of etridiazole.

TABLE 1. Acute Toxicity Profile for Etridiazole (Terrazole)

Guideline	MRID#	Study Type*	Results	Tox. Cat.	Classification
870.1100 (§81-1)	43724501	Acute Oral - Rat (2/8/94)	LD_{50} (males) = 1141 mg/kg LD_{50} (females) = 945 mg/kg LD_{50} (males and females combined) = 1028 mg/kg	III	Acceptable-Guideline
870.1200 (§81-2)	43724502	Acute Dermal - Rabbit (2/8/94)	LD_{50} (males and females combined) > 5000 mg/kg	IV	Acceptable-Guideline
870.1300 (§81-3)	43724503	Acute Inhalation - Rat (2/8/94)	LC_{50} (males and females combined) > 5.7 mg/L	IV	Acceptable-Guideline
870.2400 (§81-4)	43724504	Primary Eye Irritation - Rabbit (2/8/94)	Moderate Eye Irritant	III	Acceptable-Guideline
870.2500 (§81-5)	43724505	Primary Dermal Irritation - Rabbit (2/8/94)	Non Irritant	IV	Acceptable-Guideline
870.2600 (§81-6)	43724506	Dermal Sensitization - Guinea pig-unspecified purity of terrazole technical (1/22/93)	Moderate Dermal Sensitizer	N/A	Acceptable-Guideline

*The percent active ingredient of the technical test material used in each of the acute toxicity studies was reported as 98.6% a.i., unless specified otherwise.

TABLE 2. Subchronic and Chronic Toxicity Profile for Etridiazole (Terrazole)			
Guideline	**MRID#**	**Study Type***	**Results**
870.3100 (§82-1a)	00001700	90-Day Oral Toxicity - Rat, technical; 50% a.i. (1964)	NOAEL (males, females) = 312 ppm LOAEL (males, females) = 625 ppm based on increased liver to body weight ratios and growth depression Classification: Unacceptable-Guideline (not upgradable)
870.3150 (§82-1b)	00001699	90-Day Oral Toxicity - Dog, technical; 50% a.i. (1964)	NOAEL (males, females) > 1600 ppm LOAEL (males, females) = not established Classification: Unacceptable-Guideline (not upgradable)
870.3200 (§82-2b)	00063303	21-Day Dermal Toxicity - Rabbit, unspecified purity (1/11/65)	NOAEL (males, females) = not established LOAEL (males, females) = not established Classification: Unacceptable-Guideline (not upgradable)
870.3200 (§82-2b)	00114197	21/28-Day Dermal Toxicity - Rabbit, Terrachlor Super X Formulation (6/65)	NOAEL (males, females) = 0.65 ml/kg/day LOAEL (males, females) = 1.30 ml/kg/day based on increased kidney to body weight ratios Classification: Unacceptable-Guideline (not upgradable)
Chronic Toxicity			
870.4100 (§83-1b)	00001697	Chronic Toxicity - Dog (8/5/68)	NOAEL (males, females) = 2.5 mg/kg/day LOAEL (males, females) = 25 mg/kg/day based on increased SGOT and SAP activity, increased liver to body weight ratios, liver pathology consistent with cholestatic hepatis, secondary bile nephrosis and increased prothrombin time. Classification: Acceptable-Non Guideline
870.4200 (§83-2a)	40747901	Oncogenicity -Rat (6/23/88)	NOAEL = 100 ppm (4.8/5.9 mg/kg/day, males/females) LOAEL = 640 ppm (30.43/38.45 mg/kg/day, males/females) based on decreased body weight gain (females), increased liver weight (absolute and relative), renal tubule cell karyomegaly (males, females), hepatocytomegaly (males), spongiosis hepatis (males), cholangiectasis (females) and centrilobular pigmentation (females). Etridiazole has carcinogenic potential in the livers of

TABLE 2. Subchronic and Chronic Toxicity Profile for Etridiazole (Terrazole)			
Guideline	**MRID#**	**Study Type***	**Results**
			female rats, and the testes and thyroid of male rats. It can also induce cholangiocarcinoma, a rare tumor, predominantly in female rats. Classification: Acceptable-Guideline
870.4200 (§83-2b)	00093744	Oncogenicity -Mouse (3/14/81)	NOAEL (males, females) = 640 ppm (91 mg/kg/day) LOAEL = 1280 ppm (183 mg/kg/day) based on minor decreases in body weight and food efficiency, stomach hyperkeratosis, nephritis and adrenal and ovarian degeneration in females, lung hyperplasia in males, and spleen alterations in both sexes Under conditions of this study, there was equivocal evidence of carcinogenicity based on an increased incidence of alveologenic carcinoma female mice. Classification: Unacceptable-Guideline (not upgradable)
Developmental/Reproductive Toxicity			
870.3700 (§83-3a)	00120415	Developmental Toxicity - Rat (5/27/82)	Maternal Toxicity NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on clinical signs of toxicity (anogenital matting) Developmental Toxicity NOAEL = 30 mg/kg/day LOAEL = 75 mg/kg/day based on decreased fetal body weights and increased late resorptions Classification: Acceptable-Guideline
870.3700 (§83-3b)	00104999	Developmental Toxicity - Rabbit (5/22/79)	Maternal Toxicity NOAEL = 15 mg/kg/day LOAEL = 45 mg/kg/day based on increased mortality and decreased body weights Developmental Toxicity NOAEL = 15 mg/kg/day LOAEL = 45 mg/kg/day based on reduced fetal body weights, viability and increased incidence of external and skeletal malformations/variations Classification: Acceptable-Guideline
870.3800 (§83-4)	00001698	Multigeneration Reproductive Toxicity - Rat (1968)	Systemic/Parental/Offspring Toxicity NOAEL = 80 ppm (4 mg/kg/day) LOAEL = 640 ppm (32 mg/kg/day) based on reduced body weights of adult animals and pups Reproductive Toxicity NOAEL ≥ 640 ppm (32 mg/kg/day) LOAEL > 640 ppm (32 mg/kg/day), not established

TABLE 2. Subchronic and Chronic Toxicity Profile for Etridiazole (Terrazole)			
Guideline	**MRID#**	**Study Type***	**Results**
			Classification: Unacceptable-Guideline (not upgradable)
Mutagenicity			
870.5100 (§84-2)	00093742	Gene Mutation in *Salmonella typhimurium* and *Escherichia coli* (11/2/81)	**Negative**. Etridiazole did not induce a mutagenic or genotoxic effect under any test condition in any assay. Classification: Unacceptable-Guideline (not upgradable)
870.5100 (§84-2)	00073206	Gene Mutation in *Salmonella typhimurium* (10/77)	**Positive**. Etridiazole induced a mutagenic response in *Salmonella typhimurium* strain TA100 at noncytotoxic doses of 0.02, 0.06 and 0.2 μg/plate -S9 activation. There was, however, no evidence of a mutagenic effect in the presence of S9 activation. Etridiazole was not mutagenic in strain TA98. Classification: Acceptable-Nonguideline
870.5300 (§84-2)	00093743	Gene Mutation/ *In vitro* mammalian cell assay in Chinese hamster ovary cells (11/10/81)	**Negative**. Etridiazole did not induce a mutagenic effect in Chinese hamster ovary cells at noncytotoxic concentrations of 0.001-0.008% (equivalent to 10-80 μg/mL) -S9 activation and 0.001-0.005% (equivalent to 10-50 μg/mL) +S9 activation after a 16 or 5 hour incubation period, respectively. Classification: Acceptable-Guideline
870.5385 (§84-2)	41837501	Cytogenetics/ *In vivo* mouse micronucleus assay (10/30/85)	**Negative**. There was no evidence of either a clastogenic or aneugenic effect in male and female mice administered 1000 mg/kg etridiazole at any sacrifice time. Classification: Acceptable-Guideline
870.5900 (§84-2)	00120414	Other Mutagenic Mechanisms/ *In vitro* Sister Chromatid Exchange in Chinese hamster ovary cells (1/26/81)	**Positive**. Etridiazole induced increases in the frequency of sister chromatid exchanges per cell at concentrations of 0.002 to 0.005% (equivalent to 20 to 50 μg/mL) -S9 activation and 0.002 and 0.003% (equivalent to 20 and 30 μg/mL) +S9 activation after a 27.5 or 4 hour incubation period, respectively. Classification: Acceptable-Guideline
870.5375/ 870.5900 (§84-2)	00120416	Other Mutagenic Mechanisms/ *In vitro* Cytogenetics/ Sister Chromatid Exchange in Chinese hamster ovary cells (6/4/82)	**Positive**. Etridiazole induced increases in the frequency of sister chromatid exchanges per cell at concentrations of 0.003-0.005% (equivalent to 10-50 μg/mL) -S9 after a 27-28 hour incubation period. In addition, etridiazole induced increases in the frequency of cells with structural chromosomal aberrations at concentrations of 0.005% and 0.006% (equivalent to 50 and 60 μg/mL) -S9 activation and 0.003, 0. 005 and 0.006% (equivalent to 30, 50 and 60 μg/mL) +S9 activation after a 6 or 2 hour incubation period, respectively.

TABLE 2. Subchronic and Chronic Toxicity Profile for Etridiazole (Terrazole)			
Guideline	**MRID#**	**Study Type***	**Results**
			Classification: Acceptable-Guideline
Metabolism			
870.7485 (§85-1)	43654801	Metabolism - Rat (4/28/95)	Etridiazole is rapidly absorbed and peak elimination occurs within 48 hours of dosing. The metabolite profile in urine was similar between sexes and among the four dose groups; metabolites were identified as etridiazole carboxylic acid, ethyl (aminocarbonyl) carbamate, N-carboxy oxamic acid and N-acetyl cysteinyl conjugate of etridiazole. Classification: Acceptable-Guideline

*The percent active ingredient of the test material used in the subchronic and chronic toxicity studies ranged from 93 to 99%, unless specified otherwise.

3.2 FQPA CONSIDERATIONS

The FQPA Safety Factor Committee (SFC) (6/3/99) concluded that a safety factor is required for etridiazole since there is uncertainty due to the data gaps for the 2-generation reproductive study in rats.

The FQPA SFC recommended that the **FQPA safety factor** for protection of infants and children (as required by FQPA) be **reduced to 3x** because:

- there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity studies in rats and rabbits
- although the multi-generation reproduction study in rats was determined to be an unacceptable-guideline study and not adequate for regulatory purposes by the HIARC, it is noted that the observed offspring effects in this study occurred only at a treatment level which resulted in parental toxicity
- adequate data are available or conservative modeling assumptions are used to assess the potential for dietary (food and drinking water) exposure to infants and children.

Additionally, the FQPA SFC recommended that the weight-of-evidence for the FQPA safety factor recommendation be re-evaluated after all data requirements for etridiazole have been satisfied.

Application of the Safety Factor

Population Subgroups

The FQPA safety factor is **applicable to all population subgroups** since there is uncertainty due to the data gap for the two-generation reproduction study in rats which could identify potential reproductive effects to the parental animals or to the offspring following exposure to etridiazole.

Risk Assessment Scenarios

The FQPA safety factor for etridiazole is **applicable to chronic dietary risk assessment and all residential (non-occupational) risk assessments** since there is uncertainty due to the data gap for the two-generation reproduction study in rats which could identify potential reproductive effects to the parental animals or to the offspring following exposure to etridiazole. The safety factor is **not applicable to acute dietary risk assessment** since no increased susceptibility was demonstrated following *in utero* exposure and the two-generation reproductive study may not provide information on the potential for effects occuring after a single dose (exposure).

3.3 Other FQPA Considerations

3.3.1. Cumulative Risk

EPA does not have, at this time, available data to determine whether etridiazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this reregistration action, therefore, EPA has not assumed that etridiazole has a common mechanism of toxicity with other substances.

On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether etridiazole share(s) a common mechanism of toxicity with any other substance and, if so, whether any tolerances for etridiazole need to be modified or revoked.

3.3.2. Endocrine Disruption

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...."

EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the Federal Register of December 28, 1998 (63 FR71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of etridiazole and its end-use products for endocrine effects may be required.

3.4 DOSE RESPONSE ASSESSMENT

Table 3 presents the summary of toxicology doses and endpoints for etridiazole risk assessment.

TABLE 3: SUMMARY OF TOXICOLOGY ENDPOINT AND DOSES FOR ETRIDIAZOLE (TERRAZOLE)

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT/STUDY/RATIONALE/UF/MOE
Acute Dietary (Females 13-50)	NOAEL=15	Reduced fetal body weights, decreased viability and external and skeletal malformations/variations in the rabbit developmental toxicity study. The skeletal malformations/variations (missing sternebrae and tail defects) are presumed to occur after a single exposure (dose) and thus are appropriate for acute risk assessment. Since the selected NOAEL is based on a developmental endpoint, it is applicable only to the population subgroup, females 13-50 years old. The 100x uncertainty factor includes 10x for interspecies extrapolation and 10x for intraspecies variation. A FQPA safety factor was not applicable to acute dietary risk assessment since no increased susceptibility was demonstrated following *in utero* exposure and the multi-generation reproduction study in rats may not provide information on the potential for adverse effects occuring after a single exposure (dose).
	UF=100 FQPA SF=1	
	Acute RfD = 0.15 mg/kg Acute PAD = 0.15 mg/kg	
Acute Dietary (General Population)	An appropriate endpoint attributable to a single exposure (dose) was not identified in oral toxicity studies (including the developmental toxicity studies in rats and rabbits) that is applicable to subpopulations other than females of childbearing age (13-50 years old).	

TABLE 3: SUMMARY OF TOXICOLOGY ENDPOINT AND DOSES FOR ETRIDIAZOLE (TERRAZOLE)		
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT/STUDY/RATIONALE/UF/MOE**
Chronic Dietary	NOAEL=4.8	Increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in the two-year carcinogenicity study in rats. The HIARC re-assessed the RfD and determined that the two-year chronic toxicity study in dogs previously used to establish this value does not meet the current guideline requirements. Due to the numerous deficiences observed as a result of the age of this chronic toxicity study (1966-1969), it is not adequate for establishing the RfD. Consequently, the two-year rat carcinogenicity study was selected for this exposure scenario. The uncertainty factor includes 10x for interspecies extrapolation, 10x for intraspecies variation, 3x for the FQPA safety factor and 3x applied under FIFRA for toxicology data gaps. The FQPA safety factor for etridiazole is applied to chronic dietary risk assessment because uncertainty exists due to the lack of an acceptable multi-generation reproduction study in rats, which could identify potential toxicities following exposure to etridiazole in the offspring and/or the parental animals.
	UF=300 FQPA SF=3	
	Chronic RfD = 0.016 mg/kg/day Chronic PAD = 0.005 mg/kg/day	
Chronic (Cancer) Dietary	**Group B2 chemical - "Probable human carcinogen" - Q_1^* = 3.33 x 10^{-2} $(mg/kg/day)^{-1}$** in human equivalents [converted from animals to humans by use of the $(mg/kg\ body\ weight)^{3/4}$ cross species scaling factor].	
Dermal Absorption	A dermal absorption factor of 100% (default value)	
Short-Term (Dermal & Inhalation)	Oral NOAEL=15*	Reduced fetal body weights, decreased viability and external and skeletal malformations/variations in the rabbit developmental toxicity study. An adequate dose and endpoint for short-term dermal risk assessment could not be identified in two dermal toxicity studies classified by the HIARC as unacceptable as the result of the age of the studies and major deficiencies. Therefore, a developmental NOAEL from the developmental toxicity study in rabbits was selected because: 1) the developmental effects are considered short-term and thus are appropriate for this exposure period (i.e., 1-7 days) of concern, 2) the reproductive/fetal parameters are not evaluated in the dermal toxicity study and thus the consequences of these effects cannot be ascertained for the dermal route of exposure and 3) this endpoint will provide adequate protection for the subpopulation of females 13-50 years old (i.e. pregnant workers). Since no inhalation studies are available (with the exception of an acute inhalation toxicity study), an oral developmental NOAEL of 15 mg/kg/day would be protective of all population subgroups and is considered appropriate for short-term inhalation exposure (1 to 7 days) risk assessment.
Intermediate-Term (Dermal & Inhalation)	Oral NOAEL=4.8*	Increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in the two-year carcinogenicity study in rats. This dose/endpoint was selected due to missing or unacceptable subchronic studies in the etridiazole data base. The developmental NOAEL (15 mg/kg/day) is not recommended for this time period since the lower NOAEL (4.8 mg/kg/day) in the two-year carcinogenicity study in rats is more protective/conservative for the intermediate-term dermal and inhalation exposure scenarios/risk assessments.

TABLE 3: SUMMARY OF TOXICOLOGY ENDPOINT AND DOSES FOR ETRIDIAZOLE (TERRAZOLE)		
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT/STUDY/RATIONALE/UF/MOE**
Long-Term (Dermal & Inhalation)	Oral NOAEL=4.8*	Increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in the two-year carcinogenicity study in rats. This dose/endpoint was used for establishing the chronic RfD and is appropriate for long-term dermal and inhalation exposure scenarios/risk assessments.
MOE (Short-Term & Intermediate-Term)	A MOE of 100 is adequate for occupational exposure risk assessments. A MOE of 100 is required for non-occupational exposure risk assessments (adult golfers).	
MOE (Long-Term)	A MOE of 300 is required for occupational exposure risk assessments which includes the conventional 100x (10x for interspecies extrapolation and 10x for intraspecies variation and 3x applied under FIFRA for toxicology data gaps (i.e., the lack of acceptable chronic toxicology studies). There are no registered residential uses, therefore the FQPA safety factor is not required.	

* Since an oral NOAEL was selected, a dermal absorption factor of 100% (default value) and an inhalation absorption factor of 100% (default value) should be used during route to route extrapolation.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Etridiazole [5-ethoxy-3-trichloromethyl-1, 2, 4-thiadiazole] is an organic, non-phytotoxic soil fungicide that is used to control various species of Pythium, Phytophthora, Fusarium, damp off, and root and stem rots. Etridiazole is manufactured by Uniroyal Chemical Company, Inc., the basic producer, and its subsidiary, Gustafson, Inc., under the trade name Terrazole®. It is a reddish-brown liquid that is formulated as dusts (2.5% to 5% a.i.), granules (1.5% to 5% a.i.), wettable powders (35% a.i.), flowable concentrates (5.8% to 44.7% a.i.) and emulsifiable concentrates (4.3% to 44.3% a.i.). Tolerances are established for the residues of etridiazole and its monoacid metabolite [3-carboxy-5-ethoxy-1,2,4-thiadiazole] in or on the following raw agricultural commodities: avocados, corn, cottonseed, tomatoes, wheat, strawberries, meat, milk, poultry, and eggs (40CFR §180.370). Current uses include seed treatments, cotton (as an at-planting soil treatment), turf (limited to golf courses) and ornamentals. Etridiazole is registered for use on ten crops as a seed treatment (barley, beans, corn, cotton, peanuts, peas, sorghum, soybeans, safflower, and wheat). There are no registered homeowner uses.

A search of the Agency's Reference Files System (REFS) on 10/99 indicates that there are eleven etridiazole end-use products (EPs) with food/feed uses registered to Uniroyal and its subsidiary,Gustafson.

Table 4. Etridiazole End-Use Products with Food/Feed Uses Registered to Uniroyal

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name	Additional Active Ingredients
400-405	3/97	0.5 lb/gal EC	TERRACLOR SUPER X Emulsifiable	PCNB (2 lb/gal EC)
400-406	3/98	2.5% G	TERRACLOR SUPER X Granular	PCNB (10% G)
400-408	12/96	1.53% G	TERRACLOR SUPER X With Di-Syston	PCNB (6.5% G) and disulfoton (6.5%)
400-422	1/98	4 lb/gal EC	TERRAZOLE 4EC	
400-455	6/95	0.5 lb/gal FlC	TERRACLOR SUPER X Flowable	PCNB (2 lb/gal FlC)
400-456	12/96	3.8% G	TERRACLOR SUPER X 18.8G	PCNB (15.0% G)
400-475	1/97	0.4 lb/gal EC	TERRACLOR SUPER X Plus Di-Syston	PCNB (1.5 lb/gal EC) and disulfoton (1.5 lb/gal EC)
7501-54	11/96	5% D	TERRACLOR SUPER X 20-5 Dust With Graphite	PCNB (20% G)
7501-57	11/96	0.5 lb/gal EC	TERRA-COAT L-205N Seed Treatment Fungicide with Dye	PCNB (2 lb/gal EC)
7501-111	5/95	2.5% D	4-WAY For Seed Disease Control Seed Protectant Fungicide	Captan (18% G), Maneb (18.75% G), PCNB (10% G)
7501-153	5/95	2.5% D	4-WAY Peanut Seed Protectant Fungicide	Captan (18% G), Maneb (18.75% G), PCNB (10% G)

A review of the labels listed above and supporting residue data indicate that the following label amendments are required:

Use directions on all labels permitting an in-furrow application to cotton should be amended to prohibit the use on cotton seed previously treated with etridiazole.

Use directions on all labels permitting seed treatment applications should be amended to stipulate the requirement to dye the treated seeds with an EPA-approved dye unless treated seed meets the requirement exemptions outlined in 40CFR 153.155.

Use directions on all labels permitting seed treatment applications should be amended to prohibit the use of treated seed for food, feed, or oil purposes.

All EP labels should be amended to specify the rotational crop restrictions delineated by the confined rotational crop study. Although the etridiazole rotational crop study indicated a 120-day plant-back interval (PBI) is needed for root crops, the Gustafson labels for EPs used as seed treatments (7501-54, -57, -111, and -153) should be amended to specify a 12-month PBI for root crops owing to the requirements for the PCNB active ingredient; the labels allowing at-planting in-furrow uses on cotton already specify a 12-month PBI for root crops on account of PCNB. A 30-day PBI should be established for leafy vegetables, small grains, and other rotated crops. Alternatively, if the registrant desires shorter plantback intervals, limited crop field trials should be conducted according to OPPTS Test Guidelines 860.1900.

A comprehensive summary of the registered food/feed use patterns of etridiazole, based on the product labels registered to Uniroyal and Gustafson, is presented in Table A2 (Appendix A). A tabular summary of the residue chemistry science assessments for reregistration of etridiazole is presented in Table A3 (Appendix A). The conclusions listed in Table A3 regarding the reregistration eligibility of etridiazole food/feed uses are based on the use patterns registered by the basic producers, Uniroyal and Gustafson. All end-use product labels should be amended such that they are consistent with the basic producer's labels.

4.2 Dietary Exposure

4.2.1 Food Exposure

a. Nature of the Residue

Plants

The qualitative nature of the residue in plants is adequately understood based on cotton, soybean, and wheat metabolism studies. The currently regulated residues of concern are etridiazole and its monoacid metabolite, 3-carboxy-5-ethoxy-1,2,4,-thiadiazole. The Metabolism Advisory Review Committee (MARC) concluded on 5/99 that the residues of concern in plants consist of etridiazole and its monoacid metabolite (D255738, D. Drew/M.Centra, 11/3/99).

In the wheat metabolism study, parent compound was nondetectable in wheat grain, forage and straw grown from seed treated with [^{14}C]etridiazole at 10x the registered rate. Neither parent etridiazole or its monoacid metabolite were found in wheat grain treated at

the 10x rate. The major metabolite groups identified in wheat forage were 3-carboxy-5-hydroxyethoxy etridiazole (31.0%TRR, 0.45 ppm); combined residues of the monoacid and 3-hydroxymethyl-etridiazole (20.8%TRR, 0.30 ppm); and glucosides of 3-hydroxymethyl-etridiazole (10.0%TRR, 0.14 ppm). The major metabolite groups identified in wheat straw were 3-carboxy-5-hydroxyethoxy etridiazole (47.2%TRR, 1.94 ppm); combined residues of the monoacid and 3-hydroxymethyl-etridiazole (10.7%TRR, 0.44 ppm combined); and glucosides of 3-hydroxymethyl-etridiazole (13.7%TRR, 0.56 ppm). Natural constituents such as glycolic, malonyl oxamic, and oxalic acids accounted for 12.8-20.5% of the TRR in forage and straw and all of the ^{14}C-activity identified, 84.8% of the TRR, in grain.

In the cotton metabolism study, parent compound and related metabolites were nondetectable in cottonseed or foliage grown in soil treated with [^{14}C]etridiazole at the 100x rate and harvested at maturity 5 months after planting. Similar results were observed in soybean immature plants and seed harvested 30-45 days (forage and hay) and ~3 months (seed) after seed treatment with [^{14}C]etridiazole at 10x. Etridiazole in soybean seed and forage was extensively degraded and the major components of the ^{14}C-activity identified as endogenous biomolecules.

Livestock

The qualitative nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The current tolerance expression includes etridiazole and the monoacid. The MARC (D255738, D. Drew/M. Centra, 11/3/99) has determined that etridiazole and its monoacid metabolite are the residues of concern to be regulated in animal commodities.

The available poultry and ruminant metabolism studies indicate that etridiazole is extensively degraded, mainly to non-thiadiazole ring containing natural components; parent compound was not identified in any animal tissue, eggs or milk. No thiadiazole ring-containing metabolites were identifed in any animal tissue, eggs or milk with the exception of the monoacid in goat liver (0.002 ppm normalized to 1x maximum theoretical dietary burden) and in hen liver (0.0001 ppm- 0.0002 ppm normalized to 1x maximum theoretical dietary burden).

