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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 5, 2000

MEMORANDUM

SUBJECT: Response to Registrant's 30-day Comments on Preliminary Risk Assessment for Terrazole

FROM: Robbi Farrell, Chemical Review Manager
Special Review and Reregistration Division (7508C)

TO: Etridiazole (Terrazole®) Public Docket

The registrant for the fungicide etridiazole (Terrazole®) , Uniroyal Chemical Company, submitted comments on the preliminary human health and environmental risk assessments as requested by the Agency in a letter dated January 21, 2000. Uniroyal was provided 30 days to review and make comments on errors and other issues of concern. A copy of their comments is attached. The Agency's response to those comments follows.

The preliminary human health and environmental risk assessments have been revised, in part to reflect the comments submitted by the registrant, and in part to reflect information that was not available at the time the preliminary assessments were prepared. In addition, the estimated environmental concentrations (EECs) of Terrazole in surface waters were refined to reflect use on tees, greens and fairways only rather than entire golf courses. The revised EECs are reported in *Terrazole: Refined Tier I Chronic Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment, May 26, 2000*.

Human Health Risk Assessment

1. **Comment:** The risk assessment stated that Terrazole is used to control *Rhizoctonia*. Uniroyal stated that Terrazole, when combined with another registered fungicide active ingredient, PCNB, is used to control *Rhizoctonia*. However, Terrazole itself has no commercial activity against *Rhizoctonia*.

Response: The Agency agrees and will delete reference to *Rhizoctonia* from the risk assessment. The results of the risk assessment will not be affected.

2. **Comment:** The registrant indicated that power dust blowers and belly grinders are not used to apply Terrazole, and so should not be considered in the risk assessment.

Response: It is the Agency's policy to assess the risk of each allowed method of application. Because the current labels do not prohibit the use of dust blowers and belly grinders, the use of this equipment was considered in the risk assessment. If Terrazole is not intended for use with this equipment, the registrant may want to consider refining its labeling to reflect only the equipment that may be used.

3. **Comment:** The registrant stated that Terrazole is not being marketed for seed treatment and therefore will not submit data to support that use.

Response: As long as seed treatment is a registered use, the Agency requires that there be adequate data to assess potential risk. The removal of this use from the label will be addressed in the risk management phase.

4. **Comment:** The multigeneration reproduction toxicity study in rats was identified as a data gap in the risk assessment. The registrant has submitted a proposal to upgrade the study.

Response: That proposal is currently undergoing review in the Agency's Health Effects Division.

5. **Comment:** The registrant asked that the requirement for a chronic toxicity study in dogs be held in abeyance until new study guidelines are finalized.

Response: The chronic toxicity study in dogs referenced in the risk assessment was conducted in 1966-68 and does not meet current guidelines for a food-use chemical; therefore, EPA is requiring a new study. The study guidelines are not being revised and the guideline remains unfulfilled.

6. **Comment:** The registrant suggests that risk to surface waters based on turf use would be insignificant because the total acres treated is small.

Response: The Agency acknowledges that the area affected by this use is small; however, on a localized basis, the impact is of concern in terms of both drinking water and ecological risk.

7. **Comment:** The registrant feels that the annual turf usage (acres treated) estimates used by the Agency for the non-occupational postapplication risk assessment are too high, and suggests a lower number that would be more accurate.

Response: A lower number of acres treated per year will not change the results of the risk assessment. The Agency's postapplication risk assessments are calculated using an estimated daily dose for one person entering a treated area.

8. **Comment:** The registrant feels that the Agency overestimated the number of times per year a golfer would be exposed to treated turf.

Response: The number of times per year a golfer would be exposed to treated turf were based on data in published literature which was cited in the risk assessment. However, even at the estimate used, this risk scenario is not of concern and so the results of the overall risk assessment will not change.

9. **Comment:** The registrant states that the turf application rates (7.6 lb ai/A) used for handlers and golfers is only applicable to newly seeded turf which would likely be restricted from access for 3-4 weeks after treatment, by which time the Terrazole would have degraded.

Response: The Agency acknowledges that this is correct. Some of the handler scenarios for turf use were assessed at low, typical and high rates of application. Of these scenarios, the risk estimates either are not of concern or will still be a concern even if the application rate is lowered. The postapplication assessment used data from a turf transferrable residue study submitted by Uniroyal. The resulting margin of exposure was 17,000 and thus is not of concern.

10. **Comment:** The registrant notes that commercial applicators are rarely, if ever, contracted by golf courses.

