



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
WASHINGTON, D.C. 20460

June 06, 2003

MEMORANDUM

Subject: Response to Comments From The Bayer Environmental Science on Oxadiazon Risk Assessment [PC Code 109001, DP Barcode D290006]

From: Seyed Tadayon, Chemist
Reregistration Branch III
Health Effects Division 7509C

Thru: Cathy Eiden, Branch Senior Scientist
Reregistration Branch III
Health Effect Division 7509C

To: Mark Seaton, Chemical Review Manager
Special Review and Reregistration Division
Mail Code 7509C

The purpose of this document is to address the comments in a April 17, 2003 (received by HED May 06, 2003) letter from Bayer Environmental Science (BES) in response to the most recent Agency risk assessment document for oxadiazon.

The comments from this submission have been summarized below followed by the Agency response to each specific comment. The Bayer letter focused on different areas of the risk assessment process such as the drinking water intake, occupational risks and residential risks. This document addresses only those comments related to the occupational and residential aspects of the risk assessment.

BES comment:

Page 5 provides a use figure on golf courses of 77% and other document 77% or 65% (EFED risk assessment). The use figures should be harmonized within and between the different documents.

EPA response:

This error has been corrected in the revised chapter.

BES comment:

Page 8 provides a use figure on golf courses of 71% and other document 77% or 65% (EFED risk assessment). The use figures should be harmonized within and between the different documents.

EPA Response:

This error has been corrected in the revised chapter.

BES comment:

Page 27, Bayer finds this statement and the conclusion to be confusing. The two TTR studies (MRID# 449955-01 and 449955-02) were apparently not accepted by EPA because they used the modified California Roller sampling device and not the ORETF device. Bayer refers the Agency to the ORETF submission "Evaluation of Transferable Turf Residue Techniques (MRID# 4497203) which recommends the California roller as the ORETF technique for conducting TTR studies. Therefore, why were the studies not accepted when the modified California Roller technique and the ORETF Technique are identical ?

Bayer is also concerned about the statement that HED does not considered TTR values less than 1% of the application rate to be acceptable. Granular formulation have consistently been demonstrate to have TTR values less than 1% of the application rate. This statement appears to relate to the relationship between the generic residential SOP transfer coefficients of 14,500 cm²/hr and 8200 cm²/hr for children and TTRs less than 1% of the application rate (HED policy 12, revised 22 February 2001). Policy 12 states that the revised transfer coefficients should not be used with TTRs of less than 1% of the application rate. Based on policy 12, transfer coefficients of 43000 cm²/hr for adults and 8700 cm²/hr for children are to be used when the TTR values are less than 1%. Therefore, the oxadiazon TTR studies not considered to be acceptable should be reevaluated and used with higher transfer coefficients if the TTRs are less than 1%.

EPA response:

HED agrees that the California roller technique is the most efficient of all the measuring techniques to collect TTR data. However, a transfer coefficient (TC) measurement should be taken concurrently with the TTR measurement. In the absence of a concurrent TC measurement,

HED's Expo SAC Policy 12 indicates that the default TC values and 5% of application rate for TTR should be used to estimate short-term exposure.

In the submitted Bayer study, the TTR values measured were 0.07% of application rate for granular and 0.15% of application rate for liquid. HED Exposure SAC and the oxadiazon ORE RED chapter clearly address this policy issue. That is, if either condition applies:

- 1) TTR collected via California roller technique in absence of concurrent TC values, and/or
- 2) TTR values < 0.5% of application rate for granular and < 1% for liquid applications,

then HED uses default values as per residential SOP (Policy 12, revised 22 February 2001) for conducting exposure assessment.

The use of low TTRs with the current transfer coefficients may underestimate dermal exposure. HED further reviewed Science Advisory Council Exposure Policy 12 (February 22, 2001) and concluded that transfer coefficients of 43000 cm²/hr for adults or 8700 cm²/hr for children have been changed to 14,500 cm²/hr for adults and 5,200 cm²/hr for children (1-6 yrs) in the current revised SOP (February 22, 2001).

BES comment:

Page 33, the golf course transfer coefficients developed concurrent TTR monitoring using the modified California method. Therefore the TTRs obtained from the submitted Ronstar WP study should be used in lieu of the default 5% value.

EPA response:

The submitted study (MRID# 435178-01) measured the exposure associated with Jazzercise on turf. Jazzercise actions are significantly different from golfing actions, therefore, it is not appropriate to use the TTR values obtained from this study as surrogate data. HED used the standard default value from the SOP.

BES comment:

Page 35, TTR values should be based on the result of the Ronstar WP study and not the default values of 5%. Defaults stated in the residential sops are to be used only in the absence of chemical-specific data.

EPA response:

The tables on pages 36 (table 8), 37 (table 9) and 38 (table 10) of the risk assessment use the TTR values from study (MRID# 435178-01). The tables also show the risk *if* the standard default value is used. HED typically provides a range of risk estimates based on defaults and chemical specific data to SRRD, if required. However, risk managers base their final decision on all of the data shown for these scenarios.

BES comment:

Page 38, the Information in this table should be verified. Bayer does not understand how the percent values for the hand-to-mouth activities were derived, and why the TTR values are higher for the exposure from irrigated grass than the one for the non-irrigated grass, while the TTR based on study MRID 43517801 indicates the reverse situation. Values presented in Table 10 MRID 43517801 are different from the values presented in the revised Occupational and Residential Exposure Assessment document page 28 provides the following TTR values for non-irrigated and the irrigated plots: “ on day 0, the highest average turf-transferable residues (TTR) for non-irrigated plots was 1.22 μg per cm^2 and 0.694 μg per cm^2 on irrigated plot.”.

EPA Response:

The turf-transferable residues (TTR) values indicated in page 28 of Occupational and Residential Exposure Assessment document were obtained from the study MRID 43517801. This study was conducted with 3.0 lb ai/A. In Tables 8, 9 and 10 the TTR values have been adjusted to reflect the label rate of 4.0 lb ai/A. A correction has been made to Table 10 to present the correct TTR values for irrigated grass versus non-irrigated grass.