In the hen metabolism study conducted at a feeding level of 50 ppm for 6 days (500x the maximum theoretical dietary burden for poultry, total ^{14}C-residues (TRR) were 5.32-8.46 ppm in liver, 1.41-3.49 ppm in fat and muscle, and 0.023-1.52 ppm in eggs (residues had not plateaued in eggs by day 6); the only ring-containing metabolite identified was the monoacid which accounted for 1-2% of the TRR (0.05-0.08 ppm) in liver and was nondetectable in eggs.

After 6 days of feeding at 50 ppm of [^{14}C]etridiazole (172x the maximum theoretical dietary burden for dairy cattle) TRR were 12.6-17.6 ppm in goat liver, 0.17-5.74 ppm in kidney, muscle, and fat, and up to 0.464 ppm in milk. No ring-containing metabolites were identifed in milk or tissues with the exception of the monoacid accounting for ~2% (0.35 ppm) of the TRR in liver.

b. Residue Analytical Methods

Adequate analytical methodology is available for data collection and enforcing tolerances of etridiazole, as currently defined, on animal and plant commodities.

The Pesticide Analytical Manual (PAM) Vol. II describes a GLC/ECD method for determining etridiazole *per se* (Method I), and a HPLC/UV method for determining the monoacid metabolite (Method A), each in/on plant commodities (avocado, cottonseed, and strawberries). The reported sensitivity of the methods for residues of etridiazole and the monoacid is 0.05 ppm for each analyte. PAM Volume II does not describe any methods for enforcing tolerances for residues in animal commodities; however, the Etridiazole SRR (3/30/89) indicates that two Agency validated methods are available for tolerance enforcement, a GC/ECD method entitled, "Determination of Residues of Terrazole in Chicken Matrices," capable of quantitating etridiazole *per se* in eggs and beef liver, and a HPLC method (CAM-47-81) that determines the monoacid in eggs and beef liver. These methods should be included in future updates of PAM Volume II.

Residue data on crop and animal commodities have been collected using the above GC/ECD and HPLC methods with only minor modifications involving changes in solvents and cleanup procedures.

c. Multiresidue Method Testing

The registrant has submitted multiresidue testing data (MRID 43259601) for etridiazole and its monoacid metabolite using FDA multiresidue Protocols B, C, D, and E; Protocol A was not used as the analytes do not possess the N-methylcarbamate moiety. These data have been forwarded to FDA (DP Barcode D205025, L. Edwards, 7/24/94). The FDA PESTDATA database (PAM Volume I, Appendix I, 3rd edition, 1994) indicates that etridiazole is completely recovered (>80%) by Multiresidue Protocol D and E (PAM I Sections 232.4 and 211.1), and partially recovered (50-80%) by Multiresidue Protocol E (PAM I Section 212.1). Recovery data for the monoacid metabolite were not reported in this edition of PAM I.

d. Storage Stability Data

The requirements for supporting storage stability data for etridiazole residues in plant

commodities are satisfied for the purposes of reregistration. The available storage stability data indicate that residues of etridiazole *per se* and the monoacid are stable in frozen cottonseed for up to 12 months. These data adequately support the cotton residue field trial in which samples of cottonseed and gin trash were analyzed within ~1 year of collection, Processed fractions were not analyzed as residues were non-quantifiable in the RAC after 6x treatment.

The metabolism studies conducted on cotton, soybean, and wheat to support seed treatment uses on barley, beans, corn, cotton, peas, peanuts, safflower, sorghum, soybeans, and wheat are adequately supported by storage stability data indicating that [^{14}C]etridiazole residues were stable in frozen samples and extracts for the duration of these studies.

The requirements for storage stability data on animal commodities are not satisfied for the purposes of reregistration. Data are required depicting the storage stability of the monoacid metabolite stored frozen in animal commodities for up to 2 years. Samples from the poultry and ruminant feeding studies were stored frozen for ~6 weeks and 2 years, respectively, prior to analysis for residues of the monoacid.

The available storage stability data indicate that etridiazole *per se* is stable in poultry muscle, fat, skin, and eggs stored at -20 C for up to 6 weeks, the approximate period of frozen storage for samples in the poultry feeding study, etridiazole is not stable in frozen giblets (pooled liver, heart, and gizzard). Etridiazole *per se* was also shown to be stable in goat liver stored at -20 C for ~1 week, but declined by ~50% after 7 months of frozen storage. These data support the poultry feeding study with respect to etridiazole *per se*. As samples from the ruminant feeding study were analyzed for residues of parent compound within one month of collection, no additional data are required depicting the storage stability of etridiazole *per se* in cow tissues and milk.

e. Magnitude of the Residue in Crop Plants

For purposes of reregistration, the requirements for magnitude of the residue data in/on plants are fulfilled for the in-furrow application to cotton and are waived for the seed treatment uses on barley, beans, corn, cotton, peanuts, peas, sorghum, safflower, and wheat.

In addition to the metabolism study demonstrating that residues of parent and the monoacid are non-detectable in cottonseed or foliage harvested at maturity after treatment at 100x, adequate residue data are available to reassess the current tolerance for residues in/on undelinted cottonseed. Residues of etridiazole *per se* were <0.005 ppm (< limit of quantitation) in/on four samples of cottonseed harvested 138-145 days after in-furrow at-planting treatment with etridiazole (2.5% G) at 1.8 lb ai/A, 6x the maximum

seasonal rate (DP Barcode D244960, S. Law and D. Soderberg, 1/19/99). Data from older studies (E. Zager memo dated 2/1/82) also suggest that quantifiable residues are unlikely in cotton treated with etridiazole according to the current use pattern. In ten trials conducted in five states, cotton was treated with etridiazole (4 lb/gal EC) at-planting at 0.5-1.0 lb ai/A (1.3-2.6x rate) or postemergence (2-4 leaf stage) at 0.25 lb ai/A, and residues of etridiazole were <0.02 (<LOQ) in the majority of the samples analyzed; only one sample treated at planting at the 1.3x rate bore detectable residues of etridiazole *per se* at 0.06 ppm. Residues of the monoacid were <0.05 ppm (<LOQ) in/on all samples analyzed. The available data suggest that a tolerance at the combined LOQs is appropriate for residues of etridiazole in/on cottonseed.

Cotton gin byproducts are now considered a significant livestock feed item (OPPTS.GLN 860.1000, Table 1). HED has previously concluded (DP Barcode D244960, S. Law/D. Soderberg, 1/19/99) that residue data provided from two tests on cotton gin byproducts derived from cotton grown from seed treated at 6x partially satisfies the requirement for data on cotton gin byproducts. As data from the cotton processing and metabolism study conducted at exaggerated rates indicate that etridiazole residues are unlikely to be quantifiable in gin trash, additional data on cotton gin byproducts are not required. The available data indicate that a tolerance at the combined LOQs is needed for residues of etridiazole in/on cotton gin byproducts.

The Etridiazole SRR (3/89) required radio tracer uptake studies to support etridiazole seed treatment uses on barley, beans, peanuts, peas, safflower, soybean, and sorghum because no residue data were available to support these uses. At that time, no tolerances were established for these commodities because seed treatment uses were considered non-food uses. [Note: Tolerances were established for residues of etridiazole in/on corn and wheat commodities because the use patterns on these crops allowed pre-plant, at-planting, or postemergence treatments in addition to seed treatments. Currently, the registrant is supporting only seed treatment use on corn and wheat.] As detectable ^{14}C-activity was expected in the aerial portions of these crops, the registrant proposed conducting metabolism studies designed to provide sufficient radioactivity in the mature crop to permit residue characterization and identification (P Deschamp, 1/22/93). HED concurred (DP Barcode D188371, P. Deschamp, 3/4/93) and required metabolism studies on soybeans and wheat conducted at exaggerated rates to support reregistration of etridiazole seed treatments.

In the metabolism studies, etridiazole *per se* was non-detectable in/on all cotton, soybean, and wheat matrices analyzed. However, residues of the monoacid were detected as a component of
^{14}C-residues in wheat forage (20.8%TRR, 0.30 ppm) and straw (10.7%TRR, 0.44 ppm) treated at 10x. In addition, residues of the monoacid accounted for 4% of the TRR (0.033 ppm) in rotational wheat forage grown at the 30-day PBI in soil treated with

[^{14}C]etridiazole at ~1x rate. These data indicate that residues of the monoacid would not be expected to exceed 0.04 ppm in wheat forage and straw grown from seed treated at 1x. Based on these results, appropriate tolerances for residues of etridiazole in/on commodities grown from etridiazole treated seed should be set at the combined LOQ (0.1 ppm) of the available enforcement methods for etridiazole and the monoacid.

Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown outside of the United States in order to reassess a tolerance for tomatoes.

f. Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for cottonseed. Residues of etridiazole *per se* were <0.005 ppm (<LOQ) in/on cottonseed grown from seed treated at 6x the registered rate; as no quantifiable residues were found in the RAC samples, cottonseed processed fractions were not analyzed. The registrant did not analyze for the monoacid; however, as residues of the monoacid were nondetectable in cottonseed from the 100x metabolism study, additional data on the metabolite in cottonseed processed commodities are not required.

In addition, the requirement for magnitude of the residue in processed food/feed commodities is considered fulfilled for seed treatment uses on crops with processed commodities (barley, corn, peanuts, safflower, sorghum, soybean, and wheat). As residues of etridiazole and the monoacid were nondetectable in soybean seed and wheat grain from the exaggerated rate (10x) soybean and wheat metabolism studies, processing studies or tolerances are not required for processed fractions of barley, corn, peanuts, sorghum, safflower, soybean, and wheat.

g. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Provided that storage stability issues are resolved, the reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are satisfied. Based upon the established or reassessed tolerances for etridiazole residues in/on animal feed items, the calculated maximum theoretical dietary burdens for livestock are presented below:

Table 5. Calculation of Maximum Dietary Burdens (worst case) of Livestock for Etridiazole

Feed Commodity	% Dry Matter [a]	% Diet [a]	Tolerance (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
corn grain	88	60	0.1	0.07
corn forage	40	40	0.1	0.10
TOTAL BURDEN		100		**0.17**
Dairy Cattle				
wheat forage	25	60	0.1	0.24
sorghum grain	86	40	0.1	0.05
TOTAL BURDEN		100		**0.29**
Poultry				
corn grain	N/A	80	0.1	0.08
corn milled products	N/A	20	0.1[d]	0.02
TOTAL BURDEN		100		**0.10**
Swine				
corn grain	N/A	80	0.1	0.08
corn milled products	N/A	20	0.1[d]	0.02
TOTAL BURDEN		100		**0.10**

[a] OPPTS 860 Guidelines Table 1 (August 1996).

[b] Current or reassessed tolerance from Table 6.

[c] Contribution = [tolerance / % DM (if cattle)] X % diet).

[d] Based upon the 0.1 ppm tolerance for residues in/on corn grain.

In the ruminant feeding study conducted at feeding levels of 0.1, 1.0, and 10 ppm (0.3x, 3.4x, and 34x the dietary burden for dairy cattle), residues of etridiazole *per se* and the monoacid were non-detectable (each <0.05 ppm) in muscle, kidney, and liver at all dose levels. Fat samples from two high-dose cows bore residues of etridiazole *per se* at 0.04 and 0.12 ppm. Fat samples were not analyzed for the monoacid (residues of the metabolite were not expected in fat due to its solubility in water). Residues of etridiazole *per se* were non-detectable (<0.01 ppm) in milk samples with the exception of a few samples, at all dose levels, bearing trace amounts at 0.01 ppm. Residues of the monoacid were <0.05 ppm in milk samples from the 10 ppm feeding level. In a separate study on one cow fed at 1000 ppm (3450x) for 3 days, residues of the monoacid were 0.08 ppm in milk and non-detectable in muscle, liver, and kidney.

In the poultry feeding study, hens were dosed with etridiazole at 0.1, 1.0 or 10 ppm (1x, 10x, and 100x the dietary burden for poultry). At the 10 ppm dose (100x), residue levels of etridiazole *per se* and the monoacid were each <0.1 ppm (<LOQ) in meat, fat, skin, giblets (pooled liver, heart, and gizzard), and <0.01 and <0.05 ppm, respectively, in eggs (<LOQ). [The available storage stability data indicate that residues of etridiazole *per se* in giblets decline by 78% after 6 weeks of frozen storage, the storage interval for giblet samples from the feeding study; however, data from the poultry metabolism study indicate that residues of etridiazole and the monoacid would not exceed 0.1 ppm in liver at the 500x feeding level].

These data indicate that a Category 6(a)(3) {40CFR 180.6(a)3 "no reasonable expectation of finite residues"} situation exists with respect to residues of etridiazole and the monoacid metabolite in meat, mbyp (meat by-products), fat, and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, mbyp, and eggs. Therefore, at this time, tolerances for etridiazole in animal commodites will be revoked. However, once the outstanding storage stability data on the monoacid metabolite is submitted and reviewed, the 6(a)3 status may be reevaluated. Additionally, if the current etridiazole use patterns change, it will be necessary to reevaluate the 6(a)3 status.

h. Magnitude of the Residue in Water, Fish, Irrigated Crops

Etridiazole is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

i. Magnitude of the Residue in Food-Handling Establishments

Etridiazole is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

j. Confined Accumulation in Rotational Crops

An adequate confined rotational crop study has been submitted. Radioactive residues in rotational crops grown in [^{14}C]etridiazole-treated (0.413 lb ai/A, ~1x) soil were adequately identified/characterized. The metabolic profile of etridiazole in rotational crops is qualitatively similar to the profile elucidated in primary crops.

At the 30-day PBI, no parent compound was found in any of the rotational crop matrices analyzed, and minor amounts of the monoacid were found in wheat forage (4%TRR, 0.033 ppm[monoacid plus other compounds that are not of toxicological concern]). The principle residues identified were metabolites grouped by the registrant under the designation "F1" accounting for 12-47% of the TRR and including 2-imino-3-(β-D-glucopyranosyl) propanoic acid; 3-[3-(1,2,4-thiadiazolyl)]-2-propanoic acid; 3-(acetylamino)-3-oxopropanoic acid; glycolic acid; glycine; and acetamide. Major components of the residue also included the 3-carboxy-5-hydroxyethoxy etridiazole metabolite (7-38%TRR), and group "F4a" metabolites including 3-hydroxymethyl etridiazole conjugates and 3-carboxy- etridiazole methylester (<3-36%TRR). Minor amounts of 3-hydroxymethyl etridiazole and its reduced form (<1-8%TRR) were found.

In turnips at the 30-day PBI, TRR were 0.18-2.38 ppm; parent and the monoacid metabolite were nondetectable (<0.005 ppm). At the 120-day PBI, TRR were 0.013-0.017 ppm in turnip tops (immature) and wheat forage and straw, and <0.01 ppm in mature turnip tops and roots and wheat grain; however, no parent compound or metabolites of etridiazole were identified above 0.005 ppm in any matrix at this interval. At the 365 day PBI, TRR in turnips and wheat did not exceed 0.01 ppm.

At the 30 day PBI, TRR were 0.054 ppm in mature lettuce. At the 120 day PBI, TRR in lettuce did not exceed the trigger value of 0.01 ppm. Residues of etridiazole and the monoacid were nondetectable (<0.005 ppm) in lettuce.

Based on these results, rotational crop restrictions should be established at 30 days for leafy vegetables and 120 days for root crops, small grains and other rotated crops. However, owing to the requirements for the PCNB active ingredient, Gustafson seed treatment EP labels (7501-54, -57, -111, and -153) should be amended to specify a 12-month PBI for root crops; the labels allowing at-planting in-furrow uses on cotton already specify a 12-month PBI for root crops on account of PCNB. No tolerances for inadvertent residues of etridiazole are required for these crop groups when planted at the appropriate plantback interval.

k. Field Accumulation in Rotational Crops

Limited field studies are not required provided that all EP labels are amended to reflect

the PBIs suggested by the the results of the confined study discussed above. Alternatively, if the registrant desires shorter plantback intervals, limited crop field trials should be conducted (OPPTS Test Guidelines 860.1900).

l. Tolerance Reassessment Summary

Tolerances for residues of etridiazole are currently expressed in terms of etridiazole and its monacid metabolite under 40 CFR §180.370. The Metabolism Advisory Review Committee (MARC) has concluded that the residues of concern in plant and animal commodities include etridiazole and its monoacid metabolite. A summary of the etridiazole tolerance reassessment for crops and livestock commodities and recommended modifications in commodity definitions are presented in Table 6.

Tolerances Listed Under 40 CFR §180.370:

Provided that the requested label amendments are made, sufficient data are available to reassess tolerances for etridiazole residues in/on undelinted cottonseed. Based upon the current use patterns and the available residue data, the established tolerances for etridiazole residues in/on undelinted cottonseed can be lowered to 0.1 ppm.

Sufficient data are also available to reassess the tolerances for residues in/on corn and wheat commodities. The tolerances for residues of etridiazole in/on corn and wheat grain at 0.05 ppm should be reassessed at 0.1 ppm. The available residue data support the tolerances at 0.1 ppm for residues in/on corn forage and fodder and wheat forage and straw.

The tolerance for avocados and strawberries should be revoked as the registrant is no longer supporting those crops. Additional residue data, as outlined in the EPA import tolerance guidance document (HED SOP98-6), are required reflecting the use of etridiazole on tomatoes grown ouside of the United States in order to reassess a tolerance for tomatoes. In the absence of such data, the current tolerance for tomatoes should be revoked as the registrant is no longer supporting use on domestically grown tomatoes.

Data indicate that a Category 6(a)(3) {40CFR 180.6(a)3 "no reasonable expectation of finite residues"} situation exists with respect to residues of etridiazole and the monoacid metabolite in meat, mbyp (meat by-products), fat, and milk of cattle, goats, hogs, horses, sheep, and in poultry, poultry fat, mbyp, and eggs. Therefore, at this time, tolerances for etridiazole in animal commodites will be revoked. However, once the outstanding storage stability data on the monoacid metabolite is submitted and reviewed, the 6(a)3 status may be reevaluated. Additionally, if the current etridiazole use patterns change, it will be necessary to reevaluate the 6(a)3 status.

Tolerances Needed Under 40 CFR §180.370:

New tolerances are needed for etridiazole residues in/on the following raw agricultural commodities: cotton gin byproducts, peanut nutmeat and hay, sorghum grain and forage, barley grain and hay, and safflower seed. The available residue data indicate that tolerances for residues of etridiazole should be established on these commodities at 0.1 ppm.

In addition, new tolerances are needed for etridiazole residues in/on the following crop group: legume vegetables (succulent or dried) crop group and foliage of legume vegetables, each at 0.1 ppm.

Table 6. Tolerance Reassessment Summary for Etridiazole

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances listed under 40CFR 180.370			
Avocados	0.15	Revoke	The registrant is no longer supporting use on avocados.
Corn, field, grain	0.05	0.1	Residue data indicate that the tolerance for residues in/on corn grain should be increased to 0.1 ppm.
Corn, fodder	0.1	0.1	
Corn, forage	0.1	0.1	
Cotton, seed	0.2	0.1	The available data support lowering the tolerance. *Cotton, undelinted seed*
Strawberries	0.2	Revoke	The registrant is no longer supporting use on strawberries.
Tomatoes	0.15	**To Be Determined**	The registrant is no longer supporting use on domestically grown tomatoes. Tolerance to be determined based on import residue field trial data (HED SOP 98.6).
Wheat, grain	0.05	0.1	Residue data indicate that the tolerance for residues in/on wheat grain should be increased to

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
			0.1 ppm.
Wheat, forage	0.1	0.1	
Wheat, straw	0.1	0.1	
Eggs	0.05	Revoke	A Category 6(a)3 situation exists with respect to residues of etridiazole and the monoacid metabolite in livestock commodities.
Milk	0.05		
Fat, mbyp, and meat of poultry	0.10		
Fat of cattle, goats, hogs, horses, and sheep	0.10		
Meat and mbyp of cattle, goats, hogs, horses, & sheep	0.10		
Tolerances needed under 40CFR 180.370			
Cotton gin byproducts	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in *cotton gin byproducts.*
Foliage of legume vegetables crop group	None	0.1	Residue data support establishing a 0.1 ppm tolerance on the *foliage of legume vegetables* crop group.
Legume vegetables (succulent or dried) crop group	None	0.1	The available data support establishing a tolerance of 0.1 ppm for residues in the *legume vegetables (succulent or dried)* crop group.
Barley, grain	None	0.1	Residue data support a 0.1 ppm tolerance.
Barley, hay	None	0.1	
Peanut, nutmeat	None	0.1	
Peanut, hay	None	0.1	
Safflower seed	None	0.1	
Sorghum, grain	None	0.1	
Sorghum, forage	None	0.1	

m. Codex Harmonization

There are currently no Codex Maximum Residue Limits (MRLs) established for residues of etridiazole in/on plant or animal commodities (electronic correspondence from S. Funk, 4/20/99).

4.2.2 Dietary Exposure and Risk Analysis (Food Sources)

Acute and chronic (non-cancer) and cancer dietary exposure analyses for etridiazole were performed using the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-92 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. No Pesticide Data Program (PDP) or Food and Drug Administration (FDA) monitoring data were available and crop field trial data were not required for crops on which etridiazole is used as a seed treatment (D188371, P. Deschamp, 3/4/93). Field trial data were available only for cottonseed at a 6x application rate (in-furrow at-planting treatment). Residues of etridiazole were non-detectable (< LOQ) in the cottonseed field trial. Available metabolism data indicate that a Category 6(a)3 {40CFR 180.6(a)3 "no reasonable expectation of finite residues"} situation exists with respect to residues of etridiazole in meat, poultry, poultry and meat by-products, fat, milk and eggs. Therefore, animal commodities are not included in the dietary risk assessment. The risk assessment may be modified upon establishment of a tolerance to support use on imported tomatoes.

a. Acute Dietary Exposure Analysis

For the acute analysis, tolerance level residues and 100% CT (crop treated) were assumed for all commodities (Tier 1). Etridiazole use on domestically grown tomatoes is no longer being supported by the registrant and etridiazole may be used on imported tomatoes. A conservative 100% CT was used for all tomato commodities (assumes all tomatoes consumed are treated with etridiazole). The established tolerance for domestic tomatoes (0.15 ppm) was used for the residue level for tomato commodities.

Dietary exposures and associated acute risk for all female (13-50yrs) subgroups are shown in Table 7.

Table 7. Summary of Results of Acute DEEM Analysis for Etridiazole

Subgroups	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure (mg/kg)	% aPAD	Exposure (mg/kg)	% aPAD	Exposure (mg/kg)	% aPAD
Females (13+/pregnant/not nursing)	0.001371	< 1.0	0.002390	1.6	0.003330	2.2
Females (13+/nursing)	0.001754	1.2	0.002468	1.6	0.003019	2.0

Females (13-19/not pregnant/not nursing)	0.002008	1.3	0.003375	2.2	0.006850	4.6
Females (20+/not pregnant/not nursing)	0.001313	< 1.0	0.002457	1.6	0.004169	2.8
Females (13-50 years)	0.001541	1.0	0.002795	1.9	0.005323	3.6

aPAD = 0.15 mg/kg

The results of the acute analysis indicate that at the 95th , 99th, and 99.9th percentile the acute dietary risk associated with the proposed uses of etridiazole does not exceed the Agency's level of concern (percent aPAD does not exceed 100%).

b. Chronic (Non-Cancer) Dietary Exposure Analysis

For the chronic (non-cancer) analyses, tolerance level residues and 100% CT were assumed for all commodities (Tier 1). Etridiazole use on domestically grown tomatoes is no longer being supported by the registrant and etridiazole may be used on imported tomatoes. A conservative 100% CT was used for all tomato commodities (assumes all tomatoes consumed are treated with etridiazole). The established tolerance for domestic tomatoes (0.15 ppm) was used for the residue level for tomato commodities.

Chronic (non-cancer) dietary exposures for the U.S. population and other subgroups are presented in Table 8.

Table 8. Summary of Results from Chronic Non-Cancer DEEM Analysis for Etridiazole. (95th Percentile)

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000688	14
Non-nursing Infants	0.001024	20
Children 1-6 yrs	0.001534	31
Females 13-19 yrs (not pregnant/not nursing)	0.000676	14
Females 13-50 yrs	0.000538	11
Males 13-19 yrs	0.000767	15

cPAD = 0.005 mg/kg/day

The results of the chronic analysis indicate that at the 95th percentile of exposure, the chronic (non-cancer) dietary risk associated with the proposed uses of etridiazole does not exceed the Agency's level of concern (percent cPAD does not exceed 100%).

c. Cancer Dietary Exposure Analysis

For the cancer analysis, tolerance level residues and 100% CT were assumed for all commodities. The cancer analysis was further refined and included residue levels of ½ the combined LOQs for etridiazole and monoacid metabolite (0.05 ppm) for all commodities except tomatoes. The established tolerance for domestic tomatoes (0.15 ppm) was used for the residue level for tomato commodities. Weighted average %CT estimates (BEAD 6/99) were used in the refined cancer analysis. Imported tomato commodities were estimated by BEAD to have less than 1% CT.