Response: The Agency makes the following distinction between private and commercial applicator for purposes of the cancer risk assessment for Terrazole. A private applicator is someone who applies Terrazole at the typical application rate to his/her own property, while a commercial applicator can be expected to make up to ten times as many applications per season. The Agency acknowledges that greenhouses, nurseries and golf courses usually have their own certified pesticide applicators, and so the Agency applied a factor of 3x to reflect the relatively greater potential for exposure in these commercial operations.

11. **Comment:** The registrant contends that the risk assessment represents a worst-case scenario because it assumes dietary and worker exposure due to seed treatment of the ten registered food crops, even though seed treatment is not currently being marketed.

Response: The Agency points out that the registrant could choose to market the product for seed treatment at any time. The intent of the risk assessment is to identify risks based on what exposures could occur under the current labeling.

12. **Comment:** The registrant states that Terrazole is not used on peanuts in the U.S.

Response: The Agency's information indicates that it was used on peanuts through 1994, but not 1995 through 1998. Even if Terrazole is not currently marketed for this use, the product remains registered for this use and must be assessed as if it were being used.

13. **Comment and Response:** See number 12 above.

Environmental Fate and Ecological Risk Assessment

1. **Comment:** The registrant states that they have provided additional information to support their findings in the soil photolysis study, and hope the study's status will be upgraded.

Response: The Agency has reviewed the new information and will not require that the study be repeated. This will be reflected in the final Reregistration Eligibility Decision (RED).

2. **Comment:** The registrant states that they have provided additional information to support their findings in the anaerobic aquatic metabolism study, and hope the study's status will be upgraded.

Response: The Agency has reviewed the additional information and will not require that the study be repeated. This will be reflected in the final RED document.

3. **Comment:** The registrant states that they have provided additional information to support their findings in the terrestrial field dissipation study, and hope the study's status will be upgraded.

Response: The Agency has reviewed the additional information and will not require that the study be repeated.

4. **Comment:** Uniroyal notes that the risk assessment identified a data gap for guideline 71-4, and that a bobwhite quail reproduction study had been submitted for this guideline.

Response: The Agency has now reviewed that study and found the results comparable to those of another study used in the risk assessment. Therefore, that guideline is fulfilled. This will be reflected in the final RED document.

5. **Comment:** The registrant submitted additional information to support their findings in the freshwater chronic toxicity studies on rainbow trout and water fleas.

Response: The Agency has reviewed the additional information and determined that neither study will need to be repeated. This will be reflected in the final RED document.

6. **Comment:** The risk assessment incorrectly stated that the EC_{50} for nontarget aquatic plants was 0.007 mg ai/L.

Response: The Agency acknowledges that the correct EC_{50} is 0.072 mg ai/L. However, even with the revised toxicity estimate, acute RQ values for golf course applications are of concern.

UNIROYAL CHEMICAL

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February 25, 2000

NR 450520-00

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Attention: Ms. Roberta Farrell, Chemical Review Manager
Special Review & Reregistration Board (H7508C)

Subject: **Terrazole® RED**
EPA Reg No. 400-413
Uniroyal's Response to EPA draft chapters

Dear Ms. Farrell:

Uniroyal Chemical Company, Inc. is submitting a response to the draft chapters of the Terrazole RED. We have not conducted a comprehensive review of your extensive risk assessments because of the limited time. We may submit additional comments later and trust that the Agency will consider those. Enclosed herein are comments we feel the Agency should address.

Human Health Risk Assessment

Executive Summary

1. page 1 - The first paragraph states that Terrazole is used to control *Rhizoctonia*. Terrazole is combined with another registered fungicide active ingredient, PCNB to control *Rhizoctonia* and *Pythium* in cotton. Terrazole itself has no commercial activity on *Rhizoctonia*. Since the RED is for etridiazole (Terrazole), and its activity, *Rhizoctonia* should be deleted for technical accuracy.

Handler Risk Assessment

2. page 8 – Handler risk assessment refers to "power blower application". Belly grinders and power dust blowers are not used and should be omitted from any exposure studies. Uniroyal will be glad to amend our label to restrict the use if necessary.

Tolerances Needed Under 40 CFR § 180.370

3. page 14 – The Agency states that there is a data gap for all seed handling activities and that "Data are required for both commercial and on-farm settings". Since the seed treatment uses are not currently being marketed, Uniroyal will not conduct the requested seed treatment exposure studies. The market does not justify further data generation for this use pattern. We do, however, request that the seed treatment crops be retained for tolerance purposes since the dietary risk is acceptable. We request that the tolerance proposals (on page 13 of the document) be pursued by the Agency. This action would cover crops grown from treated seed outside the US and is consistent with world wide harmonization efforts

Hazard Profile

4. page 18 – The multi-generation reproduction toxicity study in rats is defined as a data gap. Uniroyal responded to the Agency's review of the reproductive toxicity study with a proposal to upgrade this study (MRID 44968401)

5. page 18 - EPA is working on guidelines for the modified chronic oral toxicity study in dogs. Uniroyal would like to hold the requirement in abeyance until the EPA completes the new protocol.