When tolerance level residues and 100% CT are used in the analysis, the carcinogenic risk estimate for etridiazole is **1.6×10^{-5}** for the general U.S. population. When the analysis is refined using residue levels of 1/2 the combined LOQs for etridiazole and monoacid metabolite (0.05 ppm) for all commodities except tomatoes (domestic tomato tolerance was used for tomato commodities) as well as weighted average %CT estimates (BEAD 6/99), the chronic dietary exposure is 0.000005 mg/kg/day and the carcinogenic risk estimate for etridiazole is **1.6×10^{-7}** for the general U.S. population, which is less than the level the Agency generally considers to be negligible for excess lifetime cancer risk.

4.2.3 Dietary Exposure (Drinking Water Sources)

The amount of data for etridiazole in the Pesticides in Ground Water Database (EPA 734-12-92-001, Sept. 1992) is very limited. It reported that etridiazole was sampled only in six wells in CA in 1989. Of six samples, none had detections (detection limit not reported). The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for etridiazole. Therefore, the Agency is presently relying on modeled estimated environmental concentrations (EECs). Generic Estimated Environmental Concentrations (GENEEC) and/or PRZM/EXAMS (both product estimates of pesticide concentration in a farm pond) estimate EECs in surface water and Screening Concentration in Ground Water (SCI-GROW) (an empirical model based on actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EECs in ground water. These models take into account the use patterns and environmental profile of a pesticide, but do not include consideration of the impact that processing raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for assessing whether a pesticide is likely to be

present in drinking water at concentrations that would exceed human health levels of concern.

For any given pesticide, the SCI-GROW model generates a single EEC value of pesticide concentration in ground water. That EEC is used in assessments of both acute and chronic dietary risk. It is not unusual for the ground water EEC to be significantly lower than the surface water EECs. The GENEEC model generates several time-based EEC values of pesticide concentration in surface water, ranging from 0-days (peak) to 56-days (average). The GENEEC peak EEC is used in assessments of acute dietary risk; the GENEEC 56-day (average) EEC is used in assessments of chronic (non-cancer and cancer) dietary risk. PRZM/EXAMS provides longer duration (up to 36-year) values of pesticide concentration in surface water and is mainly used when a refined EEC is needed.

The Environmental Fate and Effects Division (EFED) provided a drinking water assessment for etridiazole (11/10/99, DP Barcodes D197335, D199852, D204218, D210821, D244974, D218283, D249680, D251134, D252277, D252739). Tier 1 GENEEC estimated environmental concentrations (EECs) in surface water were estimated based on the application of etridiazole to cotton (1 in-furrow at- planting application at 0.38 lb ai/A), seed treatment (1 application at 0.001 lb ai/A) and application to golf course turf. The use on turf, which is limited to golf courses only, represents the most significant etridiazole use in terms of the potential to contaminate water. According to the registrant, the *recommended* application rate is 5.7 lb ai/A (the initial application at 3.8 lb ai/A, followed by a second application at 1.9 lb ai./A after 5-10 days). For the purpose of calculating GENEEC EECs for use in the human health risk assessment, EFED used a *typical* application rate of 7.6 lb ai/A (two applications at 3.8 lb ai/A at 10 day intervals).

EFED also submitted a Tier 1 (SCIGROW) EEC for etridiazole in groundwater based on the *typical* application rate to golf courses. EFED did not submit a Tier 1 groundwater (SCIGROW) EEC for etridiazole use on cotton.

The maximum label application rate of 3.8 lb ai/A applied five times (19 lb ai/A/yr maximum) was considered a very limited use because it is only applied on tees and greens and was therefore not used in the human health risk assessment. Note that the current maximum allowable golf course turf application rate (5 applications at 3.8 lbs a.i./A for tees and greens) may result in increased (EECs) for surface water and groundwater.

The Tier 2 (PRZM/EXAMS) model is not suitable for estimating EECs from pesticide use on turf. Therefore, a 36 year mean EEC is not available for etridiazole use on golf course turf. A Tier 2 (PRZM/EXAMS) 36 year mean surface water EEC was provided by EFED (D260263, R. Lee,11/10/99) based on the application of etridiazole to cotton (one annual

in-furrow application of 0.38 lb ai/A for 36 years).

All EECs provided by EFED reflect parent-only (etridiazole) values and do not include the regulated monoacid metabolite (3-carboxy-5-ethoxy-1,2,4-thiadiazole). EECs may be higher when the monoacid metabolite is included in the surface water and groundwater estimates.

Ground Water (EECs)

Results from Tier 1 (SCIGROW) modeling, which represents upper bound estimates of the concentration that might be found in groundwater from the typical use of etridiazole on turf, indicates that levels of etridiazole in groundwater are not likely to exceed **0.93 ppb.**

Surface Water (EECs)

Results from Tier 1 (GENEEC) modeling, which represents upper bound estimates of the concentration that might be found in surface water from the typical use of etridiazole on turf (golf courses), indicates that levels of etridiazole in surface water are not likely to exceed **230 ppb** for the peak (acute) and **170 ppb** for the average 56-day (chronic).

Further refinement of the surface water EECs from etridiazole use on golf courses is not possible as the Tier 2 models (PRZM and EXAMS) are not suitable for turf uses. A Tier 2 (PRZM/EXAMS) modeling was performed for cotton (in-furrow application of 0.38 lb ai/A for 36 years) and indicated that etridiazole concentrations would not exceed **0.05 ppb** in surface water for the 36 year mean (chronic- cancer).

Environmental Fate

Based on the available environmental fate data, etridiazole is a mobile compound with moderate persistence. Although etridazole is considered very mobile, under the proposed application rates for cotton and ornamental plants, the chemical may have a low potential to effect the quality of ground water because of its rapid dissipation via volatilization with the low application rates for these crops. However, the higher application rates proposed for turf, when combined with vulnerable conditions, are likely to result in surface water contamination. Once in an aqueous environment, etridiazole may persist due to its resistence to abiotic degradation, *i.e.*, etridiazole is stabile to hydrolysis and aqueous photolysis.

The primary route of dissipation of etridiazole is volatilization and to a lesser degree aerobic soil metabolism. Etridiazole is moderately labile. It is stable to hydrolysis and

aqueous photolysis; however, it is somewhat susceptible to soil photolysis. Under aerobic soil metabolism conditions, etridiazole dissipates slowly following a biphasic pattern consistent with a chemical that readily volatilizes and undergoes slow aerobic degradation. Similar degradation products were observed in the soil photolysis and the aerobic soil metabolism studies, although the ratios of the degradates in each of the studies were different. Terrestrial field dissipation studies show that etridiazole has low to moderate persistence ($t_{1/2}$=4-33 days) and appear to confirm substantial volatilization as evidenced by low recoveries one day after application.

The relatively rapid dissipation of etridiazole in the field suggests a low potential for the chemical to reach surface waters. However, at the proposed higher application rate, there is a high likelihood that etridiazole will reach surface waters. Golf courses represent particularly vulnerable areas for run off to surface waters. Since etridiazole dissipation is dependent on both volatilization and soil metabolism and thus is markedly impacted by the length of time that it resides in the field, etridiazole may reach surface waters following high rain events that produce runoff a few days to weeks after application. Since etridiazole is relatively stable to abiotic degradation (hydrolysis, aqueous photolysis), it may persist for considerable periods of time in aquatic areas with long residence times and low microbiological activity.

4.2.4 Drinking Water Levels of Comparison

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. HED uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative EECs provided by computer modeling (SCI-GROW, GENEEC, PRZM/EXAMS). A DWLOC may vary with drinking water consumption patterns and body weights for specific subpopulations.

HED calculates DWLOCs by a two-step process: exposure [food + (if applicable) residential] is subtracted from the PAD to obtain the maximum acceptable exposure allowed in drinking water; DWLOCs are then calculated using that value and HED default body weight and drinking water consumption figures. In assessing human health risk, DWLOCs are compared to EECs. When EECs are **less** than DWLOCs, HED considers the aggregate risk [from food + water + (if applicable) residential exposures] to not exceed a level of concern.

DWLOCs were calculated and compared to model estimates of etridiazole concentrations

in ground and surface water. Based on the acute and chronic dietary exposure estimates drinking water levels of comparison were calculated using the formulas presented below:

$$DWLOC_{chronic}(ug/L) = \frac{chronic\ water\ exposure\ (mg/kg/day)\ x\ (body\ weight)}{consumption\ (L)\ x\ 10\text{-}3\ mg/ug}$$

where chronic water exposure = [chronicPAD - chronic food exposure (mg/kg/day)]

$$DWLOCacute\ (ug/L) = \frac{[water\ exposure\ (mg/kg/day)\ x\ (body\ weight)]}{[consumption\ (L)\ x\ 10^{-3}\ mg/ug]}$$

where acute water exposure = [acutePAD - acute food exposure (mg/kg/day)]

$$DWLOCcancer\ (ug/L) = \frac{[chronic\ water\ exposure\ (mg/kg\ bw/day)\ x\ (body\ weight\ (kg))]}{[water\ consumption\ (L)\ x\ 10^{-3}\ mg/ug]}$$

$$chronic\ water\ exposure\ (mg/kg/day) = \frac{Negligible\ risk}{Q^*} - [average\ food\ exposure\ (mg/kg/day)]$$

The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kg/ 2L (adult male), 60 kg/ 2L (adult female), 10 kg/ 1L (infants and children).

Given the conservative nature of the water models, if the model estimated concentrations are lower than the DWLOCs, then the Agency can conclude with reasonable certainty that the true levels of the pesticide in the vast majority of surface and ground water that is used as drinking water would be less than the DWLOCs.

Table 9. Drinking Water Levels of Comparison

Population Subgroups	DWLOC, ppb
ACUTE	
Females 13-50 yrs	4300
CHRONIC (non-cancer)	
U.S. Population	150
Non-nursing Infants	40
Children 1-6 yrs	35
Females 13-19 (not preg/not nursing)	130
Females 13-50 yrs	130
Males 13-19 yrs	150
CHRONIC (cancer)	
U.S. Population (non-golfers)	1.0

4.3 Non-Dietary Exposure Assessment

4.3.1 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered **and** (2) there is potential exposure to handlers (i.e., mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is completed.

Short-, intermediate-, and long-term occupational exposures to etridiazole are anticipated, while non-occupational exposures (i.e., golfer exposure) are anticipated to be only short-term after application. These assumptions are based upon the labels,[1] information supplied by the registrant,[2] and usage reviews by the Biological and Economic Assessment Division (BEAD).[3]

4.3.2 Summary of Toxicity Concerns Relating to Occupational and Residential Exposures

The toxicological database on etridiazole is considered incomplete, and endpoints of concern, other than oral, are not route-specific. Although etridiazole has low acute toxicity, it does cause skin and eye irritation. Etridiazole produces tumors in rats and is considered a probable human carcinogen.[4]

a. Acute Toxicity Categories

Etridiazole has low acute oral, dermal, and inhalation toxicity and produces moderate irritation to the eyes (Toxicity Categories III and IV). It is a moderate skin sensitizer.

b. Toxicology Endpoints Used in the Risk Assessment

Short-term Dose and Endpoint For Risk Assessment (Dermal and Inhalation): A developmental NOAEL of 15 mg/kg/day based on reduced fetal body weights, decreased viability and increased skeletal malformations/variations observed at the LOAEL of 45 mg/kg/day.

Intermediate- and Long-term Dose and Endpoint for Risk Assessment(Dermal and Inhalation): A NOAEL of 4.8 mg/kg/day based on increased absolute and relative liver weights, renal tubule cell karyomegaly, hepatocytomegaly and spongiosis hepatis in male rats observed at the LOAEL of 30.43 mg/kg/day.

Except for an acute inhalation toxicity study, no inhalation studies are available. An acceptable dermal absorption study was not available. Since an oral NOAEL was selected, a dermal absorption factor of 100% (default value) and an inhalation absorption factor of 100% (default value) should be used during route to route extrapolation. In addition, the acidic pH of Terrazole technical (3-4 in water) would cause considerable skin irritation and would most likely breach the skin barrier.

The dermal and inhalation equivalent oral doses should be added together and compared to the NOAEL to determine the margin of exposure (MOE).

Carcinogenicity: Etridiazole is classified as a Group B2 carcinogen (Probable Human Carcinogen) based on the occurrence of multiple tumor types in male and female rats. The $Q_1^* = 0.0333\ (mg/kg)^{-1}$. [5]

Margins of Exposure for Occupational/Residential Exposure Risk Assessment

The HIARC determined that the risk assessment for short-, intermediate-, and long-term dermal and inhalation exposures are required. For occupational exposure, a MOE of 100 is adequate for short- and intermediate-term dermal and inhalation risk assessments, and a MOE of 300 is required for long-term dermal and inhalation exposure risk assessments due to the data gap for a chronic toxicity study in dogs. For non-occupational exposure risk assessments, a MOE of 100 is adequate for females 13-50. Because a short-term dermal toxicological endpoint of concern was not identified for the general population, and the FQPA Safety Factor Committee determined that the 3x FQPA safety factor does not apply to the acute dietary risk assessment, it is also not applicable to the short-term dermal risk assessment as both assessments are based on the same toxicity study. Therefore, a post-application re-entry risk assessment was not performed for the general population or for children on treated golf course turf.

4.3.3 Incident Data

The following is a summary of the incident data reviewed by J. Blondell of HED.[6]

A pesticide incident occurred in 1997 (Incident #5351-1), when a woman experienced

dizziness, shortness of breath, and malaise. She was participating in a study involving four workers who hand potted soil for nearly three days at a greenhouse. All applications were made at the appropriate intervals but one post treatment was done at four hours instead of twelve hours required by the label. No further information on the disposition of the case was reported.

Poison Control Center Data - 1993 through 1996

A total of 30 unintentional exposures were reported to the Toxic Exposure Surveillance System from 1993 through 1996. All thirty cases involved adults and older children ages six to nineteen, nine of which had a minor outcome, two with moderate outcome, and none that were considered life-threatening. Eight cases were seen in a health care facility, none were hospitalized, and none were admitted for critical care. There were too few cases with outcome determined to do a meaningful comparison on the number of symptomatic cases. The percent of cases seen in a health care facility was only slightly above the average for all pesticides. These comparisons are shown in the table below.

California Data - 1982 through 1995

Detailed descriptions of 10 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) were reviewed. In one case, etridiazole was judged to be responsible for the health effects. In the one case, a worker handled moist soil that was treated with etridiazole and experienced eye and skin illness for two years. The case did not require hospitalization or was not known to take time off work due to the exposure.

On the list of the top 200 chemicals for which the National Pesticide Telecommunications Network (NPTN) received calls from 1984-1991 inclusively, etridiazole was not reported to be involved in human incidents. Relatively few incidents of illness have been reported due to etridiazole.

Comparison between etridiazole and all pesticides for percent cases with symptomatic outcome (SYM), moderate or more severe outcome (MOD), life-threatening or fatal outcome (LIFE-TH), seen in a health care facility (HCF), hospitalized (HOSP), or seen in an intensive care unit (ICU) for adults and children six years and older reported to Poison Control Centers, 1993-1996.

Pesticide	SYM*	MOD*	LIFE-TH*	HCF*	HOSP*	ICU*
Etridiazole	85%	15%	0%	27%	0%	0%
ALL PESTICIDES	72%	12%	0.37%	21%	7.6%	3.3%

* Symptomatic cases based on those cases with a minor, moderate, major, or fatal medical outcome. Denominator for SYM, MOD, and LIFE-TH is the total cases where medical outcome was determined. Denominator for HCF is all exposures. Denominator for HOSP and ICU is all cases seen in a health care facility.

4.3.4 Summary of Use Patterns and Formulations

a. Occupational Use Products

According to the EPA OPP REFS label tracking system, there are 27 active labels, including 1 technical concentrate, 3 wettable powders (WP), 8 granular, 8 emulsifiable concentrate (EC), 4 flowable concentrates (FC), and 3 dust formulations. Note that products made by Scotts are not restricted-use labeled, yet may contain up to 40% etridiazole. Also note that etridiazole is combined in some active labels with other fungicides and pesticides, some of which are also carcinogens, in the same product. At the present, no policy exists for addressing multiple active ingredients, but the Agency recognizes that additional acute or chronic health risks may be added in these cases. Some of the other active ingredients, e.g. captan, disulfoton, thiophanate-methyl, and aldicarb, are being evaluated by the Agency at this time for handler and post-application health risk.

All of the labels require a minimum of a single layer of protective clothing, either long-sleeved shirt and long pants or coveralls, chemical-resistant gloves, and shoes with socks for handlers. The seed treatment dust label requires a double layer of clothing. All but two of the labels require a minimum of a dust/mist respirator for mixer/loaders or other handlers. The labels for neither the granular product nor the liquid seed treatment require use of a respirator. The Worker Protection Standard designated reentry interval (REI) for post-application workers is currently set at 12 hours after application for all products. Workers entering prior to 12 hours must wear WPS-specified clothing and may only perform limited functions.

Residential Use: There are currently no homeowner uses for etridiazole.

ACTIVE PRODUCT REGISTRATIONS

Registration Number	% Active Ingredient	Formulation	Product Name
000264-00319	2.5	G	TEMIK TSX GRANULAR PESTICIDE
000400-00405	5.8	EC	TERRACLOR SUPER X EMULSIFIABLE
000400-00406	2.5	G	TERRACLOR SUPER X GRANULAR
000400-00408	1.63	G	TERRACLOR SUPER-X SOIL FUNGICIDE W/ DI-SYSTON
000400-00413	98.6	T	TERRAZOLE TECHNICAL
000400-00416	35	WP	TERRAZOLE 35% WETTABLE POWDER
000400-00417	25	EC	TERRAZOLE 25% EMULSIFIABLE
000400-00419	5	G	TERRAZOLE 5% GRANULAR FUNGICIDE
000400-00422	44	EC	TERRAZOLE 4EC
000400-00423	40.7	F	TERRAZOLE 4 FLOWABLE FUNGICIDE
000400-00455	5.8	F	TERRACLOR SUPER X FLOWABLE
000400-00456	3.8	G	TERRACLOR SUPER X 18.8G
000400-00475	4.3	EC	TERRACLOR SUPER X PLUS DI-SYSTON EC
007501-00054	5.0	D	GUSTAFSON TERRACLOR SUPER X 20-5 DUST WITH GRAPHITE
007501-00057	5.8	EC	GUSTAFSON TERRA-COAT L-205N
007501-00111	2.5	D	GUSTAFSON 4-WAY SEED PROTECTANT
007501-00153	2.5	D	4-WAY PEANUT SEED PROTECTANT FUNGICIDE
034704-00679	5.8	EC	PCNB + LIQUID SEED TREATER
058185-00005	30	EC	KOBAN 30
058185-00007	30	WP	TRUBAN FUNGICIDE 30% WETTABLE POWDER
058185-00008	25	EC	TRUBAN FUNGICIDE 25% EMULSIFIABLE CONCENTRATE
058185-00010	15	WP	BANROT BROAD SPECTRUM FUNGICIDE 40% WETTABLE POWDER
058185-00013	5	G	TRUBAN FUNGICIDE
058185-00016	1.3	G	KOBAN 1.3 G
058185-00019	40.7	F	KOBAN FLOWABLE [40%]
058185-00020	40.7	F	TRUBAN FLOWABLE [40%]
058185-00023	3	G	BANROT 8-G FUNGICIDE

b. Type of Pesticide and Targeted Pests

Etridiazole [5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole] is a soil fungicide used to control damping off and root and stem rots caused by species of *Pythium* and *Phytophthora*. The specific mechanism of action is not known, but is believed that the thiazoles, of which etridiazole is a member, break down in the soil to either isothiocyanate or a dithiocarbamate. It is a reddish-brown liquid that is formulated as wettable powders, emulsifiable concentrates, dusts, and granules.

c. Registered Use Sites and Use Patterns

As etridiazole is used only as a soil-incorporated fungicide and seed treatment, there are a limited number of use patterns. It is used for at-planting in-furrow crop soil treatments (only cotton at this time); as a soil treatment, either by drenching or addition to potting soil, for ornamentals and interiorscapes; on ornamental turf and golf course fairways, greens, and tees, either by spray or broadcast application; and as a seed treatment, applied in either large commercial facilities, or at the farm. Total annual use of etridiazole is estimated by BEAD at approximately 75,000 lb ai (these estimates are approximate and therefore totals by crop may not exactly concur with overall total cited). An estimated 42,500 lbs ai of etridiazole is applied to cotton at planting, with a typical application rate of about 0.17 lbs ai/acre. About 28,000 lbs ai of etridiazole are believed to be applied by nurseries; mainly to control for root diseases (USDA, NAPIAP Report, 1-CA-96). About 5,000 lbs ai of etridiazole are also applied annually to golf courses. All of the dusts are formulated by one company, Gustafson, for seed treatment. Only a limited amount of seed treatment (less than 1% of the market per BEAD) is done in this country using this active ingredient, but all active labels are evaluated for handler and post-application health risks. Etridiazole is registered for use as a seed treatment on barley, beans/peas, peanuts, corn, safflower, sorghum, soybeans and wheat; of these crops, peanuts have received a modest amount of treatments with etridiazole.

At this time, products containing etridiazole are intended for occupational uses only. No homeowner uses are referenced on any etridiazole labels reviewed. The Scotts labels for turf application do not proscribe use by private individuals, but the company representative stated these products were sold to PCOs only, and sales materials are targeted at landscape and turf professionals. The 10 percent (%) granular golfcourse turf product should contain the statement "for professional use only." (memo from J.Evans to

J. Mitchell, 11/16/94 re: Graybeard Waivers, wherein EPA granted waiver for golf course use only, on condition of *specific* labeling prohibiting application to home lawns, sod farms, or municipal parks).[7] A non-occupational risk assessment is required for the exposure of the public to treated turf. Exposure of the public to etridiazole residues on golf course turf is anticipated to occur infrequently.

d. Application Rates

Application rates are based on the registered label, but also take into account the physical nature of the use site, the physical nature of the formulation (e.g., form and packaging), the equipment required to deliver the chemical to the use site, the application rate required to achieve an efficacious dose, along with seasonal limit to applications.

In-furrow crop treatment rates (soil-incorporated) for etridiazole range from 0.13 to 0.38 lbs. ai per acre. Soil is also treated for ornamental plants for nurseries and greenhouses. The typical rate for soil drench treatment is 6 ozs. ai/1000 sq. ft. (0.375 lb/1000 sq. ft. or 16.3 lb/acre), with a range of 1.5 oz. ai/1000 sq. ft. (0.093 lb) to 17.5 oz ai/1000 sq. ft. (1.09 lb ai/1000 sq. ft. or 47.6 lb ai/acre). Etridiazole can also be added dry to potting soil, typically at 1.1 oz ai/cubic yard. Application to turf on golf courses is in the range of 0.7 to 2.8 oz ai/1000 sq. ft. (1.9 lb ai/acre to 7.6 lb ai/acre). Seed treatment rates range from 0.0078 lb ai/100 lbs seed to 0.0625 lb ai/100 lb seed.

4.4 Occupational Exposure and Risk Assessment

4.4.1 Methods and Types of Equipment for Mixing, Loading, and Application

Wettable powder, flowable concentrates, and emulsifiable concentrates of etridiazole require mixing with water to the label-specified dilution. This is usually performed by scooping or pouring the formulation into a mixing tank, often of 100 gallons or more in capacity, with mechanical agitation to keep the resulting emulsion homogenized and prevent variations in application strength. Smaller amounts may be handled when applying these formulations either in a low-pressure hand wand, or via a tiller-planter (or seed drill)-mounted system, where smaller total quantities are applied. Large commercial operations, such as seed treatment, may have mechanical, automated, metered pumps that require only connecting the formulation to the pump. Small seed treatment operations, such as seed box (or "hopper box") mixing, and soil mixing may be done by measuring small amounts by hand (wearing label-required gloves) into the mixing device. Granular and dust formulations are scooped or poured (without mixing) directly into the application device.

Etridiazole emulsions and granules may be applied to cotton in-furrow using planters with spray attachments. As noted above, seed may also be treated in the planter box before planting. Emulsions may be applied to soil or turf using boom sprayers or smaller sprayers attached to tractors, all-terrain vehicles (ATVs), or mowers. Granular formulations may be applied to soil or turf using broadcast or cyclone spreaders trailered behind one of these vehicles. Portable, strap-on spreaders ("belly grinders") and push-type (cyclone) spreaders may also be used in turf maintenance, particularly for spot treatments. Hand dispersal or power dust blowers are occasionally used for application to trenches or small areas. Soil drenching may be done by automated irrigation systems (chemigation), and/or by low- or high-pressure hand-held spray wand. The label does not list hand sprinkling (i.e., watering can) and this use in commercial application is considered unlikely.

4.4.2 Handler Exposure Scenarios

HED has determined that short- (up to seven days) and intermediate-term (up to 180 days) exposure to pesticide handlers is likely during the occupational use of etridiazole in agricultural, greenhouse, nursery, and golf course environments. The anticipated use patterns and current labeling indicate 25 major occupational exposure scenarios based on the types of equipment and techniques that can potentially by use to make etridiazole applications. These 25 different scenarios, which are presented as a total of 56 methods to account for variable application rates, serve as the basis for the quantitative exposure risk assessment developed for occupational handlers. These scenarios include:

(1a) mixing and loading of wettable powder formulation for golf course ground boom application;
(1b) mixing and loading of wettable powder formulation for chemigation application;
(2) loading granular formulation for in-furrow soil application;
(3a) mixing and loading liquid (EC/FC) formulation for in-furrow soil application;
(3b) on-farm seed treatment using liquid formulation;
(3c) loading/application of liquid (EC/FC) formulation for seed treatment (commercial, Uniroyal Vitavax study data);
(4d) seed handling during liquid seed treatment (commercial, Uniroyal Vitavax study data);
(5) loading dust [using wettable powder as surrogate] formulation for seed treatment (commercial);
(6a) spraying golf course turf with groundboom equipment;
(6b) applying liquid in-furrow [groundboom surrogate];
(7) loading and applying granular formulation in-furrow (broadcast surrogate);

(8) mixing, loading, and applying liquid (EC/FC) in-furrow [groundboom surrogate];
(9a) treating seed manually using dust formulation on farm (study data);
(9b) treating seed manually using liquid (EC) formulation on farm;
(10) mixing, loading, and applying liquid (EC/FC) formulation as drench using low-pressure hand wand;
(11) mixing and applying wettable powder formulation as soil drench using high pressure hand wand;
(12) loading and applying granular formulation to golf course turf with "belly grinder";
(13) loading and applying granular formulation to golf course turf with push-type cyclone spreader;
(14) loading and applying granular formulation to turf using tractor-drawn broadcast spreader;
(15) mixing, loading, and applying wettable powder formulation to golf course turf with ground boom;
(16) loading and mixing granular formulation with soil;
(17) mixing and applying wettable powder formulation to potting soil;
(18, 19) loading and applying granular formulation to soil using a belly grinder;
(20, 21) loading and applying granular formulations to soil using push-type cyclone spreader;
(22, 23) loading and applying granular formulation to soil by a spreader drawn by a tractor;
(24) loading and applying granules with a power duster (no data); and
(25) applying granules by hand to soil trench or turf.

All scenarios use PHED surrogate exposure data unless otherwise noted.

4.4.3 Handler Exposure Scenarios -Assumptions

Handler exposure assessments are completed by HED using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure. Daily dermal and inhalation exposures, dose

levels, and risks to handlers were calculated as described below. The first step is to calculate daily dermal and inhalation exposure using the following:

$$\text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) = \text{Unit Exposure}\left(\frac{\text{mg ai}}{\text{lb ai}}\right)*\text{Rate}\left(\frac{\text{lb ai}}{\text{Acre}}\right)*\text{ Daily Treated}\left(\frac{\text{Acres}}{\text{day}}\right)$$

Where:

Daily Dermal Exposure = Amount deposited on the surface of the skin that is available for dermal absorption, also referred to as potential dose (mg ai/day);
Unit Exposure = Normalized exposure value derived from February, 1998 PHED Surrogate Exposure Table, no chemical-specific handler data were available for this assessment (mg ai/pound ai applied);
Use Rate = Normalized application rate based on a logical unit treatment such as acres, a practical maximum value is generally used (lb ai/A) for each scenario; and
Daily Acres Treated = Normalized application area based on a logical unit treatment such as acres (A/day).

Daily inhalation exposures were calculated using the following:

$$\text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right)= \text{Unit Exposure}\left(\frac{\text{ug ai}}{\text{lb ai}}\right)*\frac{1\text{ mg}}{1000\text{ ug}}*\text{Rate}\left(\frac{\text{lb ai}}{\text{acre}}\right)*\text{Daily Treated}\left(\frac{\text{Acres}}{\text{day}}\right)$$

Where:

Daily Inhalation Exposure = amount that is available for absorption, also referred to as potential dose (mg ai/day);
Unit Exposure = Normalized exposure value derived from February, 1998 PHED Surrogate Exposure Table, no chemical-specific handler data were available for this assessment (mg ai/pound ai applied);
Use Rate = Normalized application rate based on a logical unit treatment such as acres, a maximum value is generally used (lb ai/A); and
Daily Acres Treated = Normalized application area based on a logical unit treatment such as acres(A/day).

Daily dermal and inhalation doses were then calculated by normalizing the daily dermal and inhalation exposure values by body weight. For occupational handlers using etridiazole, a body weight of 60 kg was used for determining short-term MOEs because the short-term dermal and inhalation endpoints were based on a developmental study; 70 kg (average adult body weight) was used for intermediate and long-term exposure scenarios because the toxic endpoint was not sex-specific.

Since the toxicity endpoints are based on oral studies, [and etridiazole is caustic when applied to skin], a dermal absorption factor of 100% is assumed. Absorbed dermal and inhalation doses for all durations were calculated using the following formula:

$$\text{Potential Daily Dose}\left(\frac{\text{mg ai}}{\text{kg/day}}\right) = \text{Daily Exposure}\left(\text{mg ai /day}\right) * \left(\frac{1}{\text{body weight (kg)}}\right)$$

Once the route specific daily doses are calculated, the Margin of Exposures (MOEs) are calculated as follows:

$$\text{MOE (unitless)} = \frac{\text{NOAEL (mg / kg / day)}}{\text{Daily Dose (mg / kg / day)}} * \text{Absorption Factor (100\%)}$$

* NOAEL and the Daily Dose are for the same route of exposure (i.e. both inhalation or dermal).

Since the dermal and inhalation toxicity endpoints are the same for the same exposure durations the route-specific MOEs can be combined to express a total MOE for the occupational scenario:

$$\text{MOE}_{\textit{(short and intermediate term, dermal and inhalation)}} = \frac{1}{\frac{1}{\text{MOE}_{dermal}} + \frac{1}{\text{MOE}_{inhalation}}}$$

The following assumptions and factors were used in order to complete this exposure assessment:

Average work day interval represents an 8 hour workday (e.g., the acres treated or volume of spray solution prepared in a typical day). For example, groundboom applications in an agricultural setting are based upon an 80 acre day because HED believes it normally takes 8 hours to complete that type of application with common equipment. On the other hand, groundboom applications on golfcourse turf are based upon treating 40 acres, because 40 acres represent a 36 hole golfcourse (accounts for approximately 10 percent of all golfcourses in the United States). The 40 acres assumption is not likely the maximum which can be treated on a single day; however, the 40 acres assumption is based upon the fact that an applicator would only treat any given golfcourse one single time on any given day. Other exceptions:

potting activities are assumed to be equal to potting soil for 4 hours as in the

registrant-submitted study;
the amount of soil-drench applied per day by chemigation or high-pressure hand wand is based on mixing and applying 1000 gallons(rationale:this is an HED default value and label instructions state 200 ft^2 may be covered for each 100 gallons mixed, and 2000 ft^2 is a reasonable area to cover in one day).
the default daily application rate for mixing, loading, and applying soil drench by low-pressure hand wand is 40-50 gallons/day.

- Daily acres and volumes (as appropriate) to be treated in each scenario are shown in appended Table B1 (Appendix B).[8]
- Calculations generally reflect a range of application rates for specific crops recommended by the available etridiazole labels to assess risk levels associated with the various use patterns. The use data provided by the registrant concerning the "typical" application rates that are commonly used for etridiazole were also considered and used where appropriate.
- Due to a lack of scenario-specific data HED often calculates unit exposure values using generic protection factors (PF) that are applied to represent various risk mitigation options (i.e., the use of Personal Protection Equipment (PPE) and engineering controls). PPE protection factors include those representing a double layer of clothing (50 percent PF), chemical resistant gloves (90 percent PF) and respiratory protection (98 percent PF) for use of an organic vapor respirator. Engineering controls are generally assigned a PF of 98 percent.
- For short- and intermediate-term occupational exposure scenarios, an MOE of 100 (10x for intra-species and 10x for interspecies variability) is adequate. There are no anticipated long-term exposures for handlers.
- For the cancer assessment, the scenarios represent: 1) typical exposures (eg., typical application rates) experienced by growers who apply etridiazole to their own fields, greenhouse, golf course, etc., and 2) a multiplier of up to ten times the number of applications per season which represents typical exposures experienced by commercial handlers. Because greenhouses, nurseries, and golf courses usually have their own certified pesticide applicators, a lower multiplier such as 3x was used to represent the range from small to large operations.
  For the cancer assessment, it was also assumed that workers are exposed for 35 years over a 70 year lifetime (non-occupational golfer exposure length is 50 years).

4.4.4 Handler Exposure Data Sources

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of etridiazole. It is the

policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[9] However, some use scenarios exist for etridiazole which are not well represented by the PHED surrogate chemical database.

One of the use scenarios for which there is no chemical-specific handler data is the preparation of treated soil by the addition of wettable powder or granular etridiazole. A Uniroyal-sponsored study of greenhouse worker exposure to potting soil treated with Terrazole was submitted, but the handler exposure was not measured. Therefore, the Agency's best estimate of exposure is to use the PHED surrogate data for mixer/loader of wettable powder or granular formulation, as shown in Table B1 and Tables B4-B6 (Appendix B).

The greenhouse worker study findings indicated two-thirds of the soil handlers' exposure was from inhalation.[10] The vapor pressure of Terrazole technical grade is 0.0107 mm Hg (MRID 429122-08), which is relatively high and may cause default inhalation values to underestimate exposure. Therefore, mixer/loaders of all etridiazole formulations should continue to use dust/mist respirators when loading outdoors, and use organic vapor filter cartridge respirators when in enclosed areas. An engineered local exhaust system should be installed wherever frequent indoor exposures are anticipated.

The Agency has no surrogate exposure data, and hence no defaults, for seed treatment. Therefore the Agency requested permission from Uniroyal to use a seed treatment worker exposure study (MRID 447315-01)[11] which was submitted for the reregistration of another Uniroyal product (Vitavax®). The exposure data from this study, which are reviewed under a separate document,[12] were adjusted for liquid formulation etridiazole application rates and used to predict worker exposures and risks in a commercial seed treatment setting (Table B2, Appendix B). Peanuts were used for the risk assessment as BEAD has noted this is a current use crop. Note that while the Vitavax study showed less than 1% of dose attributable to inhalation, the etridiazole-specific soil handling study showed that 70% of the total dose was due to inhalation. Therefore, the inhalation component of this scenario may be significantly underestimated. There were no data for application of a dust in a commercial seed treatment setting, so the PHED values for mixing and loading wettable powders were used as a surrogate and results are included in the short- and intermediate-term handler exposure tables (Tables B4 and B5). "Typical" volumes of seed treated per day were estimated based on the *average* amount handled by current equipment, using current label rates, study data, Registrant information, and the median of 6 hours per day performing commercial seed treatment. "High" volume estimates used the same data but manufacturer's high range of equipment capacity.

On-farm seed treatment is considered by most sources to represent a relatively small

proportion of the total use of treated seed in the U.S., owing to the greater time, labor, and equipment commitment required compared to use of commercially treated seed. However, an Agency estimate of the on-farm percent of treatment is approximately 20% of the total market, so an exposure assessment is indicated. The only applicable study available to HED was conducted by Fenske, et al., and published in 1990.[13] Fenske, et al., monitored 12 workers (in a total of 60 exposure periods) treating seed by hand using a dust formulation of Lindane insecticide. There are currently available enclosed systems for treating seed on farm, so a range of exposure will be presented based on mixing/loading using PHED values for wettable powder and treating seed with dust by hand using the Fenske, et al., study values (see Table B3, Appendix B). The combined dermal and inhalation exposure estimated by Fenske, adjusted to lb ai handled, was 10.4 mg/lb ai. Weights and measures for cotton seed and seed treatment (TerraClor Super X 20-5) rates from the September 28, 1998 SMART meeting have been used to represent a typical use scenario. The Fenske, et al., study indicated that each worker could load seed into a 12 bushel grain drill (planting machinery) and mix in a dust seed treatment, each treatment requiring about 5 minutes. The Uniroyal document states that cotton may be planted at 18 lb seed/acre, and HED estimates as much as 80 acres may be planted in a day, or 1440 lbs of seed treated per day. Therefore the worker would handle 0.72 lb ai per day, for an exposure of:
0.72 lb ai/day x 10.4 mg/lb ai = 7.5 mg/day. This value is closely correlated with the hourly rate of exposure estimated by Fenske et al.

Other handler exposure estimates were made using the PHED. The PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts: a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table B1. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of

standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.[3]

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include administrative controls (such as decreasing the application rate), the use of personal protective equipment or PPE and the use of engineering controls. Occupational handler exposure assessments are completed by HED using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure or cancer risk. [Note: administrative controls available generally involve altering application rates for handler exposure scenarios. these are typically not utilized for completing handler exposure assessments because of the negotiation requirements with registrants.] The baseline clothing/PPE ensemble for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no gloves and no respirator. The first level of mitigation generally applied is PPE. As reflected in the calculations included herein, PPE involves the use of an additional layer of clothing, chemical-resistant gloves and a respirator (or the least additional PPE, such as a pair of gloves, which provides an adequate MOE). The next level of mitigation considered in the risk assessment process is the use of appropriate engineering controls which, by design, attempt to eliminate the possibility of human exposure. Examples of commonly used engineering controls include closed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets.

4.4.5 Handler Exposure and Non-Cancer Risk Estimates

The risk assessment that has been completed for the occupational handler scenarios is presented in Tables B4 through B8 (Appendix B). HED anticipates that etridiazole occupational exposures will only occur in a short-term or intermediate-term pattern. HED defines chronic exposures as use of the chemical for greater than 180 days per year and it is anticipated that etridiazole will not be used in this manner. [Note: Readers are cautioned to consider the merits of each exposure scenario when reviewing these tables as risk mitigation options are not universally applicable in all settings (e.g., there are no feasible engineering controls for exposure during hand wand application)].

4.4.6 Short-term and Intermediate-term Dermal and Inhalation Handler Exposure Assessment

Tables B1 and B4-B8 (Appendix B) include all of the information required to calculate MOEs such as the acres treated per day (A/day), application rate (lb ai/A) and the dermal

and inhalation unit exposures for each occupational handler exposure scenario at each level of mitigation (i.e., a single layer of clothing -- long-pants and long-sleeved shirts; no chemical resistant gloves and no respiratory protection, PPE use, and engineering controls). Separate MOEs were calculated for dermal and inhalation by comparing the NOAEL to the relevant daily dose level. Since both dermal and inhalation risk assessments use the same dose/endpoint for short-term and intermediate-term exposure scenarios, the MOEs are based on the sum of the dermal and inhalation doses for each period. As a result, only a single MOE value is presented for both the dermal and inhalation exposure scenarios for each period. A MOE of 100 or greater is adequate for short- or intermediate-term exposures. A MOE of 100 or greater does not exceed HED's level of concern and further mitigation is not required (i.e., the risk mitigation is not increased).

In cases where the risk assessment indicated an unacceptable level of risk at the baseline clothing scenario (i.e., MOE <100), HED applied varying levels of mitigation to each scenario until either an acceptable level of risk was attained or an exhaustive level of risk mitigation was applied and an acceptable level of risk could not be attained. Tables B4 and B5 contain the baseline clothing risk assessment (MOEs) for the short- and intermediate-term exposure scenario calculations, respectively. Tables B4 and B5 include the risk assessments that were completed for etridiazole at increasing levels of risk mitigation. Table B6 estimates the cancer risk for all levels of handler protection or engineering control, where available. As indicated above, risk mitigation options used by HED for occupational pesticide handlers include (1) the use of PPE (Personal Protective Equipment) that includes an additional layer of clothing, chemical resistant gloves, and respiratory protection (or the least additional PPE to afford the required protective MOE); and (2) the use of appropriate engineering controls. The risk assessments were completed for handlers using no gloves, then wearing single-layer PPE and chemical-resistant gloves (typical label PPE), using a second layer (i.e., coveralls over work clothes) of PPE and an organic-vapor respirator, and finally, using engineering controls.

Table B1 (Appendix B) summarizes the caveats and parameters specific to the data used for each exposure scenario. These caveats include descriptions of the source of the data and an assessment of the overall quality of the data. Generally, the assessment of data quality is based on the number of observations and the available quality control data. Quality control data are assessed based on grading criteria established by the PHED Task Force. Additionally, it should be noted that all calculations were completed based on current HED policies pertaining to the completion of occupational and residential exposure/risk assessments (e.g., rounding, exposure factors, and acceptable data sources).

Margins of Exposure (MOEs) are used to determine if the use of a chemical is of concern. MOEs are also used to evaluate a chemical via various application methods, application

rates, daily treatment of acreage and use of mitigation measures (when feasible). The only long-term occupational exposures are expected to be for post-application exposure to treated soil, as in a greenhouse or nursery. Therefore, for etridiazole handlers (loaders and applicators), an MOE greater than or equal to 100 does not exceed HED's level of concern. Short-term and intermediate-term dermal and inhalation MOEs were calculated for each scenario before combined ST and IT MOEs were determined (Tables B4-B7, Appendix B).

Risks for handlers were assessed using the short-term and intermediate-term toxicological endpoints. Results from each assessment are presented below.

4.4.7 Occupational Handler Exposure Risks

a. Combined Dermal and Inhalation Risks

The combined baseline (single layer of clothing) dermal and inhalation MOEs ranged from 0.79 to 290,000 for short-term, and from 0.29 to 11,000 for intermediate-term exposure. Twenty-two of 56 short-term exposure scenarios at baseline had combined-route MOEs less than 100, while 29 intermediate-term scenarios had MOEs below 100. With the addition of gloves, MOEs ranged from 5.5 to 3.3×10^5 for short-term, and from 2.1 to 1.3×10^5 for intermediate-term exposure. With gloves, 14 of 56 short-term exposure scenarios had MOEs below 100, and 20 of 56 intermediate-term scenarios MOEs were below 100. Of the scenarios which did not exceed an MOE of 100 with gloves, additional coveralls and organic-vapor respirator use increased the MOE to greater than 100 for none of the short-term (range 8.9-6300) and two intermediate-term (range 3.3 to 120) scenarios. Engineering controls were applied to the remaining 18 scenarios where feasible, but 11 were not feasible. Ten short-term and 8 intermediate-term scenarios had MOEs greater than 100 with engineering controls, with a range of 190-4300 for short-term and 71-1600 for intermediate-term scenarios.

b. Short-term Dermal and Inhalation Risk Estimates

The MOE uncertainty factor = 100; the following scenarios are presented which have combined short-term dermal and inhalation MOEs greater than or equal to 100. Scenarios that are not listed did not have feasible control methods to adequately reduce risk and are discussed following this section.

Baseline

(1b) Mixing and loading wettable powder for chemigation application (all rates).
(2) Loading granular formulation for in-furrow soil application (all rates).
(3b) Mixing and loading liquid formulation for on-farm seed treatment (all rates).
(3d) Commercial seed treatment using liquid: seed bag handler (typical, high rates).
(5a) Applying to turf/golf course with groundboom sprayer (all rates).
(5b) Applying liquid to soil in-furrow (all rates).
(6) Loading and applying granules to soil in-furrow (all rates).
(7) Mixing, loading and applying EC/FC (liquid) formulation to soil in-furrow (low/typical rates).
(9) Mixing, loading, and applying EC (liquid) as a drench using low pressure hand wand (typical rate).
(10) Mixing, loading, and applying EC (liquid) using high-pressure hand wand for drench (typical rate).
(13) Loading and applying granules (1.3%) to golf course turf using tractor-pulled spreader (typical rate).
(15) Loading and applying granules to potting soil (high rate).
(16) Loading and applying wettable powder to potting soil (high rate).
(21) Loading and applying granules (8%) to soil using tractor-pulled spreader (typical rate).
(22) Loading and applying granules (5%) to soil using tractor-pulled spreader (typical rate).

Single-layer PPE with Gloves

(3a) Mixing and loading liquid formulation for application to soil in-furrow (all rates).
(3c) Commercial seed treatment using liquid formulation: loader/applicator (typical rate).
(4) Loading dust for commercial seed treatment (low/typical rate).
(7) Mixing, loading and applying EC (liquid) formulation to soil in-furrow (all rates).
(8) Mixing, loading and applying dust as a seed treatment in hopper box (study data).

Double Layer of Clothing and Organic Vapor Respirator

No additional scenarios had MOEs greater than 100.

Engineering Controls

(1a) Mixing and loading wettable powder for turf/golf course groundboom application (all rates).
(4) Loading dust (surrogate WP data) for commercial seed treatment (all rates)
(14) Mixing, loading, and applying WP in water-soluble bag to golf course turf using groundboom (all rates).

Scenarios for Which MOEs Do Not Exceed 100 with Maximum Controls

(11) Loading and applying granules (1.3G) to golf course turf using belly grinder (typical rate).
(12) Loading and applying granules (1.3G) to golf course turf using push-type spreader (typical rate).
(15) Loading and applying granules to potting soil (high rate).
(17) Loading and applying granules (8G) to soil using belly grinder (typical rate).
(18) Loading and applying granules (5G) to soil using belly grinder (typical rate).
(19) Loading and applying granules (5G) to soil using push-type spreader (typical rate).
(20) Loading and applying granules (8G) to soil using push-type spreader (typical rate).
(24) Dispersing granules by hand.

There are **no data** for one scenario at any level of exposure:
(23) Loading and applying granules using a power dust blower.

d. Combined Intermediate-term Risk Estimates

The MOE uncertainty factor =100 for intermediate-term exposures; all of the same (above) scenarios had MOEs greater than or equal to 100 for intermediate-term, except for the following changes:

Baseline:
Scenarios with MOEs *less* than 100:
(3d) Commercial seed treatment using liquid (seed bag handler).
(5a) Applying to turf/golf course with groundboom sprayer (high rate).
(9) Mixing, loading, and applying EC/FC (liquid) as a drench using low pressure hand wand (typical rate).

Single-layer PPE with Gloves

Additional Scenarios with MOEs equal to or greater than 100. including those listed for short-term exposure risk estimates:

(1b) Mixing and loading wettable powder for chemigation application. (typical/high rates).

(9) Mixing, loading, and applying EC/FC (liquid) as a drench using low pressure hand wand (typical rate).

Double Layer of Clothing and Organic Vapor Respirator

Additional scenarios with MOEs equal to or greater than 100, including those listed for short-term exposure risk estimates:

(4) Loading dust (wettable powder surrogate) for commercial seed treatment (low rate).

(5a) Applying to turf/golf course with groundboom sprayer (high rate).

Engineering Controls (Closed Mixing/loading, Wettable Powder in Water-Soluble Bag)

No other scenarios had MOEs greater than 100 than those listed for short-term exposure risk estimates.

Scenarios For Which No Feasible Controls Currently Exist:

Low-pressure handwand sprayer
High-pressure handwand sprayer
Loading and/or applying granular formulation (not available at this time)
Loading and/or applying dust formulation (not available at this time)

There are currently no feasible engineering controls for the above-listed situations, which include the scenarios which did not have MOEs greater than 100 with maximum protection or controls. Therefore the only ways to reduce worker exposure are to use a different method, such as chemigation instead of hand drenching, or to reduce the amount of active ingredient applied. Closed loading systems are a solution in some cases, providing approximately 98% reduction in exposure for the loader, but are not currently available for etridiazole granules or dusts, and are not generally available for the small-scale granular or dust application methods. Note also that there are no known enclosed-cab type of golf course turf application equipment.

4.4.8 Handler Dermal and Inhalation Cancer Risk Assessment

On August 29, 1990, the Carcinogenicity Peer Review Committee classified Terrazole as

a Group B_2 - probable human carcinogen (based on liver tumors in male rats) and determined that the most potent unit risk or Q_1^* is 3.33×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents. A 100 percent absorption factor is assumed for both the dermal and inhalation exposure routes in this risk assessment. If a cancer risk estimate which incorporates both dermal and inhalation exposures is 10^{-4} or lower for occupationally-exposed populations, the current Agency policy states that "OPP will continue to carefully evaluate pesticides with risks in this range [10^{-6} to 10^{-4}] and will seek ways to reduce individual cancer risks to the greatest extent feasible, preferably to 10^{-6} or less" (D. Barolo memo 8/14/96). Therefore, a cancer risk assessment was done accounting for handler exposures via dermal and inhalation routes and inclusive of all known methods of exposure reduction.

When cancer risk estimate is quantified using a Q_1^*, risk is expressed as a probability. For example, the probability frequently considered to represent an acceptable risk level for the general population is 1×10^{-6} (one in a million). When this approach is used, the implicit assumptions are that any exposure will lead to some level of risk and that risk is directly and linearly proportional to exposure, regardless of the dosing schedule.

Average Daily Doses (ADDs) were calculated for baseline, PPE, and engineering controls for each exposure scenario when data were available from chemical-specific studies or PHED. The daily dermal and inhalation doses found in Tables B4-B7 were used to calculate ADDs. When ADDs are calculated, the doses for each exposure route are summed. Once the Average Daily Dose is calculated, a Lifetime Average Daily Dose (LADD) can be calculated. To obtain the cancer risk estimate associated with a specific exposure scenario, the LADD is multiplied by Q_1^*.