Dietary Exposure (Drinking Water Sources)

6. page 45 – The estimated environmental concentrations of Terrazole in surface water was based on the turf (golf course) use. However, as this use accounts for less than approximately 6000 total acres treated, it seems unlikely that use of Terrazole on such limited acreage would significantly impact drinking water.

Non-Occupational Post-Application Exposure and Risks

TRADE SECRET

7. [redacted]

TRADE SECRET

8. page 82 – A golfer is assumed to play an average of 18 times per year. While this may be true, it is incorrect to assume exposure to Terrazole on each of the 18 times. Terrazole is applied for control of *Pythium* disease, which occurs primarily during periods of very high humidity with daytime temperatures above 84 degrees F, and nighttime temperatures greater that 68 degrees F. Because of these unusual environmental requirements, the disease is not a year round problem, and does not occur across the U.S. On an annual basis, approximately 54% of total Terrazole sales occurs in the southern Atlantic states, primarily during the months of August, September and October. 20% of the total sales occurs in New England and another 20% in the northern midwestern states, both in the July and August time period. Only 6% of the total sales occurs in Texas, with virtually no sales of Terrazole occurring west of the Rockies. Using a worst case scenario then, the assumption should be that exposure occurs only during 25% (3 months out of 12 in a year) of the average 18 times a year that a golfer plays, or 4.5 times per year. It also should be noted that the short seasonality of the disease generally requires only 3 - 4 applications during any one year, which further supports use of a worst case assumption of 4.5 exposures per year.

9. page 83 – The application rate used in exposure assessments for both turf workers and non-occupational exposure is the high label rate of 7.6 lbs. ai. / A. While it cannot be argued that this is, indeed, the high label rate, it should be noted that this rate is only used for application to newly seeded turf. That being the case, there is little, if any, post application exposure to Terrazole from this use, as newly seeded turf is always restricted from contact activities until the seed has germinated and the new seedlings have become established, usually 3 - 4 weeks after treatment. By this time, the Terrazole has certainly degraded. A more realistic assumption would be to use the high label rate for established turf, where immediate post application exposure is possible. This rate is 5 ozs. product / 1000 sq. ft., or 4.75 lbs. ai. / A. Further, it needs to be noted that the label only allows for use of this high rate on the initial application - all subsequent applications are made at rates between 1.9 - 3.8 lbs. ai. / A. Finally, it must be noted that the label has a restriction on the maximum amount applied in any given year- that amount is 20 ozs. of product / 1000 sq. ft., or 19 lbs. ai. per acre.

10. Appendix 6B - The etridiazole handler cancer risk estimate looks at the number of private and commercial applications made per year. Golf courses use in-house personnel to make their pesticide applications. Commercial applicators are rarely, if ever, used.

Summary of Use Patterns and Formulations

11. In general, the risk assessment to humans, both dietary and applicator exposure is exaggerated. This is because the Agency is considering all the seed treatment crops in their risk analysis. The agency should at least mention that their risk analysis is considered "worst case" because all registered use patterns are considered. The REAL exposure is many magnitudes less than reported in the Risk Assessment. The crops registered for seed treatment use consist of beans, corn, wheat, peanuts, peas, sorghum, barley, safflower, and soybeans. Cotton can be either seed treatment or in-furrow. However, as Uniroyal detailed in our "Smart" meeting with the Agency on 9/28/98 of the 5 registered products for seed treatment uses, none are currently being marketed.

12. page 56 – Some of the statements made on *page 56, Sec c. Registered Use Sites and Use Patterns*, are not accurate:

    a) "All of the dusts are formulated by..." should say registered rather than formulated. The products are not currently being formulated.

    b) "Only a limited amount of seed treatment ... is done in this country using this active ingredient..." should say, " Although there are registered products for seed treatment, it is not currently being sold for that use."

    c) Uniroyal is not aware of any seed treatment use on peanuts. The Agency should double-check its source of this information and revise the last sentence, which is inaccurate: "of these crops, peanuts have received a modest amount of treatments with etridiazole."

13. page 63 – Uniroyal is not aware of any use on peanuts in the US. therefore, the statement "Peanuts were used for the risk assessment as Bead has noted this is a current use crop." should be amended.