Average Daily Dose is calculated:

Average Daily Dose (mg/kg/day) =

Potential daily $dose_{Dermal}$ (mg/kg/day) + Potential daily $dose_{Inhalation}$ (mg/kg/day)

Lifetime Average Daily Dose is calculated:

Lifetime Average Daily Dose (mg/kg/day) =

Average Daily Dose (mg/kg/day) x (days worked/365 days per year) x (35 years worked/70 year lifetime)

Cancer Risk is calculated:

$$\text{Cancer Risk} = \text{LADD (mg/kg/day)} \times Q_1^* \text{ (mg/kg/day)}^{-1}$$

4.4.9 Handler Dermal and Inhalation Cancer Risk

a. Summary

The Average Daily Doses (ADD) of baseline, PPE and engineering controls are presented for each exposure scenario in the appended Tables B4-B7. The lifetime average daily dose and cancer risk estimate values are also calculated for each exposure scenario. The number of treatments per crop per season were used to determine application frequency for private handlers and commercial handlers.

b. Combined Dermal and Inhalation Cancer Risks

The following two tables and descriptions summarize regular handler and commercial handler cancer risk estimates for all etridiazole exposure scenarios in this risk assessment. Exposure scenarios for which combined dermal and inhalation cancer risk estimates exceed 1×10^{-4} are presented.

Using double-layer protective clothing and an organic vapor cartridge respirator, for typical application rates, four scenarios for applying granules to soil using different equipment had cancer risk estimates greater than 1×10^{-4} for single site operations. With the same PPE, eight different types of commercial handler scenarios had cancer risk estimates greater than 1×10^{-4}. At the highest level of mitigation available, using water-soluble packaging for wettable powders where applicable, none of the private or commercial handler exposure scenarios for which controls were possible yielded cancer risk estimates greater than 1×10^{-4}. However, there were six scenarios that lacked such a control method and had risk estimates greater than 1×10^{-4}. There were no data for the granule blower scenario.

Private (Non Commercial Applicator) Handlers Table

Private (Single-Site) Handler Scenario	Lowest Cancer Risk Estimate	Highest Cancer Risk Estimate
Baseline	$6.2\ 10^{-9}$	$2.0\ 10^{-3}$
Single-layer PPE + Gloves	$5.3\ 10^{-9}$	$3.2\ 10^{-4}$

Double-layer PPE + Respirator	$2.9\ 10^{-8}$	$2.0\ 10^{-4}$
Engineering Controls	$2.9\ 10^{-8}$	$7.8\ 10^{-6}$

Assuming typical application rates. Reference Attachment Table B6.

Commercial Handlers Table

Commercial Handler Scenario	Lowest Cancer Risk Estimate	Highest Cancer Risk Estimate
Baseline	$1.9\ 10^{-8}$	$6.0\ 10^{-3}$
Single-layer PPE + Gloves	$1.6\ 10^{-8}$	$9.6\ 10^{-4}$
Double-layer PPE + Respirator	$8.6\ 10^{-8}$	$5.9\ 10^{-4}$
Engineering Controls	$2.9\ 10^{-7}$	$3.9\ 10^{-5}$

Assuming typical application rates; frequency increased to represent commercial application. Reference Attachment Table B6.

4.4.10 Summary of Risk Concerns for Handlers, Data Gaps, and Confidence in Exposure and Risk Estimates

A margin of exposure (MOE) of 100 or greater for short- and intermediate-term occupational exposure does not exceed HED's level of concern. About 40% (22 of 53) of the short-term and half (29 of 53) of the intermediate-term exposure risk assessments for etridiazole handler scenarios exceeded the level of concern with only a single layer of clothing. Only by use of additional personal protective equipment (PPE) or engineering controls were most MOEs elevated to at least 100. Typical worker clothing is represented by the scenarios with a single layer of work clothes and chemical-resistant gloves. Of the short-term scenarios using single layer clothing with gloves, 14 of 53 had an MOE which still exceeded the level of concern of 100. Of 53 intermediate-term exposure scenarios with single layer PPE and gloves, 20 had MOEs below 100, which exceeds the level of concern. An additional layer of clothing and respiratory protection had very little effect on short-term MOEs, and effectively raised only one short-term and two intermediate-term scenarios above the minimum MOE of 100. As these values are based on chemical

surrogate data with lower vapor pressures, the effect of adding respiratory protection would probably be greater than indicated, but the baseline inhalation exposure would also be greater. Double-layer clothing, or coveralls over work clothes, and respirators also add the risk of heat stress and decrease range of motion, visibility, and communication. Therefore engineering controls are preferred to additional PPE. The engineering control which was applicable to most scenarios was a water soluble bag for the wettable powder. Currently, the WSB is not available for etridiazole. Also, for several scenarios which are common in nursery and turf work, there were no feasible engineering controls. All of these involved application of granular formulation by various means. An enclosed system for handling and loading granular products would be desirable to reduce handler exposure, but is also not available at this time. The hand-held application methods have no known engineering controls, but some may be replaced by use of chemigation. There is a lack of data for dust exposures.

Worker cancer risks were estimated for private and commercial handlers using *typical* application rates. Baseline (no glove, single layer of clothing) cancer risks exceeded 10^{-4} in one-third (10 of 34) of private and one-half of commercial (15 of 34) applicator scenarios. Cancer risks exceeded 1.0×10^{-4} for one-quarter (9 of 34) of "private" or non-commercial applicator exposure scenarios, where workers wore a single layer of clothing and chemical-resistant gloves. For commercial applicators wearing the same protective equipment, one third (12 of 34) had cancer risk estimates greater than 1.0×10^{-4}. By using additional PPE and/or engineering controls, all handler scenarios cancer risks were reduced below 1.0×10^{-4}, except for those application methods (six scenarios) which had no known method of engineering control or no data (2 scenarios). Again, most of these were the scenarios involving application of granular products to turf and soil, discussed above.

In general, there is very little data available on any hand applications of pesticide in dust formulations. Specifically, a data gap exists for on-farm handling of dust for seed treatment without gloves (the amount on the outside of the gloves could be a surrogate, but that information was not available from the study used). Other 'dust' scenarios used data from studies of wettable powders as a surrogate. Also, there is no non-proprietary information available for closed mixing/loading systems for granular products. This information would be useful in mitigating those risks by engineering controls.
There is also no specific data on soil incorporated liquids and granules, probably owing to the general presumption that these scenarios result in minimal exposures. The surrogate PHED scenarios used for soil-incorporated applications are therefore considered to be an over-estimate of anticipated exposures.

Due to the relatively high vapor pressure of etridiazole, and the data from the submitted

soil handling study that indicate the majority of soil handler exposure was by the inhalation route, the HED is concerned about handler exposure to etridiazole, particularly in enclosed areas, such as greenhouses. The following data is required:

- Product chemistry data to determine the vapor pressure of the dry formulations, in order to determine if handling dry formulations also present a significant respiratory hazard.
- 875.1200 Guideline applicator study data for dermal exposure: indoors
- 875.1400 Guideline applicator study data for inhalation exposure: indoors

Further information about toxicity by inhalation would also help in conducting the worker risk assessment.

4.5 Occupational Post-Application Exposure and Risk Assessment

HED is concerned about potential occupational post-application exposure to etridiazole from handling or other contact with treated soil or seeds. Treated seeds may be handled during the planting process, although labeling generally calls for use of gloves when handling these seeds. Contact with soil after in-furrow application is considered unlikely or minimal. Based on typical activities in greenhouses and nurseries, contact with treated soil is likely. Uniroyal submitted 3 residue studies (including a combined greenhouse worker/soil dissipation exposure study) that address the dissipation of etridiazole on turf and soil. The studies are reviewed in detail in Section 4.5.2 Post Application Exposure Data Sources.

4.5.1 Post-Application Exposure: Assumptions

The calculations used to estimate *Daily Dermal Dose* and *MOE* for the dermal post-application scenarios are similar to those described above for the handler scenarios. The only significant differences are: (1) the manner in which the *Daily Dermal Dose* is calculated using transfer coefficient, transferable residue levels, and accounting for the dissipation of etridiazole over time; and (2) inhalation exposures were not calculated for most post-application scenarios (i.e., *Total Daily Dose* in the *MOE* calculation only represents dose levels resulting from dermal exposures because the data reflect inhalation exposures that have been shown historically to account for a negligible percentage of the overall body burden). However, due to the higher vapor pressure of etridiazole, relative to other pesticides and fungicides, and because the post-application study of greenhouse workers using treated soil found inhalation exposure to be a significant portion of their total dose, inhalation exposure will be considered a contributor to that exposure scenario. Margins of exposure of 100 or greater for short- and intermediate-term and 300 or greater

for post-application exposure do not exceed HED's level of concern for long-term exposure.

Because etridiazole is designed to act in the soil, or "soil-incorporated," post-application agricultural exposure is considered to be negligible as long as the soil is not directly contacted. In plant nurseries and greenhouses the treated soil may be contacted frequently and throughout the year. When it is applied to golf course turf, some residue remains on the grass itself, even though it is generally watered in after application, and golf courses are watered frequently (often daily).

The typical occupational work day interval is generally considered to be 8 hours, and this is considered reasonable for activities such as mowing and turf maintenance. However, since the primary concerns for post-application etridiazole exposure are greenhouse or nursery workers handling treated soil, a reasonable duration of exposure for handling treated soil is considered to be 4 hours of activity on a single day. Additionally, the 4 hour value is also used to estimate the duration of a game of golf (18 holes). Because a turf transferable residue (TTR) study was conducted, the residue value from the study can be used to determine the post-application dose:

Dermal dose is calculated:

Dermal dose (mg ai/kg/day) =

(TTR(t) [μg/cm^2] x Tc (cm^2/hr) x DA x 0.001 mg/μg conversion x # hours worked/day) / body weight (kg)

Where:

Dermal dose (t) = dermal dose attributable to exposure at time (t) when engaged in a specific mechanical activity or job function (mg ai/kg/day);
Turf transferable residue (TTR) = transferable residue that represents the amount of residue on turf that is available for dermal exposure at time (t) [μg/cm^2]; as defined above;
Tc = transfer coefficient or measure of the relationship of exposure to transferable residue concentrations while engaged in a specific mechanical activity or job function; transfer coefficients of 1000 and 500 were assumed for push-type mowers and tractors, respectively;
DA = dermal absorption (%);100% dermal absorption was assumed;
Hours worked/day = exposure duration or hours engaged in specific mechanical activity (hrs/day); and
Body weight = body weight (kg) (60 kg for short-term exposure; 70 kg for intermediate and long-term and cancer risk.)

4.5.2 Post-Application Exposure: Data Sources

Chemical-Specific Studies

Four post-application studies were submitted to the Agency; a "Magnitude of the residue" study; a "transfer of the residue" study; and a greenhouse worker/soil dissipation combined study. The studies and results are discussed below.

Magnitude of Residue Study

A study of residue dissipation after initial and repeated application of Terrazole® 35 WP Fungicide to turf (MRID#432878-01)[14] was submitted in support of the etridiazole Data Call-In (DCI) notice of July 2, 1991. The study was reviewed and compared to the EPA OPPT Series 875.2100 Post-Application Exposure Monitoring Test Guidelines requirements.[15] The study partially met the Guideline criteria. However, the study results were largely unacceptable because of deficits in study design. Only the relative magnitude of the residues may be considered from the data.

The study consisted of planting Bermuda Grass on a study plot, mowing it every 2 days, and applying the etridiazole. Magnitude of residue samples were taken at 0, 6, and 12 hours after initial application, then at 1, 3, 5, 7, 10,12, 15, 18, 20, 25, and 30 days. A total of 54 samples of turf were collected by cutting the grass at the soil line. A minimum of ½ lb untreated and 1/4 lb treated turf were collected for each sample.

Field data were collected in November and December of 1993 on the island of Hawaii. Hexane was used to extract the etridiazole from the turf clippings. Also, rather than shaking the solution to dislodge residues, as stated in the Guidelines, the samples were homogenized. The results of the analyses showed that the residues ranged from 320 ppm at 0 hours after application number 1 to about 70 ppm at 6 hours to about 0.2 ppm at 30 days after the first application (15 days after the fourth application). Because the analyses did not measure dislodgeable foliar residue, but rather, total residue of the grass clippings, this study is not useful in determining actual occupational or non-occupational exposures. However, it is useful to note that the total residue determined by this method always diminished by half within 6 hours and to 1-2 ppm within 5 days post application, indicating a short (less than 6 hours) half-life and a lack of accumulation when applied as labeled.

Transfer of Residue Study

A study of residue transfer after initial and repeated application of Terrazole® 35 WP

Fungicide to turf (MRID #432878-02)[16] was submitted in support of the Terrazole Data Call-In (DCI) notice. Although residues on turf are not typically required, the author states this study has been submitted to the U.S. Environmental Protection Agency (EPA) to demonstrate that transferable residues are less than the expected levels. The study was reviewed and compared to the EPA OPPT Series 875.2100 (Post-Application Exposure Monitoring Test Guidelines). The study partially met the Guideline criteria. However, the measured transferable residues were mostly below the laboratory level of quantitation (LOQ) and therefore provide mostly negative information (eg., the study shows only the upward bounds of residue transfer, not the lower levels). EPA found the study data inadequate due to insufficiently low LOQ.

The Terrazole WP was applied at an initial rate of 8 oz product (2.8 oz ai)/1000 square feet and followed by applications at 4.5 oz product (1.6 oz ai)/1000 sq. ft. each, every five days thereafter. The study consisted of planting Bermuda Grass on a study plot, mowing it every 2 days, and applying the etridiazole. Transferable residue samples were taken at 0, 6, and 12 hours after initial application, then at 1, 3, 5, 7, 10,12, 15, 18, 20, 25, and 30 days. A total of 60 samples were collected on cloth dosimeters: the cotton cloths were covered with plastic and a 12 kg. weighted roller was rolled back and forth over the cloth ten times. Control samples were collected only once, at the beginning of the study. Analysis results were corrected for fortification recovery rates.

The results of the analyses of the dosimeters showed that the transferable residues were mostly (53/60) nondetectable. The highest residue detected was 0.13 $\mu g/cm^2$, immediately post-application on the first application (this was at the highest rate), but two simultaneous samples found levels at the limit of quantitation. Only three other samples out of sixty were above the limit of quantitation for the laboratory analysis method. Those were 0.06 $\mu g/cm^2$ immediately after the second application (5 days), and 0.10 and 0.11 $\mu g/cm^2$, both immediately after the third application. The Agency estimated a transferable residue of 4.3 g/cm based on 5% of the application rate (default transfer factor). Therefore the study residue level represents about 0.2% of the application rate, which is low but within the range of potential exposures anticipated from contact with turf, based on other similar studies. These exposure estimates are shown in Table B7.

Greenhouse Worker/Soil Residue Study

A study of dermal and inhalation etridiazole exposure to workers using potting soil and soil residue dissipation after application of Terrazole® 35 WP and Truban® 5G Granular Fungicide to potting soil in a greenhouse (MRID#442278-01) was submitted. This study partially met the requirement in OPPTS Series 875 of the Occupational and Residential Exposure Test Guidelines (U.S. EPA 1997). The field data presented in this study are

based upon well-documented procedures with adequate quality controls. This data can be useful in determining exposures to etridiazole-containing compounds in the greenhouse setting, particularly given the general dearth of data specific to this exposure.

The study used four volunteer workers to fill plastic pots with soil treated with Terrazole® 35 WP (wettable powder) in three re-entry scenarios and Truban® 5G Granular in one other scenario. The study consisted of 15 replicates, and each replicate consisted of one worker filling the plastic pots with treated soil inside a greenhouse. Four replicates were obtained at four hours post-application, four at 12 hours post-application, and three at 24 hours post-application of the Terrazole. Four replicates were obtained at 4 hours post-application of the Truban. Field data were collected from December 16, 17 and 18, 1996 in a commercial greenhouse in Half Moon Bay, California.

Dermal exposure was assessed by analyzing an whole-body dosimeter consisting of a cotton long underwear worn under work clothing, which consisted of long denim pant and a long-sleeved cotton shirt, shoes and socks. Cotton gauze swabs were used to wipe face and neck. Hand exposure was determined using four 500-ml aliquots of a solution of 0.01 percent Aerosol OT ® (sodium dioctyl sulfosuccinate) in distilled water for two hand washes and rinses. The total dermal exposure, adjusted for field fortification recoveries, and standardized to an 8-hour work day, was 433 μg for 4 hour re-entry post-application of Terrazole 35WP; at 12 hours post-application, 249 μg; and at 24 hours post-application, 310 μg. For Truban 5G, at 4 hours post application, the 8-hour projected dermal exposure, adjusted for field recoveries, was 134 μg.

Inhalation exposure was measured using personal air sampling pumps. The sampling pumps were calibrated to draw 1.5 liters per minute (lpm) and post-calibrated at the end of each sampling period with a Kurz Mass Flow Meter. The sampling train consisted of a cassette containing a mixed cellulose ester filter in series with a glass absorber tube containing XAD sorbent resin, which was attached to the collar of the coveralls near the worker's breathing zone. The average inhalation exposure, adjusted for field recoveries, and standardized to an 8-hour shift, for the 4-hour post application worker exposed to Terrazole 35W was 851 μg; for the 12-hour post application work the eight hour dose was 497 μg; for the 24-hour post application work the eight-hour dose was 768 μg . For Truban 5G 4-hour post application the 8-hour projected exposure was 284 μg. The inhalation dose comprised 70-77 percent of the total dose from inhalation and dermal exposures for either Terrazole 35W or Truban 5G. This information supports the use of conservative estimates for etridiazole handler and post-application exposures as the database used by HED is generally based upon surrogate chemicals that have lower vapor pressures than etridiazole.

This study also measured the dissipation of etridiazole in soil after separate application of

Terrazole 35WP and Truban 5G. The authors proposed the development of a transfer factor for dosage of ai, based on the total exposure in micrograms (dermal and inhalation) divided by the dislodge able soil residue (ug/G) yielding a factor of G/hr. Unfortunately, analysis of the data shows that the residue does not decline evenly in a linear or loglinear fashion, and in fact measured residues are greater on the third day than at eight hours after treatment. Using linear regression of the log-transformed data ($R^2 = .21$) allow examination of the data enough to show that there is very slow decline of the residues in the soil (2%/day), requiring 28 days to decrease by one-half.

4.5.3 Post-Application Exposure and Non-Cancer Risk Estimates

The exposure and risk estimates for post-application exposure to potting soil and turf contact activities are shown in Table B7. Greenhouse or nursery workers are expected to be exposed to the post-application residues of potting soil on a regular basis, for an estimated 4 hours per day. The 12-hour re-entry dose for potting soil handling from the submitted study was used to estimate an MOE of 900 for intermediate or long-term exposures, and a cancer risk of 2.9×10^{-5}. Different levels of contact with treated turf were estimated, using riding mowing to represent the lower and push mowing the higher range of exposure. It is assumed that the transfer coefficient of 1000 cm^2/hr for push-mowing is inclusive of the limited amount of higher contact activities such as hand trimming performed on the golf course. The MOE for push mowing for intermediate-term duration is 320. The lifetime cancer risk for mowing is estimated at 2.0×10^{-5} to 4.0×10^{-5}, based on the turf residue data.

As there are no study data available on exposure to fungicide residue on treated seed, the exposure has been estimated by assuming that the total amount of etridiazole applied to the seed is available, and the unit exposure for handling granular formulations in PHED was used to determine the dose. Post-application exposure estimates for farmers and workers handling and loading treated seed for planting are summarized in Table 8. The short-term MOEs ranged from 48,000 to 60,000 based on the treatment rates and estimated acreage for planting cotton seed (80 acres and 1440 lbs of seed, the same parameters as were used previously for mixer/loaders of dust formulation.) The intermediate-term MOEs ranged from 18,000 to 22,000. Estimated cancer risks for private farmers handling and planting cotton seed were in the range of 6.8×10^{-8} to 8.4×10^{-8}. Commercial planters (20 days per year) have an estimated cancer risk of 2.0×10^{-7} to 2.4×10^{-7}.

These exposure estimates are expected to cover the most common risks that can be anticipated from occupational post-application exposure to etridiazole. The turf study that

risk assessments are based on had significant flaws, yet it is felt that this chemical-specific data is more reflective of actual residues than the defaults. Workers in greenhouses could be exposed to soil more than the estimated 120 days per year, but the four-hour exposure estimate and 12-hour dose used in calculating the risk are expected to be conservative enough to cover typical worker activities. It is also assumed that workers will avoid, or have negligible contact with soil-incorporated etridiazole used during planting.

4.5.4 Summary of Occupational Handler Post-Application Risk Concerns, Data Gaps, and Confidence in Exposure and Risk Estimates

As stated above, the MOEs for post-application worker exposure scenarios were all greater than 100. The potting soil scenario is believed to be highly conservative, as the worker was potting bare-handed using soil treated only 12 hours previously at the highest label rate for four hours. This scenario should be adequately protective for other soil-contact activities as well, such as transplantation and irrigation work. However, the soil residue dissipation data also show that etridiazole, at least in dry soil, dissipates very slowly. All post-application exposure estimates were based on the submitted studies. The turf transferable residue study, due to the low number of detectable residues and the single location, was considerably weaker than the potting soil study. However, the detectable residues in the turf study (about 0.2%) were all consistently low and not inconsistent with other similar studies.

Greenhouse or nursery workers are expected to be exposed to the post-application residues of potting soil on a regular basis (potentially more than six months per year), for an estimated 4 hours per day. The MOE for long-term exposure is 300. The 12-hour re-entry dose for potting soil handling from the submitted study was used to estimate an MOE of 900 for intermediate or long-term exposures, and a cancer risk of 2.9×10^{-5}. Mowing treated turf was used to represent the typical golf course maintenance activity level. The MOE for mowing for intermediate-term duration is 320. The lifetime cancer risk for mowing is estimated at 8.1×10^{-5}, based upon the residue study data.

4.6 Non-Occupational Exposure and Risk Assessment

4.6.1 Non-Occupational Handler Exposures and Risks

None of the etridiazole labels have non-occupational (residential) uses, therefore no residential handler scenarios were evaluated.

4.6.2 Non-Occupational Post-Application Exposure and Risks

a. Post Application Exposure Scenarios

Non-occupational exposure to etridiazole is most likely to occur on a golf course, where it may be applied repeatedly throughout the year and within a few hours of public usage. The emulsified product is applied by a boom-type sprayer and granules are applied by hand- or push-type spreader. The labels do not indicate any other usage in a public area. While it is most likely that adult golfers could be exposed to etridiazole after application on golf courses, it is possible that younger children, either golfing or accompanying adult golfers could also be exposed. However, a risk assessment for this exposure scenario for the general population, including infants and children, was not conducted since a short-term dermal toxicological endpoint of concern was not identified for the general population. A risk assessment was conducted for female golfers of child-bearing age (13-50 years old) using the developmental NOAEL of 15 mg/kg/day. Because the FQPA Safety Factor Committee determined that the 3x FQPA safety factor does not apply to the acute dietary risk assessment, it is also not applicable to the short-term dermal risk assessment as both assessments are based on the same toxicity study. Therefore, an MOE of 100 or greater is adequate for female golfers 13-50 years old.

Because a chemical-specific study of transferable turf residue was submitted to the Agency, the data from that study were used to determine the health risk presented by post-application entry onto a golf course, and it was not necessary to use the EPA's *SOPs For Residential Exposure Assessments*. The formula for calculation of golfing exposure, however, used information from the SOPs. The equations used for the calculations in Table B8 (Appendix B) were the same equations as previously presented in the occupational post-application portion of the RED with the following changes:

- ED (exposure duration) in the calculation of daily dose is 4 hours per day for golfers, rather than the 8 hours per day used in the occupational post-application assessment. This is based on the average reported time required to play 18 holes of golf.
- For the purposes of cancer risk assessment, a golfer is assumed to play an average of 18 times per year. This frequency is based on national surveys of golfers.[18]

- The application rate used in the non-occupational assessment is the same as was used for turf workers, which is the maximum rate of 7.6 lb ai/acre.
- Adults including females over 13 years old were assumed to weigh 60 kg for calculation of short-term exposures, including golfing.
- Post-application was assessed on the same day the pesticide is applied because it was assumed that the golf course is open every day and the user could be exposed to soil immediately after application. Therefore, post-application exposures were based on day zero, 12-hour post-application residues.
- Due to a lack of scenario-specific exposure data, HED has calculated exposure values for adults using surrogate dermal transfer coefficients that represent reasonable low (100 cm^2/hour for adult golfing), and high (1000 cm^2/hour for mowing) contact activities.

b. Non-Occupational Post-Application Risk Assessments

Because an acceptable study of turf residue transfer was submitted by the Registrant, it is not necessary to use the Residential SOP defaults for the residues to assess non-occupational exposure to turf. Using the transferable residue at 12 hours post-application, which is the duration of the current re-entry interval, the MOEs for golfing adults including females 13-50 years of age were determined (see Table B8, Appendix B). For adult golfers, the short-term MOE using the study data is 17,000, which does not exceed HED's level of concern. Cancer risk estimates were determined for all adult golfers. The exposure estimate was derived from the turf transferable residue study data and assumed a four hour exposure occurring 18 times a year. The estimated cancer risk for adult golfers is 8.9×10^{-7}.

4.6.3 Post-Application: Data Gaps and Confidence in Exposure and Risk Estimates

This risk assessment assumes that the only significant post-application exposure to etridiazole, based on the types of application, is contact with treated soil, seed, or turf. The likely and predictable soil and turf exposures have been estimated for workers and non-workers. The turf transferable residue study had significant weaknesses (discussed above) but was considered adequate for use in this assessment and preferable to the default values provided by the Residential SOPs. The post-application treated seed handler exposure assessment was based upon assumptions of 100% available residue and the use of PHED surrogate data. These are considered highly conservative assumptions. The MOEs for all post-application exposure assessments, given the stated limitations, did not exceed the Agency's level of concern.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

5.1 Acute Aggregate Risk (food + water)

Acute risk estimates from aggregate exposure to etridiazole in food and water do not exceed the Agency's level of concern. For the Tier 1 acute dietary exposure analysis, tolerance level residues were used and 100% crop treated was assumed for all commodities. For all female (13-50 yrs) subgroups (the population of concern), less than 4.6% of the aPAD is occupied by dietary (food) exposure at the 99.9th percentile of exposure. Thus, the acute dietary (food) risk associated with etridiazole use is below the Agency's level of concern. Using conservative (Tier 1) screening level models, the estimated concentration of etridiazole (using 7.6 lbs ai/acre/year on turf) in groundwater (SCI-GROW) is 0.93 ppb and the estimated peak concentration in surface water (GENEEC) is 230 ppb.The acute DWLOC for females is 4300 ppb. The Tier 1 surface water EEC of 230 ppb and the Tier 1 groundwater EEC of 0.93 ppb are well below the DWLOC. Therefore, HED concludes with reasonable certainty that acute aggregate exposure to etridiazole (for female 13-50 years old) does not exceed the Agency's level of concern.

Table 10. Drinking Water Levels of Comparison for Acute Aggregate Exposures

Scenario/ Population Subgroup	aPAD, mg/kg	Dietary Exposure, mg/kg	Maximum Surface Water Exposure[1]	EEC Surface Water, ppb GENEEC	EEC Ground Water, ppb SCIGROW	DWLOC, ppb
Females (13-50 years old)	0.15	0.005323	0.144677	230	0.93	4300

[2] Maximum Water Exposure (mg/kg) = aPAD (mg/kg) - Dietary exposure from DEEM (mg/kg)

5.2 Short-Term Aggregate Risk (food + water + non-occupational)

The short-term (non-cancer) aggregate risk estimate includes chronic dietary (food and water) and short-term non-occupational (golf course) exposures only. There are no homeowner uses for etridiazole. In aggregating short-term risk, HED considered background chronic dietary food exposure and short-term dermal exposures (golf course scenario) along with potential drinking water exposures. The short-term food MOE is 7.5×10^3. The short -term non-occupational (golfer) MOE is 1.7×10^4. The total short-term food and non-occupational aggregate MOE value for females (13+yrs) is 5.2×10^3 . This MOE is much greater than the acceptable short-term MOE of 100. For surface water and groundwater, the estimated average concentrations of etridiazole (57 ppb and 0.93 ppb, respectively) are less than the DWLOC of 4300 ppb. Therefore, short-term aggregate exposure for females of child-bearing age (13-50 yrs) to etridiazole does not exceed the Agency's level of concern.

An aggregate short-term risk assessment for the general population, including infants and children, was not conducted since the short-term dermal toxicological endpoint was based on an *in utero* effect and is not applicable to these populations.

Table 11. Short-term Aggregate Risk Estimates for Etridiazole

	Population Subgroup	Females (13-50yrs)
	Acceptable short-Term Aggregate MOE	100
Food Only	Short-term oral NOAEL (mg/kg/day) [Females 13-50yrs]	15
	Chronic Food Exposure (mg/kg/day) (Females 13-19 years old = highest exposed subgroup)	0.002008
	Food MOE	7.5×10^3
Non-occupational Oral	Short-term oral NOAEL (mg/kg/day)	N/A
	ADD Oral Exposure (mg/kg/day)	
	Oral MOE	

Non-occupational Dermal	Short-term NOAEL (mg/kg/day)	15
	ADD Dermal Exposure (mg/kg/day)	8.7×10^{-4}
	Dermal MOE	1.7×10^{4}
Non-occupational Inhalation (Adult handler)	Short-term NOAEL (mg/kg/day)	N/A
	ADD Inhalation Exposure (mg/kg/day) (treating turf and flowers)	
	Inhalation MOE (treating turf and ornamentals)	
	Food + non-occupational AGGREGATE MOE	5.2×10^{3}
Drinking water	Short-term oral NOAEL (mg/kg/day)	15
	Allowable short-term surface water exposure (mg/kg/day)	0.14
	Short-term surface water DWLOC (ppb)	4300
	Surface water EEC (ppb)	57
	Ground water EEC (ppb)	0.93

5.3 Intermediate-Term Aggregate Risk (food + water + non-occupational)

Since recreational, non-occupational activities on golf courses are considered short-term exposures and no residential (homeowner) exposure scenarios exist, an intermediate-term aggregate risk assessment is not required.

5.4 Chronic (Non-Cancer) Aggregate Risk (food + water)

The chronic aggregate risk estimate includes chronic dietary (food and water) exposures only. There are no homeowner uses for etridiazole.

Chronic (non-cancer) aggregate risk estimates from aggregate exposure to etridiazole in food and water exceed the Agency's level of concern for infants and children. The chronic (non-cancer) dietary (food) risk associated with the registered uses of etridiazole is

below the Agency's level of concern. When tolerance level residues and 100% crop treated was assumed in the chronic (non-cancer) dietary analysis (Tier 1), the highest percent of cPAD occupied for all subgroups was 31% for children (1-6 years). For ground water, the Tier 1 EEC of 0.93 ppb is less than the DWLOCs for all population subgroups. For surface water, the Tier 1 EEC of 57 ppb is less than the DWLOC for the U.S. population and female (13-19 yrs and 13-50 yrs) and male (13-19 yrs) subgroups. The chronic surface water EEC of 57 ppb exceeded the DWLOC for non-nursing infants (< 1yr) and children 1-6 years old (40 and 35 ppb, respectively). HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to chronic DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. The Tier 2 surface water EEC of 0.05 ppb (for 36 year use on cotton) does not exceed the DWLOCs for any subpopulation, including infants and children.

In accordance with OPP policy (S. Johnson, 11/17/97) if the EECs exceed the DWLOCs, water monitoring data are necessary to refine the drinking water exposure estimate. SRRD and EFED should determine the nature and extent of the water monitoring data required.

Table 12. Drinking Water Levels of Comparison for Chronic (Non-Cancer) Aggregate Exposures

Scenario/ Population Subgroup[1]	cPAD, mg/kg/day	Dietary Exposure, mg/kg/day	Maximum Surface Water Exposure	EEC Surface Water, ppb GENEEC (turf use)	EEC Surface Water, ppb PRIZM/ EXAMS (cotton use)	EEC Ground Water, ppb SCIGROW (turf use)	DWLOC, ppb
U.S Population	0.005	0.000688	0.004312	57	0.05	0.93	150
Non-Nursing Infants(<1yr)	0.005	0.001024	0.003976	57	0.05	0.93	40
Children (1-6 yrs)	0.005	0.001534	0.003466	57	0.05	0.93	35
Females (13-19yrs)	0.005	0.000676	0.004324	57	0.05	0.93	130
Females (13-50yrs)	0.005	0.000538	0.004462	57	0.05	0.93	130
Males (13-19)	0.005	0.000767	0.004233	57	0.05	0.93	150

[1] Population subgroups chosen were those with the highest food exposure

[2] Maximum Water Exposure (mg/kg/day) = cPAD (mg/kg/day) - Dietary exposure from DEEM (mg/kg/day)

5.5 Cancer Aggregate Risk (food + water +[non-occupational for golfers])

The cancer aggregate risk estimate includes chronic dietary (food and water) and non-occupational (golf course) exposures only. There are no homeowner uses for etridiazole.

For golfers and non-golfers, cancer aggregate exposure and risk estimates exceed the Agency's level of concern. The estimated non-occupational cancer risk for adult golfers is 8.9×10^{-7}. When a refined (1/2 LOQ residue levels and estimated percent crop treated information) dietary exposure analysis is performed, the carcinogenic dietary risk estimate for etridiazole is 1.6 x 10-7 for the general U.S. population (estimated dietary exposure is 0.000005 mg/kg/day). The cancer dietary (food) risk estimate associated with the proposed uses of etridiazole does not exceed the Agency's level of concern. The cancer DWLOC for the US population is 1 ppb. Using a Tier 1 screening level model (GENEEC) for turf, the estimated levels of etridiazole in surface water is 57 ppb (56 day average). The Tier 1 surface water EEC (turf) exceeds the cancer DWLOC. HED notes that the EEC values provided by EFED for the GENEEC Tier 1 model for comparison to chronic DWLOCs are not long- term average values. Long- term average values are more appropriate for comparison to chronic DWLOCs. Using a Tier 2 screening level model (PRZM/EXAMS) for 36 year use on cotton, the estimated level of etridiazole in surface water is 0.05 ppb. The Tier 1 groundwater (SCIGROW) EEC is 0.93 ppb. The Tier 2 surface water EEC (cotton) and Tier 1 groundwater EEC do not exceed the cancer DWLOC.

In accordance with OPP policy (S. Johnson, 11/17/97) if the EECs exceed the DWLOCs, water monitoring data are necessary to refine the drinking water exposure estimate. SRRD and EFED should determine the nature and extent of the water monitoring data required.

Table 13. Drinking Water Levels of Comparison for Cancer Aggregate Exposures

Scenario /Population	Q* $(mg/kg/day)^{-1}$	Dietary Exposure Risk	Non-Occupational Exposure Risk	Maximum Surface Water Exposure mg/kg/day	EEC Surface Water, ppb GENEEC (turf use)	EEC Surface Water, ppb PRIZM/ EXAMS (cotton use)	EEC Ground Water, ppb SCIGROW (turf use)	DWLOC ppb
U.S Population (General)	3.3×10^{-2}	1.6×10^{-7}	N/A	3.0×10^{-5}	57	0.05	0.93	1
U.S. Population (Adult Golfers)	3.3×10^{-2}	1.6×10^{-7}	1.3×10^{-6}	N/A	57	0.05	0.93	N/A

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*List of references is not complete; some studies missing from the PDMS citations

Toxicology Supporting Documents

DP Barcode (s): None
Subject: Terrazole: Report of the Toxicology Science Advisory Council
From: Joycelyn E. Stewart
To: Pauline Wagner, Jess Rowland and Michelle Centra
Dated: April 12, 1999
MRID (s): 00114197, 00063303, 00120415, 00104999, 00001698, 00001697

DP Barcode (s): None
Subject: ***TERRAZOLE***-Report of the Hazard Identification Assessment Review Committee.
From: Michelle M. Centra
To: Pauline Wagner and Jess Rowland
Dated: June 29, 1999
MRID (s): 00104999, 40747901, 00093744, 00073206, 00093742, 00093743, 41837501, 00120416, 00120414, 00120415, 00001698, 43724501, 43724502, 437245503, 43724504, 43724505, 437245506

DP Barcode (s): None
Subject: ***TERRAZOLE***-Report of the FQPA Safety Factor Committee.
From: Brenda Tarplee
To: Steve Knizner
Dated: June 3, 1999
MRID (s): None

DP Barcode (s): None
Subject: Peer Review of Terrazole.
From: Kerry L. Dearfield
To: Herman T. Toma
Dated: January 9, 1991
MRID (s): 40747901, 00093744, 00093742, 00073206, 00093743, 00120414, 00120416, 43654801, 00120415, 00104999, 00001698, 43654801

DP Barcode (s): None
Subject: Terrazole® Quantitative Risk Assessment (Q1*) Based on Charles River Sprague-Dawley Rat Chronic Dietary Study With With 3/4's Interspecies Scaling Factor.
From: Lori L. Brunsman
To: Jess Rowland
Dated: February 10, 1999
MRID (s): 40747901

DP Barcode (s): D261093
Subject: **Etridiazole**. Toxicology Chapter of the Reregistration Eligibility Decision. Chemical Number 084701. DP Barcode D261093.
From: Michelle Centra
To: Roberta Farrell
Dated: July 15, 1999
MRID (s): 44660701, 42192001, 00121856, 44591801, 44581601, 00132879, 44308301, 00111922, 00109739, 00114267, 00109748, 00109741, 00151785, 00109742-45, 41487001, 40072105, 00132878, 00029455, 40730604, 40384701, 41116901, 00132859, 00151790, 00159797, 00114260, 41706906, 00114261, 43315001, 00144308, 00132880, 00088624, 00083644, 41091007, 00114263, 44591701, 40730601, 44701001, 00121859, 00132874, 40072104, 42908101, 43021601, 44694501, 44710501, 00138159, 40072106, 44767501

DP Barcode (s): D262018
Subject: **Etridiazole.** Revised Toxicology Chapter of the Reregistration Eligibility Decision. Chemical Number 084701. DP Barcode D262018.
From: Michelle M. Centra
To: Danette Drew and Roberta Farrell
Dated: December 20, 1999
MRID (s): 44660701, 42192001, 00121856, 44591801, 44581601, 00132879, 44308301, 00111922, 00109739, 00114267, 00109748, 00109741, 00151785, 00109742-45, 41487001, 40072105, 00132878, 00029455, 40730604, 40384701, 41116901, 00132859, 00151790, 00159797, 00114260, 41706906, 00114261, 43315001, 00144308, 00132880, 00088624, 00083644, 41091007, 00114263, 44591701, 40730601, 44701001, 00121859, 00132874, 40072104, 42908101, 43021601, 44694501, 44710501, 00138159, 40072106, 44767501

APPENDIX A
Etridiazole
PRODUCT AND RESIDUE CHEMISTRY

Tables A1-A3

Case No. 0009
Chemical No. 084701

Case Name: Terrazole
Registrant: Uniroyal Chemical Company, Inc.
Product(s): 98.6% T (EPA Reg. No. 400-413)

Table A1. PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	Y	42912204 [3], 42954701 [3], CSF 3/6/95 [4]
830.1600	Description of materials used to produce the product	Y	**00001553**, 42912201 [3]
830.1620	Description of production process	Y	**00001553**, 42912201 [3]
830.1670	Discussion of formation of impurities	Y	42912202 [3]
830.1700	Preliminary analysis	Y	**00158120**, 42912203 [3], 43597401 [4]
830.1750	Certified limits	Y	42912204 [3], CSF 3/6/95 [4]
830.1800	Enforcement analytical method	Y	**00158120**, 42912203 [3], 43597401 [4]
830.6302	Color	Y	**00001553**
830.6303	Physical state	Y	**00001553**
830.6304	Odor	Y	**00001553**
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**00001553**, 42912210 [3], 42912211 [3], 42912212 [3]
830.6314	Oxidation/reduction: chemical incompatability	Y	42912213 [3]
830.6315	Flammability	Y	**00001553**

Guideline Number	Requirement	Are Data Requirements Fulfilled?	MRID Number [2]
830.6316	Explodability	Y	**00062469**
830.6317	Storage stability	Y	**00001553**, 43232001 [5]
830.6319	Miscibility	Y	**00062469**
830.6320	Corrosion characteristics	Y	**00001553**, 43232002 [5]
830.7000	pH	Y	**00001553**
830.7050	UV/Visible absorption	N [6]	
830.7100	Viscosity	Y	42912214 [3]
830.7200	Melting point/melting range	N/A [7]	
830.7220	Boiling point/boiling range	Y	**00001553**
830.7300	Density/relative density/bulk density	Y	**00001553**
830.7370	Dissociation constants in water	Y	42912209 [3]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	42515901 [8]
830.7840	Water solubility: column elution method; shake flask method	Y	**00001553**, **00001644**, 42912205 [3], 42912206 [3], 42912207 [3]
830.7950	Vapor pressure	Y	**00001553**, 42912208 [3]

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were reviewed under the Terrazole (SRR) Reregistration Standard dated 3/30/89; and all other references were reviewed as noted.

[3] CBRS No. 12714, D195979, 3/18/94, K. Dockter.

[4] CBRS No. 15417, D213928, 5/8/95, K. Dockter.

[5] CBRS No. 13768. D203660, 6/22/94. K. Dockter.

[6] The OPPTS Series 830. Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[7] Data are not required because the T/TGAI is a liquid at room temperature.

[8] CBRS No. 10875, D184741, 1/8/93, F. Toghrol.

Table A2. Food Feed Use Patterns Subject To Reregistration for Etridiazole (Case 0009).

Site Application Type Application Timing	Formulation [EPA Reg. No.]	Max. Single Application Rate[a]	Use Limitations[b]
Barley, Peas, and Soybean			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.20-0.25 oz ai/bushel seed	
Beans			
Seed treatment	5% D [7501-54]	0.1 oz ai/bushel seed	
	0.5 lb/gal EC [7501-57]	0.125 oz ai/100 lbs seed	
Corn and Sorghum			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.1-0.125 oz ai/100 lbs seed	
Cotton			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.80-1.0 oz ai/100 lbs seed	

(Continued; footnotes follow)

Site Application Type Application Timing	Formulation [EPA Reg. No.]	Max. Single Application Rate[a]	Use Limitations[b]
In-furrow At-planting	1.53% G [400-408] 2.5% G [400-406] 3.8% G [400-456] 0.4 lb/gal EC [400-475] 0.5 lb/gal EC [400-405] 0.5 lb/gal FlC [400-455]	0.23-0.38 lb ai/A	Apply only at planting. The labels prohibit the feeding or grazing of cotton foliage by livestock, and specify a 12-month plantback interval for root crops unless PCNB is registered for use on these crops. Applications of the EC and FlC formulations are made in 5-15 gal/A of water.
Peanuts			
Seed treatment	2.5% D [7501-111] [7501-153] 5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.15-0.25 oz ai/100 lbs seed	
Safflower			

(Continued; footnotes follow)

Site Application Type Application Timing	Formulation [EPA Reg. No.]	Max. Single Application Rate[a]	Use Limitations[b]
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-54]	0.2-0.25 oz ai/100 lbs seed	
Wheat			
Seed treatment	5% D [7501-54] 0.5 lb/gal EC [7501-57]	0.1-0.125 oz ai/bushel seed	

[a] A maximum of one application/season is implied by the labeled use pattern.

[b] Labels allowing seed treatment uses prohibit the use of treated seed for food, feed, or oil purposes and require that the treated seed be dyed.

Table A3. Residue Chemistry Science Assessments for Reregistration of Etridiazole.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A	Yes	See Table A.
860.1300: Plant Metabolism	N/A	No	**00001689** **00028419** 00093751 43940001[2] 44054701[3] 44285201[4] 44453201[5]
860.1300: Animal Metabolism	N/A	No	00093753 00093754
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	**00001570** **00001645** **00002229** **00002239** 00002257 00028423 00028424 00028428 00014333 00093752 **00139669**
- Animal commodities	N/A	No	00001695 00093752 00093755
860.1360: Multiresidue Methods	N/A	No	43259601[6]
860.1380: Storage Stability Data	N/A	Yes[7]	00093754 00093755 44285001[8] 43305701[9]
860.1500: Crop Field Trials			

(Continued: footnotes follow)

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
Legume Vegetables (Succulent or Dried)			
- Beans	None	No[10]	
- Peas	None	No[10]	
- Soybean, seed	None	No[10]	
Foliage of Legume Vegetables			
- Soybean, forage and hay	None	No[10]	
Fruiting Vegetables			
- Tomato	0.15 [§180.370]	Yes[11]	
Cereal Grains Group			
- Barley, grain	None	No[10]	
- Corn, field, grain	0.05 [§180.370]	No[10]	
- Sorghum, grain	None	No[10]	
- Wheat, grain	0.05 [§180.370]	No[10]	
Forage, Fodder and Straw of Cereal Grains			
- Barley, hay and straw	None	No[10]	
- Corn, fodder and forage	0.1 [§180.370]	No[10]	
- Sorghum, forage and stover	None	No[10]	
- Wheat, forage and straw	0.1 [§180.370]	No[10]	
- Wheat, hay	None	No[10]	
Miscellaneous Commodities			

(Continued; footnotes follow)

Table B (*continued*).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Cottonseed	0.2 [§180.370]	No	00014318 00028427 00064191 00064194 44285901[13]
- Cotton gin by products	None	No	44285901[13]
- Peanut, nutmeat and hay	None	No[10]	
- Safflower	None	No[10]	
- Strawberries	0.2 [§180.370]	No[12]	
860.1520: Processed Food/Feed			
- Barley, corn, peanut, safflower, soybean, and wheat	None	No[14]	
- Cottonseed	None	No	44285901[13]
860.1480: Meat, Milk, Poultry, and Eggs			
- Eggs	0.05 [§180.370]	No	00093755 00093756
- Milk	0.05 [§180.370]	No	00093747 00093748
- Poultry fat, mbyp, and meat	0.1 [§180.370]	No	00093755 00093756
- Cattle, goats, hogs, horses, and sheep fat, mbyp, and meat	0.1 [§180.370]	No	00093747 00093748

(Continued; footnotes follow)

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1400: Water Fish and Irrigated Crops	None	N/A	
860.1460: Food Handling	None	N/A	
860.1850: Confined Rotational Crops	N/A	No	44311401[15]
860.1900: Field Rotational Crops	None	Yes[16]	

1. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Etridiazole Reregistration Standard dated 9/80, and *italicized* references were reviewed or summarized in the Residue Chemistry Chapter of the Etridiazole Second Round Review (SRR) dated 3/30/89. All other references were reviewed as noted.

2. DP Barcode D224428, D. Hrdy, 11/14/97

3. DP Barcode D228163, D. Hrdy, 5/30/97

4. DP Barcode D244973, D. Drew, 10/29/98

5. DP Barcode D244975, S. Law, 9/29/98

6. DP Barcode D205025, L. Edwards, 7/15/94

7. Data are required depicting the storage stability of the monoacid metabolite stored frozen in animal commodities for up to 2 years. Samples from the poultry and ruminant feeding studies were stored frozen for approximately 6 weeks and 2 years, respectively, prior to analysis for residues of the monoacid.

8. DP Barcode D244972, D Soderberg, 1/20/99

9. DP Barcode D255738, D. Drew/M. Centra, 11/3/99

10. HED concluded (DP Barcode D188371, P. Deschamp, 3/4/93) that metabolism studies conducted at exaggerated rates on wheat and soybean would support seed treatment uses on barley, beans, corn, cotton, peanuts, peas, safflower, sorghum, soybeans, and wheat. Adequate metabolism studies on cotton, soybean, and wheat (DP Barcodes D224428, D228163, and D244973; D Hrdy/D. Drew; 5/30/97, 11/14/97, and 10/29/98) support the residue data requirements for these seed treatment uses.

11. The registrant is no longer supporting uses on tomatoes grown domestically. In order to establish a tolerance on imported tomatoes, additional field trial data, as outlined in the EPA Import Tolerance Guidance document (HED SOP 98.6), are required.

12. The registrant is no longer supporting uses on strawberries.

13. DP Barcode D244960, S. Law/D. Soderberg, 1/19/99

14. As residues of etridiazole and the monoacid metabolite were nondetectable in soybean seed and wheat grain from the exaggerated rate (10x) soybean and wheat metabolism studies, processing studies and tolerances are not required for the processed fractions of barley, corn, peanuts, safflower, sorghum, soybeans and wheat.

15. DP Barcode D244963, D. Drew, 12/3/98

16. If the registrant wants shorter PBIs than those recommended by the Agency in the review of the confined rotational crop study, limited field trial data are required.

APPENDIX B
Etridiazole
HANDLER AND POST-APPLICATION EXPOSURE
RISK ASSESSMENT

Tables B1-B9

APPENDIX B
Etridiazole
HANDLER AND POST-APPLICATION EXPOSURE
RISK ASSESSMENT

Tables B1-B9

Note:

Explanation of column headings for Etridiazole handler risk assessment tables.

Application rates represent the highest rates (from all labels with that formulation type) for various agricultural crops and turf applications. These rates are expressed as: low, mid-range (med), and maximum (high). This translates to the highest application rate for various crops. Separate categories (such as mixing/loading WP for chemigation vs. groundboom) are presented because of the distinct differences in application rates and acres treated. More or less categories may be used to represent the handler exposure in the final version.

Application rates are generally in lbs ai/acre. However, exceptions exist, such as lbs ai/lbs seed treated. Low-pressure handwand application is expressed in lbs ai/thousands of square feet. High-pressure handwand application rates are in lbs ai/gallon. Likewise, the number of units treated will correspond, for example:

lbs ai/acre x acres/day = lbs ai/day

The number of treatments per year is also based on label information. However, the "private", farmer, or golf-course grounds supervisor, may treat different areas or crops at different times. Generally, this column will be equal to the label maximum number of applications. Sometimes it is lower or higher based on use information. The "commercial" number of treatments is the estimated number of applications for a professional pesticide applicator not associated with a single location. The "default," used in the absence of specific information, is 10 times the private applicator rate.

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors			
Mixing/Loading Wettable Powder for Groundboom Application to Golf Course Turf (1a) or chemigation (1b)	PHED V1.1	(1a) 40 acres. (1b) 2 acres	**Single Layer, No Gloves:** Dermal replicates = 22-45, ABC grade. Hand replicates = 7, ABC grade. **Low Confidence** due to the low number of hand replicates; medium confidence in inhalation data. **Single Layer, Gloves:** "Best Available" grades: Inhalation ABC grades; 44 replicates; Hand replicates = 24, ABC grade. **Medium Confidence.** **Engineering Controls** (to represent water-soluble packets): "Best Available" grades: Hands acceptable grade; dermal and inhalation all grades. Hands = 5 replicates; dermal =6 to 15 replicates; inhalation = 15 replicates. Low confidence in hands, dermal and inhalation data. PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator.
Loading Granular for In-Furrow Application (2)	PHED v 1.1	80 acres / 230[U]	Single layer, no gloves: Dermal replicates = 33 - 78, ABC grade. Hand = 10 replicates, All grade. **Low Confidence** due to the poor grade quality of the hand replicates and low replicate number. Single Layer, gloves: Dermal replicates = 33 - 78, ABC grade. Hand = 45 replicates, AB grade. **Medium Confidence** Coveralls over single layer, plus gloves: Dermal replicates = 12 - 59, ABC grade. Hand = 45 replicates, AB grade. **Low Confidence** due to the low replicate number for many body parts. Inhalation: 58 replicates, AB grade. **High Confidence** Engineering Control: No data available.