Environmental Fate and Ecological Risk Assessment

Environmental Fate Assessment

1. Page 18 – Appendix I - EPA noted that the results from the dark control of the soil photolysis study markedly differed from the results of the aerobic soil metabolism study in spite of the fact that both soils were the same. Uniroyal is providing a response that will reconcile the differences noted (Tab 1) and allow the study to be upgraded.

2. page ii – The Agency classified the Anaerobic Aquatic Metabolism study (MRID 43504305) as invalid. Uniroyal is submitting a response (Tab 2) to EPA's review indicate that, (I), soil was appropriately extracted to exhaustively remove radioactive residues, including etridiazole, and (2), anaerobicity was maintained throughout the incubation period based on dissolved oxygen and redox values that are included in the response.

3. page 22 – EPA's memorandum of 11/10/99 notes that the Terrazole Field Dissipation studies (MRID 44689601) conducted on turf was classified as invalid due to high variability in half-life estimates in turf. They also indicated storage stability deficiencies. The Agency further indicated that the study should be conducted on turf in one representative site. The registrant should also monitor volatiles in the field. Uniroyal is providing the Agency with kinetic calculations to determine etridiazole half-lives on turf at the two field sites as well as to explain reasons for the different values, where appropriate. Uniroyal also addresses the issue of storage stability of soil and turf as well as the issue of field volatility. It is Uniroyal's expectation that this response will make the turf dissipation acceptable and obviate the need for a further study.

Toxicity to Terrestrial Animals

4. page 30 – The Agency noted a data gap for guideline 71-4, avian reproduction study of bobwhite quail using technical grade active ingredient. A bobwhite quail reproduction study with Terrazole technical was submitted on July 12, 1995 (MRID No. 43744101).

Toxicity to Freshwater Aquatic Animals

5. page 33 – Uniroyal is including a response to the questions raised in EPA's letter dated February 8, 2000 (Tab 4) concerning the Terrazole trout early life stage and *Daphnia* chronic studies (MRID 42834604, and 42834605). This information in addition to the electronic copy of the biology data (survival, reproduction, length and dry weight) for the *Daphnia* study should fulfill the requirements for guideline 72-4(a) and 72-4(b). The three excel files are survival.xls, reprod.xls and lenwt.xls.

   a) In the trout early life stage test, an error was noted in the reporting of some control samples, and this has been corrected. The single replicate control sample that reported a finite level of Terrazole was attributed to analytical processing, and did not affect the study outcome.

b) In the *Daphnia* life cycle test, there were low levels of contamination in half of the control and solvent control samples between test days 0 and 14. Experiments to isolate the cause of the contamination indicated that it occurred during the actual analytical procedure. The results clearly showed that control daphnids were not exposed to Terrazole during the 21-day test.

6. page 36 – Please note that the EC_{50} for nontarget aquatic plant (algae) toxicity (*Kirchenaria subcapitata*) is 0.072 ppm, as stated in the report, and not 0.007 ppm, as stated in the assessment. (MRID No. 428346-06).

Should you have any questions, please call Betsy Katzman at (203) 393-2163.

Sincerely,

UNIROYAL CHEMICAL COMPANY, INC.

Betsy K Katz for
Willard F. Cummings
U.S. Registration Manager
Crop Protection
Research & Development

TRANSMITTAL BIBLIOGRAPHY

DATE: February 25, 2000

REFERENCE: Uniroyal's Response to EPA draft chapters

PRODUCT: Etridiazole EPA Reg No. 400-413

MRID # (by EPA)	VOL. #	GUIDELINE REF. #	CITATION
45052001	1	161-3	Schocken, M. J., (February 2000) Response for the Etridiazole Soil Photolysis Study. Unpublished report prepared by Uniroyal Chemical Company, Inc., Crop Protection R&D, 74 Amity Rd., Bethany, CT 06524-3402. 5 pages.
45052002	2	162-3	Schocken, M. J., (February 2000) Response for the Etridiazole Anaerobic Aquatic Metabolism Study. Unpublished report prepared by Uniroyal Chemical Company, Inc., Crop Protection R&D, 74 Amity Rd., Bethany, CT 06524-3402. 6 pages.
45052003	3	164-1	Schocken, M. J., (February 2000) Response for the Terrazole Field Dissipation. Unpublished report prepared by Uniroyal Chemical Company, Inc., Crop Protection R&D, 74 Amity Rd., Bethany, CT 06524-3402. 14 pages.
45052004	4	72-4(a) 72-4(b)	Lengen, M. R., (February 2000) DER Response for the Toxicity Tests with Terrazole and Rainbow trout and *Daphnia magna*. Unpublished report prepared by Uniroyal Chemical Company, Inc., Crop Protection R&D, 74 Amity Rd., Bethany, CT 06524-3402. 25 pages.