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixing/Loading Liquid (EC/FC) for In-Furrow Application (3a)	PHED v. 1.1	80 acres / 230[b]	Single layer, no gloves: Dermal = 72 to 122 replicates, AB grade. Hand = 53 replicates, AB grade. **High Confidence** Single layer, gloves: Dermal = 72 to 122 replicates, AB grade. Hand = 59 replicates, AB grade. **High Confidence** Inhalation: Replicates = 85, AB grade. **High Confidence.**
Mixing/Loading Liquid (EC) for On-Farm Seed Treatment (3b)	PHED v. 1.1	1400 lbs cotton seed 7200 lbs peanut seed (for 80 A/day)	
Commercial Seed Treatment Loader/Applicator: Liquid Formulation (3c)	Uniroyal Data	330,000 lbs seed	See Study Review; based on geometric mean of data and "typical" volume of seed handled per day.
Commercial Seed Handler/Bagger: Liquid Formulation (3d)	Uniroyal Data	330,000 lbs seed	See Study Review; based on geometric mean of data and "typical" volume of seed handled per day.
Loading Dust for Commercial Seed Treatment (WP Surrogate) (4)	PHED v. 1.1	330,000 lbs seed	See Wettable Powder (1a); wettable powder has similar particulate size to dusts therefore used as a surrogate when there is a lack of data. PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator. No Data for Engineering Control

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Applicator Descriptors			
Applying Liquid to Golf Course Turf with a Groundboom Sprayer (5a)	PHED V1.1	40 acres.	Single layer, no gloves: Dermal replicates = 23 to 42, AB grade. Hand replicates = 29, AB grade. The neck location is limited to 23 observations; the next lowest number of observations is 32. **High Confidence.** Single layer, gloves: Dermal replicates = 23 to 42, AB grade. Hand replicates = 21, ABC grade. The neck location is limited to 23 observations; the next lowest number of observations is 32. **Medium Confidence**. Inhalation: 22 replicates, AB grade. **High Confidence** Engineering Control: Enclosed cab (groundboom): Dermal replicates = 20 to 31, ABC grade. Hand replicates = 16, ABC grade. **Medium Confidence**; inhalation: 16 replicates, AB grade. **High Confidence**
Applying Liquid In-Furrow to Soil (5b)	PHED v. 1.1	80 / 230[U] acres	
Loading and Applying Granular In-Furrow to Soil (6)	PHED v. 1.1	80 / 230[U]	Single layer, no gloves: Dermal Replicates = 1 to 5, AB grade. Hand replicates = 5, AB grade. **Low Confidence** due to inadequate replicate number. Single layer, gloves: Dermal replicates = 1 to 5, AB grade. Hand replicates = 0. **Low Confidence** due to inadequate replicate number. **NOTE**: Gloved hand replicates are unavailable for this exposure scenario. The only way to estimate gloved hand exposure is to reduce the "no glove" hand value by 90%. Inhalation: 5 replicates, AB grade. **Low Confidence** due to the low replicate number.
Mixer/Loader/Applicator Descriptors			
Mixing, loading and Applying Liquid (EC/FC) In-Furrow (groundboom MLAP surrogate) (7)	PHED v. 1.1	80 / 160[U]	Single layer, no gloves: Dermal = 17 to 67, ABC grade. Hand = 29 replicates, ABC grade. **Medium Confidence** Single layer, gloves:Dermal = 17 to 67, ABC grade. Hand = 32 replicates, AB grade. **Medium Confidence.**
Mixing/Loading/Applying as a Seed Treatment (dry) in planter box (8a)	Fenske Study data	1440 lbs seed (study data and cotton data)	All data were for gloved hands; seed treatment only, not planting; 60 replicates (see study).

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Treating Seed Manually Using Liquid (EC/FC) formulation on Farm (8b)	PHED v. 1.1 (surrogate)	1440 lbs seed (study data and cotton data)	No chemical-specific data: surrogate liquid mixer/loader (4a)
Mixing/Loading/Applying EC/FC as Liquid Drench using Low-pressure Hand Wand (9)	PHED v. 1.1	50 gallons at final dilution	Single layer, no gloves: Dermal replicates = 9 to 80, ABC grade. Hand replicates = 70, All grade. **Low Confidence** due to inadequate replicate number and low hand grades used (lots of "E" grade.) Single layer, gloves: Dermal replicates = 9 to 80, ABC grade. Hand replicates = 10, ABC grade. **Low Confidence** due to inadequate replicate number. The gloved hand estimates are based almost entirely on non-detects. Inhalation: 80 replicates, ABC grade. **Medium Confidence**. PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator Engineering controls not feasible.
Mixing/Loading/Applying EC as Liquid Drench using High-pressure Hand Wand (10)	PHED v. 1.1	1000 gallons	Single layer, no gloves: Dermal replicates = 7 to 13, AB grade. Hand replicates = 0. "No glove" hand data are unavailable for this use scenario. (2 of 13 nondetect). **Low Confidence** Single layer, gloves: Dermal replicates = 7 to 13, AB grade. Hand replicates = 13, C grade. **Low Confidence** due to inadequate replicate number. Inhalation: 13 replicates, A grade. **Low Confidence** due to inadequate replicate number.
Loading and Applying Granular Formulation to Golf Course Turf Using a Belly Grinder (11)	PHED v. 1.1	1 acre	Single layer, no gloves:Dermal replicates = 29 to 45, ABC grade. Hand replicates = 23, ABC grade. **Medium Confidence**. Single layer: gloves: Dermal replicates = 29 to 45, ABC grade. Hand replicates = 20, All grades. **Low Confidence** Inhalation: 40 replicates, AB grade. **High Confidence** PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Loading and Applying Granular Formulation to Golf Course Turf Using Push-Type Spreader (12)	PHED v. 1.1	5 acres	Single layer, no gloves: Dermal replicates = 0 to 15, C grade. Hand replicates = 15, C grade. **Low Confidence** due to inadequate replicate number. There are no head or neck replicates for this clothing scenario. All other body parts contain 15 replicates. Single layer, gloves: Dermal replicates = 0 to 15, C grade. Hand replicates = 0. **Low Confidence** due to inadequate replicate number. There are no head, neck or hand replicates for this clothing scenario. All other body parts contain 15 replicates. Inhalation: 15 replicates, B grade. **High Confidence**.
Loading and Applying Granular Formulation to Golf Course Turf Using Tractor-drawn Spreader (13)	PHED v. 1.1	5 acres	Add scenarios (2) and (6)
Mixing, Loading, and Applying WP to Golf Course Turf with Ground Boom (14)	PHED v. 1.1	40 acres	Combine Scenarios (1a) and (5a) Engineering: WSB or enclosed-cab Groundboom (5b) PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator
Loading and Applying Granules to Potting Soil (15)	PHED v. 1.1	10 cubic yards	Use hand dispersing granules as surrogate (same as 24): Single layer, no glove: Dermal replicates = 16, ABC grade. Hand replicates = 0. **Low Confidence** due to lack of "no glove" replicates for this use scenario. Single layer, glove: Dermal replicates = 16, ABC grade. Hand replicates = 15, ABC grade. **Medium Confidence**. The 15 hand replicates are all nondetect (LOQ = 41 μg). Inhalation: 16 replicates, ABC grade. **Medium Confidence**. PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator
Loading and Applying Wettable Powder to Potting Soil (16)	PHED v. 1.1	10 cubic yards	Use mixing/loading WP as surrogate (mixed dry): (1a)

Table B1: Exposure Scenario Descriptions for the Use of Etridiazole			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Loading and Applying Granules to Soil using Belly Grinder (17,18)	PHED v. 1.1	1 acre	See Scenario 11 PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator
Loading and Applying Granules to Soil using Push-Type Spreader (19,20)	PHED v. 1.1	1 acre	See Scenario 12 PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator
Loading and Applying Granules to Soil using Tractor-Drawn Spreader(21,22)	PHED v. 1.1	5 acres	See Scenario 13 PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator
Loading/Applying Granular via Power Dust Blower (23)	NO DATA	NO DATA	NO DATA
Applying Granules by Hand to Soil Trench or Turf (24)	PHED v. 1.1	5000 sq. ft.	Single Layer, No Glove: Dermal replicates = 16, ABC grade. Hand replicates = 0. **Low Confidence** due to lack of "no glove" replicates for this use scenario. Single Layer, gloves: Dermal replicates = 16, ABC grade. Hand replicates = 15, ABC grade. **Medium Confidence**. Inhalation: 16 replicates, ABC grade. **Medium Confidence** PHED data used for baseline,50% Protection Factors (PFs) added for Coveralls; 90% Inhalation Protection Factor added for Organic Vapor/Pesticide Respirator

[a] Standard Assumptions based on an 8-hour work day as estimated by HED, or BEAD data, or Registrant data. The area treated per day also represents amount to be mixed up per day.

U Uniroyal estimated acreage/day

[b] "Best Available" grades are defined by HED SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates

Table B2: Worker Exposure Calculated from Uniroyal Study of Vitavax Application in Commercial Seed Treatment Using Terra-Coat L-205N Application Rates

Level of Protective Equipment	Handler Job Description	Dermal and Inhalation Total Unit Dosage (mg/lb ai)[a]	Lb Treated per Day[b]	Label Application Rate:Terra-Coat Liquid (lb ai/lb seed treated)	Total Dose (mg/kg/day)	IT MOE[d]	Work days/Year	LADD (mg/kg/day)	Cancer[f]
Single Layer with Gloves	Loader/Applicator	0.064	330000	0.00016	0.048	99	60	4.0E-03	1.3E-04
Single Layer with Gloves	Loader/Applicator	0.064	800000	0.00016	0.12	40	60	NA	NA
Single Layer with Gloves	Seed Handler	0.0024	330000	0.00016	0.0018	2500	60	1.5E-04	5.0E-06
Single Layer with Gloves	Seed Handler	0.0024	800000	0.00016	0.0044	1000	60	NA	NA
Single Layer No Gloves (calculated)	Loader/Applicator	0.356	330000	0.00016	0.27	18	60	2.2E-02	7.3E-04
Single Layer No Gloves (calculated)	Loader/Applicator	0.356	800000	0.00016	0.65	6.9	60	NA	NA
Single Layer No Gloves (calculated)	Seed Handler	0.015	330000	0.00016	0.011	420	60	9.3E-04	3.1E-05
Single Layer No Gloves (calculated)	Seed Handler	0.015	800000	0.00016	0.027	160	60	NA	NA

IT = Intermediate-Term

NA = Not applicable to this scenario: cancer risks are based on "typical" application rates and volumes, not the higher rate.

[a]Total (Dermal + Inhalation) Unit Dose was calculated from Vitavax study for lindane residues MRID 447315-01; inhalation dose less than 1% of total.

[b] Pounds treated per day based on study findings and equipment manufacturer's specifications; typical and high capacity used.

[c]Total (Dermal + Inhalation) Daily Dose (mg ai/kg/day) = (mg/lb ai) x lb treated/day * application rate (mg/lb seed) / Body weight (70kg for intermediate-term) x Absorption (100%)

[d]MOE = NOAEL (mg/kg/day) / Daily Dose (mg/kg/day); where intermediate-term NOAEL = 4.8 mg/kg/day

[e]LADD = Lifetime Avg Daily Dose = $\frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr * 35 years working}}{\text{70 years (lifetime) x 365 days/yr}}$

[f]Cancer risk = LADD x Q_1* [0.0333 (mg/kg/day)$^{-1}$]

Table B3: MOE and Cancer Risk Estimate for On-Farm Dust Formulation Seed Treatment
Based on Data from Fenske et al. Study; Mixer/Loader, Single Layer PPE With Gloves

Formulation	Dermal Unit Dosage (mg/lb ai)[a]	Inhalation Unit Dose (mg/lb ai)[a]	Typical Lb Treated per Day[b]	Application Rate (lb ai/lb seed) Cotton	Dermal Dose (mg/day)	Inhalation Dose (mg/day)	Total Dose (mg/day)[c]	ST MOE[d]	IT/LT MOE[e]	LADD (mg/kg/day)[f]	Cancer[g]
Terraclor Super X 20-5	10.4	0.0024	1440	0.0005	7.5	0.0017	7.5	130	45	8.9E-03	3.0E-04

Mixer/Loader Only. No Application Data.
Formulation adjusted for Terraclor Super X 20-5 (dust formulation) application rate.
Study findings adjusted for body surface areas per Exposure Factors Handbook 1997 and standard respiratory rate for handlers of 29 l/min.
IT = Intermediate-Term duration; ST = Short-term duration
Cancer risks are based on "typical" application rates and volumes

[a] Unit Doses (dermal and inhalation) were calculated from published study (see References) measuring lindane residues; note inhalation dose less than 1% of total.

[b] Pounds treated per day based on study findings and equipment and Registrant-submitted data for cotton seed application.

[c] Total (Dermal + Inhalation) Daily Dose (mg ai/kg/day) = (mg/lb ai) x lb treated/day * application rate (mg/lb seed) / Body weight (70kg for intermediate-term) x Absorption (100%)

[d] ST = Short-term MOE = NOAEL (mg/kg/day) / Daily Dose (mg/kg/day); where short-term NOAEL = 15 mg/kg/day; 60 kg b.w.

[e] MOE = NOAEL (mg/kg/day) / Daily Dose (mg/kg/day); where intermediate-term NOAEL = 4.8 mg/kg/day; 70 kg b.w.

[f] LADD = Lifetime Avg Daily Dose = $\frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr [60 days/yr] * 35 years working}}{\text{70 years (lifetime) x 365 days/yr}}$

[g] Cancer risk = LADD x Q_1* [0.0333 (mg/kg/day)$^{-1}$]

Table B4: Etridiazole Handler Risk Assessment: Short-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls over Clothing and Organic Vapor Respirator			Engineering Controls: Soluble Bag for WP; Gloves for M/I Only		
Exposure Scenario	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE
(1a) Mixing/Loading Wettable Powder for Turf/Golf Course Groundboom Application:Low Rate	3.2	280	3.2	70	280	56	90	2800	87	1200	4.9E+04	1200
(1a) Typical Rate	1.6	140	1.6	35	140	28	45	1400	43	600	2.5E+04	590
(1a) High Rate	0.80	69	0.79	17	69	14	22	690	22	300	1.2E+04	290
(1b) Mixing/Loading Wettable Powder for Chemigation Application (lb/1000 Gal):Low Rate	320	2.7E+04	310	6600	2.7E+04	5300	NE	NE	NE	NE	NE	NE
(1b) Typical Rate	160	1.4E+04	160	3500	1.4E+04	2800	NE	NE	NE	NE	NE	NE
(1b) High Rate	110	9500	110	2400	9500	1900	NE	NE	NE	NE	NE	NE
(2) Loading Granular for in-Furrow Application: UniRoyal Estimated Rate	2300	1.2E+04	1900	4700	1.9E+04	3800	NE	NE	NE	NE	NE	NE
(2) Typical Rate	5600	2.8E+04	4600	6.8E+03	2.8E+04	5500	NE	NE	NE	NE	NE	NE
(2) High Rate	3500	1.7E+04	2900	4.3E+03	1.7E+04	3400	NE	NE	NE	NE	NE	NE
(3a) Mixing/Loading EC/FC (Liquid) for In-furrow Application: Low Rate	11	2.6E+04	11	1400	2.6E+04	1300	NE	NE	NE	NE	NE	NE
(3a) Typical Rate	20	4.9E+04	20	2.6E+03	4.9E+04	2400	NE	NE	NE	NE	NE	NE
(3a) High Rate	10	2.5E+04	10	1.3E+03	2.5E+04	1200	NE	NE	NE	NENE	NE	NE
(3b) Mixing/Loading Liquid for On-Farm Seed Treatment: Low (Peanuts)	550	1.3E+06	550	7.0E+04	1.3E+06	6.6E+04	NE	NE	NE	NE	NE	NE
(3b) Typical (Peanuts)	280	6.7E+05	280	3.5E+04	6.7E+05	3.3E+04	NE	NE	NE	NE	NE	NE
(3b) High (Cotton)	350	8.3E+05	350	4.4E+04	8.3E+05	4.1E+04	NE	NE	NE	NE	NE	NE
(3c) Loader/Applicator: EC/FC Liquid for Commercial Seed Treatment: Typical Rates (Uniroyal Study)	49	1.2E+04	48	280	1.2E+04	270	NE	NE	NE	NE	NE	NE
(3c) High Volume	20	5100	20	110	5.2E+03	110	NE	NE	NE	NE	NE	NE
(3d) Seed Handler/bagger: Liquid for Commercial Seed Treatment: Typical Rates (Uniroyal Study)	1200	9.7E+04	1200	7900	9.7E+04	7300	NE	NE	NE	NE	NE	NE
(3d) High Volume	480	4.0E+04	480	3300	4.0E+04	3000	NE	NE	NE	NE	NE	NE

Table B4: Etridiazole Handler Risk Assessment: Short-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls over Clothing and Organic Vapor Respirator			Engineering Controls: Soluble Bag for WP, Gloves for M/L Only		
Exposure Scenario	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE
(4) Loading Dust for Commercial Seed Treatment: (WP surrogate) Low Rate	12	1000	12	260	1000	200	330	NE	NE	NE	NE	NE
(4) Typical Rate	5.9	510	5.8	130	510	100	170	5.1E+03	160	NE	NE	NE
(4) High Rate	0.61	52	0.60	32	130	26	41	1300	40	560	2.3E+04	540
(5a) Applying to Turf/Golf Course with Groundboom Sprayer: Low Rate	680	1.3E+04	800	850	1.6E+04	800	NE	NE	NE	NE	NE	NE
(5a) Typical Rate	420	8000	400	420	8.0E+03	400	NE	NE	NE	NE	NE	NE
(5a) High Rate	210	4000	200	210	4.0E+03	200	NE	NE	NE	NE	NE	NE
(5b) Applying Liquid In-furrow (Groundboom Surrogate): Low Rate	2200	4.1E+04	2100	2200	4.1E+04	2100	NE	NE	NE	NE	NE	NE
(5b) Typical Rate	4200	8.0E+04	4000	4.2E+03	8.0E+04	4000	NE	NE	NE	NE	NE	NE
(5b) High Rate	2100	4.0E+04	2000	2.1E+03	4.0E+04	2100	NE	NE	NE	NE	NE	NE
(6) Combined Loading + Applying Granules In-Furrow to Soil: Low Rate	1100	6700	920	2200	6700	1700	NE	NE	NE	NE	NE	NE
(6) Typical Rate	2000	1.3E+04	1800	4.3E+03	1.3E+04	3200	NE	NE	NE	NE	NE	NE
(6) High Rate	1600	1.0E+04	1400	3.4E+03	1.0E+04	2600	NE	NE	NE	NE	NE	NE
(7) M/L/Applying EC/FC In-Furrow to Soil: Low Rate	120	3.4E+04	120	2100	2.3E+04	1900	NE	NE	NE	NE	NE	NE
(7) Typical Rate	160	4.6E+04	160	2.8E+03	3.1E+04	2600	NE	NE	NE	NE	NE	NE
(7) High Rate	80	2.3E+04	80	1.4E+03	1.5E+04	1300	NE	NE	NE	NE	NE	NE
(8) Mixing/Loading/ Applying as a Seed Treatment (dry) in planter box [Fenske study data] (per lb seed)	NO UN-GLOVED DATA	5.2E+05	NO DATA	120	5.2E+05	120	NE	NE	NE	NE	NE	NE
(9) Mixing/Loading/ Applying EC/FC as Drench using Low Pressure Handwand:Typical (per Gallon diluted mixture)	140	4.8E+05	140	3.3E+04	4.8E+05	3.1E+04	NE	NE	NE	NE	NE	NE

Table B4: Etridiazole Handler Risk Assessment: Short-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls over Clothing and Organic Vapor Respirator			Engineering Controls: Soluble Bag for WP; Gloves for M/L Only		
Exposure Scenario	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE
(10) Mixing/Loading/ Applying EC/FC using High Pressure Handwand (ie, Nursery/Greenhouse): High Rate	330	6700	320	320	6.7E+03	310	NE	NE	NE	NE	NE	NE
(11) Loading+Applying Granules (1.3G) to Golf Course Turf using Belly Grinder: Typical Rate/Acre	20	3200	20	22	3.2E+03	21	35	3200	35	No Data	No Data	No Data
(12) Loading+Applying Granules (1.3G) to Golf Course Turf Using Push Type Spreader: Typical rate/Acre	14	6300	14	31	6.3E+03	31	53	6.3E+04	53	No Data	No Data	No Data
(13) Loading+Applying Granules (1.3G) to Golf Course Turf Using Tractor-pulled Spreader: (2 scenarios added) Typical Rate	4600	1.4E+04	3400	4.6E+03	1.4E+04	3500	NE	NE	NE	NE	NE	NE
(14) Combined Mixing/Loading +Applying WP to Golf Course Turf via Groundboom (2 scenarios added): Low Rate	3.2	270	3	53	220	42	66	2100	64	630	1.4E+04	600
(14) Typical Rate	1.6	140	2	33	140	27	41	1300	40	400	8.8E+03	380
(14) High Rate	0.80	68	0.8	16	68	13	21	670	20	200	4.4E+03	190
(15) Mixing/Loading Applying Granules to Potting Soil (per CU yd)	3.4E+05	1.7E+06	2.9E+05	4.2E+05	1.7E+06	3.3E+05	NE	NE	NE	No Data	No Data	No Data
(16) Mixing/Loading/ Applying WP to Potting Soil (per Cu Yd)	370	3.2E+04	370	7.62E+03	3.12E+04	6100	NE	NE	NE	NE	NE	NE
(17) Loading+Applying Granules (8G) to Soil using Belly Grinder: Typical Rate/Acre	5.80	930	5.7	6	930	6	10	930	9	No Data	No Data	No Data

Table B4: Etridiazole Handler Risk Assessment: Short-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls over Clothing and Organic Vapor Respirator			Engineering Controls: Soluble Bag for WP; Gloves for M/L Only		
Exposure Scenario	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE	Dermal ST MOE	Inhalation ST MOE	Combined ST Dermal & Inhalation MOE
(18) Loading+Applying Granules (5G) to Soil using Belly Grinder: Typical Rate/Acre	5.1	830	5.1	6	830	5.5	9	830	14	No Data	No Data	No Data
(19) Loading+Applying Granules (5G) to Soil Using Push Type Spreader: Typical rate/Acre	3.6	1600	3.5	8	1600	7.9	14	1.6E+04	15	No Data	No Data	No Data
(20) Loading+Applying Granules (8G) to Soil Using Push Type Spreader: Typical rate/Acre	4.0	1800	4.0	9	1800	8.8	15	1.8E+04	15	No Data	No Data	No Data
(21) Loading+Applying Granules (8G) to Soil Using Tractor-pulled Spreader: (2 scenarios added) Typical rate/ Acre	1300	4000	1000	1300	4000	1000	NE	NE	NE	No Data	No Data	No Data
(22) Loading+Applying Granules (5G) to Soil Using Tractor-pulled Spreader: (2 scenarios added) Typical rate/ Acre	150	440	110	150	440	110	NE	NE	NE	No Data	No Data	No Data
(23) Loading/Applying Granular via Power Dust Blower	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
(24) Dispersing Granules By Hand	4.9	1100	4.9	7.4	1100	7.3	13	1.1E+04	13	No Data	No Data	No Data

Note: table values were calculated using a spreadsheet and then rounded to two significant figures.
ST = Short Term (generally seven days or less)
'No Data' indicates data not available for that scenario.
"NE" = scenario not evaluated.
Equations used in this table include:

Daily dermal exposure (mg ai/day) = Unit exposure (mg ai/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)
[Note: (lb ai/acre) and (A/day) are replaced, respectively, with (lb ai/gal) and (gal/day), or lb ai/lb seed when appropriate.]

Daily exposure (mg ai/day) = [Unit exposure (μg/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)] / (1000 μg/mg)
Potential absorbed daily dermal or inhalation dose = (mg ai/kg/day) x Absorption (100%) / Body weight
Body weight = short-term 60 kg; intermediate-term 70 kg

MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)
$MOE_{Combined} = 1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$

Table B5: Etridiazole Handler Risk Assessment: Intermediate-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls Over Single Layer Clothing With Gloves and OV Respirator			Engineering Controls: Closed System or Soluble Bag (for WP), Gloves for M/L Only		
Exposure Scenario	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT /LT Dermal & Inhalation MOE
(1a) Mixing/Loading Wettable Powder for Turf/Golf Course Groundboom Application: Low Rate	1.2	100	1.2	26	100	21	33	1000	32	450	1.8E+04	440
(1a) Typical Rate	0.60	51	0.59	13	51	10	17	510	16	230	9.2E+03	220
(1a) High Rate	0.30	26	0.29	6	26	5	8	260	8	110	4.6E+03	110
(1b) Mixing/Loading Wettable Powder for Chemigation Application (lb/1000 Gal):Low Rate	120	1.0E+04	120	2600	1.0E+04	2000	NE	NE	NE	NE	NE	NE
(1b) Typical	61	5200	60	1300	5200	1100	NE	NE	NE	NE	NE	NE
(1b) High	41	3600	41	900	3600	720	NE	NE	NE	NE	NE	NE
(2) Loading Granular for in-Furrow Application: UniRoyal Estimated Rate	870	4300	720	1800	7200	1400	NE	NE	NE	NE	NE	NE
(2) Typical Rate	2100	1.0E+04	1700	2.5E+03	1.0E+04	2000	NE	NE	NE	NE	NE	NE
(2) High Rate	1300	6500	1100	1600	6500	1300	NE	NE	NE	NE	NE	NE
(3a) Mixing/Loading EC/FC (Liquid) for In-furrow Application: Low (Uniroyal Rate)	4	9700	4	510	9700	480	NE	NE	NE	NE	NE	NE
(3a) Typical Rate	8	1.8E+04	8	9.6E+02	1.8E+04	910	NE	NE	NE	NE	NE	NE
(3a) High Rate	4	9200	4	4.8E+02	9200	460	NE	NE	NE	NE	NE	NE
(3b) Mixing/Loading EC/FC for On-Farm Seed Treatment: Low Rate (Peanuts)	210	5.0E+05	210	2.6E+04	5.0E+05	2.5E+04	NE	NE	NE	NE	NE	NE
(3b) Typical (Peanuts)	100	2.5E+05	100	1.3E+04	2.5E+05	1.2E+04	NE	NE	NE	NE	NE	NE
(3b) High (Cotton)	130	3.1E+05	130	1.6E+04	3.1E+05	1.5E+04	NE	NE	NE	NE	NE	NE

Table B5: Etridiazole Handler Risk Assessment: Intermediate-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls Over Single Layer Clothing With Gloves and OV Respirator			Engineering Controls: Closed System or Soluble Bag (for WP), Gloves for M/L Only		
Exposure Scenario	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT /LT Dermal & Inhalation MOE
(3c) Loader/Applicator: EC/FC for Commercial Seed Treatment: Typical Rate (Uniroyal Study)	18	4.7E+03	18	100	4.7E+03	100	NE	NE	NE	NE	NE	NE
(3c) Loader/Applicator: Liquid for Commercial Seed Treatment: High Volume (Uniroyal Study)	7	1.9E+03	7	43	1.9E+03	42	No Data	No Data	No Data	No Data	No Data	No Data
(3d) Seed Handler/bagger: Liquid for Commercial Seed Treatment: Typical Rates (Uniroyal Study)	440	3.6E+04	430	3000	3.6E+04	2700	NE	NE	NE	NE	NE	NE
(3d) High Volume (Uniroyal Study)	180	1.5E+04	180	1224	1.5E+04	1100	NE	NE	NE	NE	NE	NE
(4) Loading Dust for Commercial Seed Treatment: Low (WP surrogate)	4.4	380	4	96	379	76	120	3.8E+03	120	1700	6.8E+04	1600
(4) Typical (WP surrogate)	2.2	190	2	48	190	38	62	1.9E+03	60	830	3.4E+04	800
(4) High (WP surrogate)	0.23	20	0.22	12	47	10	15	470	15	210	8.5E+03	200
(5a) Applying to Turf/Golf Course with Groundboom Sprayer: Low Rate	250	4.8E+03	240	320	6.0E+03	300	NE	NE	NE	NE	NE	NE
(5a) Typical Rate	160	3.0E+03	150	160	3.0E+03	150	NE	NE	NE	NE	NE	NE
(5a) High	79	1.5E+03	75	79	1.5E+03	75	100	1.5E+04	100	NE	NE	NE
(5b) Applying Liquid In-furrow: Low (Uniroyal Rate)	820	1.5E+04	770	820	1.5E+04	770	NE	NE	NE	NE	NE	NE
(5b) Typical Rate	1.6E+03	3.0E+04	1.5E+03	1600	3.0E+04	1500	NE	NE	NE	NE	NE	NE
(5b) High	790	1.5E+04	750	790	1.5E+04	750	NE	NE	NE	NE	NE	NE
(6) Combined Loader+Applicator Granules In-Furrow to Soil (Low) Uniroyal rate	400	2500	340	840	2500	630	NE	NE	NE	NE	NE	NE

Table B5: Etridiazole Handler Risk Assessment: Intermediate-term MOEs

	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls Over Single Layer Clothing With Gloves and OV Respirator			Engineering Controls: Closed System or Soluble Bag (for WP); Gloves for M/I Only		
Exposure Scenario	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT /LT Dermal & Inhalation MOE
(6) Typical Rate	770	4.8E+03	660	1.6E+03	4.8E+03	1210	NE	NE	NE	NE	NE	NE
(6) High Rate	600	3.8E+03	520	1.3E+03	3.8E+03	950	NE	NE	NE	NE	NE	NE
(7) Combined Loader+Applicator EC/FC In-Furrow to Soil (Uniroyal Rate)	44	1.3E+04	44	780	8500	720	NE	NE	NE	NE	NE	NE
(7) Typical Rate	60	1.7E+04	60	1.1E+03	1.1E+04	960	NE	NE	NE	NE	NE	NE
(7) High Rate	30	8.5E+03	30	526	5.7E+03	480	NE	NE	NE	NE	NE	NE
(8) Mixing/Loading/ Applying as a Seed Treatment (dry) in planter box [Fenske study data] (per lb seed)	No Data	1.9E+05	No Data	45	1.9E+05	45	No Data	No Data	No Data	No Data	No Data	No Data
(9) Mixing/Loading/ Applying EC/FC as Drench using Low pressure Handwand: Typical (per Gallon diluted mixture)	53	1.8E+05	53	1.3E+04	1.8E+05	1.2E+04	NE	NE	NE	No Data	No Data	No Data
(10) Mixing/Loading/ Applying EC/FC using High Pressure Handwand (ie, Nursery/Greenhouse): High	120	2.5E+03	120	120	2.5E+03	120	NE	NE	NE	No Data	No Data	No Data
(11) Loading+Applying Granules (1.3G) to Golf Course Turf using Belly Grinder: Typical Rate/Acre	7.5	1.2E+03	7	8	1.2E+03	8	13	1200	13	No Data	No Data	No Data
(12) Loading+Applying Granules (1.3G) to Golf Course Turf Using Push Type Spreader: Typical rate/Acre	5.1	2.4E+03	5	11	2.4E+03	11	20	2.4E+04	20	No Data	No Data	No Data

Table B5: Etridiazole Handler Risk Assessment: Intermediate-term MOEs												
	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls Over Single Layer Clothing With Gloves and OV Respirator			Engineering Controls: Closed System or Soluble Bag (for WP); Gloves for M/L Only		
Exposure Scenario	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT /LT Dermal & Inhalation MOE
(13) Loading+Applying Granules (1.3G) to Golf Course Turf Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	1700	5.1E+03	1300	1.7E+03	5.1E+03	1300	NE	NE	NE	NE	NE	NE
(14) Combined M/L/App WP to Golf Course Turf via Groundboom (2 scenarios added): Low	1.2	100	1	20	81	16	25	800	24	240	5.3E+03	230
(14) Typical Rate	0.60	51	0.60	12	51	10	15	500	15	150	3.3E+03	140
(14) High Rate	0.30	25	0.29	6	25	5	8	250	7	74	1.6E+03	71
(15) Mixing/Loading Applying Granules to Potting Soil (per CU yd)	1.3E+05	6.3E+05	1.1E+05	1.6E+05	6.3E+05	1.3E+05	NE	NE	NE	No Data	No Data	No Data
(16) Mixing/Loading/ Applying WP to Potting Soil (per Cu Yd)	140	1.2E+04	140	2900	1.2E+04	2300	No Data	No Data	No Data	No Data	No Data	No Data
(17) Loading+Applying Granules (8G) to Soil using Belly Grinder: Typical Rate/Acre	2.2	350	2	2	350	2	4	350	4	No Data	No Data	No Data
(18) Loading+Applying Granules (5G) to Soil using Belly Grinder: Typical Rate/Acre	1.9	310	2	2	310	2	3	310	3	No Data	No Data	No Data
(19) Loading+Applying Granules (5G) to Soil Using Push Type Spreader: Typical rate/Acre	1.3	610	11	3	610	3	5	6100	5	No Data	No Data	No Data
(20) Loading+Applying Granules (8G) to Soil Using Push Type Spreader: Typical rate/Acre	1.5	680	1.5	3	680	3	6	6800	6	No Data	No Data	No Data

Table B5: Etridiazole Handler Risk Assessment: Intermediate-term MOEs

Exposure Scenario	Baseline (Single Layer Clothing)			Single Layer Clothing With Chemical Resistant Gloves			Coveralls Over Single Layer Clothing With Gloves and OV Respirator			Engineering Controls: Closed System or Soluble Bag (for WP), Gloves for M/L Only		
	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT Dermal & Inhalation MOE	Dermal IT MOE	Inhalation IT MOE	Combined IT /L.T Dermal & Inhalation MOE
(21) Loading+Applying Granules (8G) to Soil Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	500	1500	370	500	1500	370	NE	NE	NE	NE	NE	NE
(22) Loading+Applying Granules (5G) to Soil Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	55	170	41	55	170	41	61	1700	59	No Data	No Data	No Data
(23) Loading/Applying Granular via Power Dust Blower	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
(24) Dispersing Granules By Hand	1.8	420	2	2.8	420	3	4.9	4200	4.9	No Data	No Data	No Data

Note: table values were calculated using a spreadsheet and then rounded to two significant figures.
IT = Intermediate Term, generally one week to several months duration.
"No Data" indicates data not available for that scenario.
"NE" indicates scenario not evaluated.
Equations used in this table include:

Daily dermal exposure (mg ai/day) = Unit exposure (mg ai/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)
[Note: (lb ai/acre) and (A/day) are replaced, respectively, with (lb ai/gal) and (gal/day), or lb ai/lb seed when appropriate.]

Daily exposure (mg ai/day) = [Unit exposure (μg/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)] / (1000 μg/mg)
Potential absorbed daily dermal or inhalation dose = (mg ai/kg/day) x Absorption (100%) / Body weight
Body weight = short-term 60 kg; intermediate-term 70 kg
MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)
$MOE_{Combined} = 1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$

Table B6: Etridiazole Handler: Cancer Risk Estimates										
Exposure Scenario	Private Applications Per Year	Commercial Applications Per Year	Baseline (Single Layer Clothing without Gloves)		Single Layer Clothing With Chemical Resistant Gloves		Coveralls Over Single Layer Clothing With Gloves and OV Respirator		Engineering Controls: Closed System or Soluble Bag (for WP); Gloves for M/L Only	
			(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	Single Layer with Gloves (Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk
(1a) Mixing/Loading Wettable Powder for Turf/Golf Course Groundboom Application:Typical	5	15	1.9E-03	5.6E-03	1.1E-04	3.2E-04	6.8E-05	2.0E-04	5.0E-06	1.5E-05
(1b) Mixing/Loading Wettable Powder for Chemigation Application (lb/1000 Gal):Typical	3	30	1.1E-05	1.1E-04	6.2E-07	6.2E-06	4.0E-07	4.0E-06	2.9E-08	2.9E-07
(2) Loading Granular for in-Furrow Application: UniRoyal Estimated Rate	1	5	3.0E-07	1.5E-06	1.5E-07	1.1E-06	NE	NE	NE	NE
(2) Loading Granular for In -furrow Application: Typical	3	12	3.8E-07	1.5E-06	3.2E-07	1.3E-06	NE	NE	NE	NE
(3a) Mixing/Loading EC (Liquid) for In-furrow Application: Low (Uniroyal rate)	1	5	5.4E-05	2.7E-04	4.5E-07	2.3E-06	3.2E-07	1.6E-06	1.6E-07	8.1E-07
(3a) Mixing/Loading EC/FC (Liquid) for In-furrow Application: Typical	3	12	8.6E-05	3.4E-04	7.2E-07	2.9E-06	5.1E-07	2.0E-06	2.6E-07	2.6E-06
(3b) Mixing/Loading EC/FC for On-Farm Seed Treatment: Typical (Peanuts)	3	12	6.4E-06	2.5E-05	1.2E-07	3.5E-07	NE	NE	NE	NE
(3c) Loader/Applicator: EC/FC (Liquid) for Commercial Seed Treatment: Typical Rates (Uniroyal Study)	20	60	2.4E-04	7.3E-04	4.3E-05	1.3E-04	No Data	No Data	No Data	No Data
(3d) Seed Handler/bagger: Liquid for Commercial Seed Treatment: Typical Rates (Uniroyal Study)	20	60	1.0E-05	3.1E-05	1.6E-06	4.8E-06	No Data	No Data	No Data	No Data
(4) Loading Dust for Commercial Seed Treatment: Typical (WP surrogate)	20	60	2.0E-03	6.0E-03	1.1E-04	3.4E-04	7.3E-05	2.2E-04	5.4E-06	1.6E-05
(5a) Applying to Turf/Golf Course with Groundboom: typical	5	15	7.3E-06	2.2E-05	7.3E-06	2.2E-05	5.5E-06	1.6E-05	2.5E-06	7.6E-06
(5b) Applying Liquid In-furrow: low (Uniroyal rate)	1	7	2.8E-07	2.0E-06	2.8E-07	1.4E-06	NE	NE	NE	NE
(5b) Applying Liquid In-furrow: (typical rate)	3	12	4.4E-07	1.8E-06	4.4E-07	1.8E-06	NE	NE	NE	NE

Table B6: Etridiazole Handler: Cancer Risk Estimates										
Exposure Scenario	Private Applications Per Year	Commercial Applications Per Year	Baseline (Single Layer Clothing without Gloves)		Single Layer Clothing With Chemical Resistant Gloves		Coveralls Over Single Layer Clothing With Gloves and OV Respirator		Engineering Controls: Closed System or Soluble Bag (for WP); Gloves for M/L Only	
			(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	Single Layer with Gloves (Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk
(6) Combined Loader + Applicator Granules In-Furrow to Soil (Low) Uniroyal Rate	1	5	6.4E-07	3.2E-06	3.5E-07	1.7E-06	NE	NE	NE	NE
(6) Combined Loader + Applicator Granules In-Furrow to Soil (typical)	3	12	9.9E-07	4.0E-06	5.4E-07	2.2E-06	NE	NE	NE	NE
(7) Mixer/Loader/ Applying EC/FC In-Furrow to Soil (Uniroyal rate)	1	7	5.0E-06	3.5E-05	3.1E-07	2.1E-06	NE	NE	NE	NE
(7) Mixing/Loading/ Applying EC/FC In-Furrow to Soil (typical rate)	3	12	1.1E-05	4.4E-05	6.8E-07	2.7E-06	NE	NE	NE	NE
(8) Mixing/Loading/Applying as a Seed Treatment (dry) in planter box [Fenske study data] (per lb seed)	7	21	No Data	No Data	3.4E-06	1.0E-04	No Data	No Data	No data	No Data
(9) Mixing/Loading/Applying EC/FC as Drench using Low pressure Handwand:Typical (per Gallon diluted mixture)	3	30	1.2E-05	1.2E-04	5.6E-08	5.6E-07	NE	NE	NE	NE
(10) Mixing/Loading/Applying EC/FC using High Pressure Handwand (ie, Nursery/Greenhouse): High	3	30	5.5E-06	5.5E-05	5.8E-06	5.8E-05	3.5E-06	3.5E-05	No Data	No Data
(11) Loading+Applying Granules (1.3G) to Golf Course Turf using Belly Grinder: Typical Rate/Acre	4	12	1.2E-04	3.5E-04	1.1E-04	3.3E-04	1.7E-05	1.7E-04	No Data	No Data
(12) Loading+Applying Granules (1.3G) to Golf Course Turf Using Push Type Spreader: Typical rate/Acre	4	12	1.7E-04	5.1E-04	7.7E-05	2.3E-04	1.1E-05	1.1E-04	No Data	No Data
(13) Loading+Applying Granules (1.3G) to Golf Course Turf Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	4	12	6.8E-07	2.0E-06	6.8E-07	2.0E-06	4.6E-07	1.4E-06	NE	NE
(14) Combined Mixing/Loading/ Applying WP to Golf Course Turf via Groundboom (typical rate)	5	15	1.9E-03	5.6E-03	1.1E-04	3.3E-04	7.3E-05	1.5E-04	7.8E-06	1.6E-05

Table B6: Etridiazole Handler: Cancer Risk Estimates										
Exposure Scenario	Private Applications Per Year	Commercial Applications Per Year	Baseline (Single Layer Clothing without Gloves)		Single Layer Clothing With Chemical Resistant Gloves		Coveralls Over Single Layer Clothing With Gloves and OV Respirator		Engineering Controls: Closed System or Soluble Bag (for WP); Gloves for M/L Only	
			(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	Single Layer with Gloves (Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk	(Private) Cancer Risk	(Commercial) Cancer Risk
(15) Loading + Applying Granules to Potting Soil (per CU yd)	3	9	6.2E-09	1.9E-08	5.3E-09	1.6E-08	NE	NE	NE	NE
(16) Mixing/Loading/Applying WP to Potting Soil (per Cu Yd)	3	9	4.8E-06	1.4E-05	2.9E-07	8.6E-07	NE	NE	NE	NE
(17) Loading+Applying Granules (8G) to Soil using Belly Grinder: Typical Rate/Acre	3	9	3.1E-04	9.2E-04	2.9E-04	8.6E-04	1.8E-04	5.3E-04	No Data	No Data
(18) Loading+Applying Granules (5G) to Soil using Belly Grinder: Typical Rate/Acre	3	9	3.4E-04	1.0E-03	3.2E-04	9.6E-04	2.0E-04	5.9E-04	No Data	No Data
(19) Loading+Applying Granules (5G) to Soil Using Push Type Spreader: Typical rate/Acre	3	9	5.0E-04	1.5E-03	2.2E-04	6.7E-04	1.3E-04	3.9E-04	No Data	No Data
(20) Loading+Applying Granules (8G) to Soil Using Push Type Spreader: Typical rate/Acre	3	9	4.4E-04	1.3E-03	2.0E-04	6.0E-04	1.1E-04	3.4E-04	No Data	No Data
(21) Loading+Applying Granules (8G) to Soil Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	3	9	1.8E-06	5.3E-06	1.8E-06	5.3E-06	1.2E-06	3.7E-06	No Data	No Data
(22) Loading+Applying Granules (5G) to Soil Using Tractor-pulled Spreader: Typical rate/ Acre (2 scenarios added)	3	9	1.6E-05	4.8E-05	1.6E-05	4.8E-05	1.1E-05	3.4E-05	No Data	No Data
(23) Loading/Applying Granular via Power Dust Blower	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
(24) Dispersing Granules By Hand, based on SOP	3	9	3.6E-04	1.1E-03	2.4E-04	7.2E-04	2.5E-05	7.4E-05	NA	NA

Note: table values were calculated using a spreadsheet and then rounded to two significant figures.
"No Data" indicates data or control method not available for that scenario.
NE = Scenario not evaluated; NA = not applicable to this scenario
Equations used in this table include:

Daily dermal exposure (mg ai/day) = Unit exposure (mg ai/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)
[Note: (lb ai/acre) and (A/day) are replaced, respectively, with (lb ai/gal) and (gal/day), or lb ai/lb seed when appropriate.]

Daily exposure (mg ai/day) = [Unit exposure (μg/lb ai) x Application Rate (lb ai/A) x Daily Treatment (A/day)] / (1000 μg/mg)
Potential absorbed daily dermal or inhalation dose = (mg ai/kg/day) x Absorption (100%) / Body weight

Body weight = short-term 60 kg; intermediate-term 70 kg

MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)

$MOE_{S1,Combined} = 1 / (1/MOE_{S1,dermal} + 1/MOE_{S1,inhalation})$

Cancer risk = LADD x Q_1^* [0.0333 (mg/kg/day)$^{-1}$]

LADD = Lifetime Avg Daily Dose = $\frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr * 35 years working}}{\text{70 years (lifetime) x 365 days/yr}}$

Table B7: Occupational Post-Application Exposure Risks:
Terrazole Turf Residues: Post Application Day 0 (12 Hour Post-Application Study Data):
MOEs and Cancer Risk

Person/Activity	Study Residue (μg/cm2)	Transfer Factor = cm^2/hr	Dose mg/kg/day (Study Data)	ST MOE	IT MOE	Activity (Days/ Year)	IT LADD (mg/kg/day)	Cancer Risk (Study)
Occupational Exposures								
Tractor-Mowing[a]	0.13	500	3.7E-03	3500	1300	120	6.1E-04	2.0E-05
Push-Mowing	0.13	1000	7.4E-03	1700	650	120	1.2E-03	4.0E-05
Potting/handling treated soil[b]	0.37[c]	NA	5.3E-3	2400	900	120	8.7E-04	2.9E-05

[a] Turf transferable residues study: EPA MRID 432878-02.

[b] Potting soil study: EPA MRID 442787-01.

[c] Soil residue = total dose as mg / 4 hr day from study; there is no appropriate transfer factor

Turf transferable residues study: EPA MRID 432878-02.

ST = Short-term exposure duration seven days or less

IT = Intermediate Term exposure duration, generally one week to several months.

[Calculations performed on a spreadsheet before rounding to two places; therefore there may appear to be errors due to rounding]

Dermal dose (mg ai/kg/day) = (TTR(t) [μg/cm^2] x Tc (cm^2/hr) x DA x 0.001 mg/μg conversion x # hours (4) worked(or played)/day) / body weight (70 kg)

"NA" indicates data not applicable for that scenario.

MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)

LADD = Lifetime Avg Daily Dose = $\frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr * 35 years working}}{\text{70 years (lifetime) x 365 days/yr}}$

Cancer risk = LADD x Q_1* [0.0333 (mg/kg/day)$^{-1}$]

Table B8: Post-application Handling of Seed Treated with Terrazole For Planting Cotton
Single Layer No Gloves Scenario

Formulation	Mixer/Loader + Applicator Unit Exposure: (mg/lb ai handled)		Application Rate (lb ai/100 lb cotton seed)	Dermal Dose (mg ai/day)	Inhalation Dose (mg ai/day)	MOE: Total Dose: Dermal + Inhalation		LADD:		Cancer Risk	
	Dermal	Inhalation				Short-Term	Intermediate-Term	Private Farm (7 days)	Commercial (20 days)	Private Farm (7 days)	Commercial (20 days)
Dust	0.018	0.0029	0.05	0.013	0.0021	60,000	22,000	2.1E-06	5.9E-06	6.8E-08	2.0E-07
Liquid			0.0625	0.016	0.0026	48,000	18,000	2.5E-06	7.3E-06	8.4E-08	2.4E-07

[Calculations performed on a spreadsheet before rounding to two places; therefore there may appear to be errors due to rounding]

Assumption: cotton seed treated using either dust or liquid at label rates shown in table.

Cotton seed planted over 80 acres = 1440 lbs seed handled per day.

Dose (mg ai/day) = PHED unit exposure for loading & applying granular formulation (mg/lb ai handled) x Application rate/lb seed x seed handled (lb/day)

Body weight = short-term 60 kg; intermediate-to-long term or cancer risk = 70 kg

MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)

LADD = Lifetime Avg Daily Dose = $\frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr * 35 years working}}{\text{70 years (lifetime) x 365 days/yr}}$

Cancer risk = LADD x Q_1* [0.0333 $(mg/kg/day)^{-1}$]

Table B9: Terrazole Turf Residues: Post Application Day 0 (12 hr Post-Application): MOEs and Cancer Risk							
Non-Occupational Exposures							
Person/Activity	Study Residue (μg/cm2)	Transfer Factor = cm2/hr	Dose mg/kg/day	ST MOE	Activity (Days/ Year)	LADD mg/kg/day	Cancer Risk Estimate
Golfing Adult (60 kg)	0.13	100	8.7E-04	1.7E+04	18	2.6E-05	8.7E-07

Turf transferable residues study: EPA MRID 432878-02.

[Calculations performed on a spreadsheet before rounding to two places; therefore there may appear to be errors due to rounding]

ST = Short Term exposure, generally less than one week

Dermal dose (mg ai/kg/day) = (TTR(t) [μg/cm^2] x Tc (cm^2/hr) x DA x 0.001 mg/μg conversion x # hours (4) played/day) / body weight (kg)

Body weight = short-term 60 kg; intermediate-to-long term or cancer risk = 70 kg

MOE = NOAEL (mg/kg/day) / Potential Daily Dose (mg/kg/day)

$$\text{LADD} = \text{Lifetime Avg Daily Dose} = \frac{\text{Absorbed daily dose (based on 70 kg body wt) x Exposure Days/Yr * 50 years playing}}{\text{70 years (lifetime) x 365 days/yr}}$$

Cancer risk = LADD x Q_1^* [0.0333 (mg/kg/day)$^{-1}$]

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Chemical:	**Etridiazole**
PC Code:	**084701**
HED File Code	**14000 Risk Reviews**
Memo Date:	**06/06/2000**
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