

US EPA ARCHIVE DOCUMENT



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

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

June 3, 1998

MEMORANDUM

**SUBJECT:** REVIEW OF DICOFOL OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT RED REBUTTAL (MRID No. 445528-01; Reregistration Case No. 0021; Chemical No. 010501) DP Barcode D246346.

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6/3/98

**TO:** Mary Rust, Biologist  
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**THRU:** Sue Hummel, Branch Senior Scientist  
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*Sue Hummel*

Rohm and Haas has submitted a rebuttal to the Agency's RED. This review of that rebuttal covers only the sections pertaining to the non-dietary occupational and residential assessments. The most significant aspect affecting the outcome of the risk assessment is the selection of the toxicological endpoints. Table 1 illustrates the differences in the selected toxicological endpoints. The combined effect of Rohm and Haas' short-term endpoint and dermal absorption value selected for the risk assessment results in an estimated risk of approximately 330 times lower [i.e., (Rohm & Haas NOEL 20 mg/kg/day / Agency NOEL 4 mg/kg/day) × (Agency dermal absorption 100% / Rohm & Haas dermal absorption 1.5%) = 333] than that selected by the Agency. The combined effect of Rohm and Haas' intermediate-term endpoint and dermal absorption value selected for the risk assessment results in an estimated risk of approximately 4,400 times lower than that selected by the Agency.

Table 1. Presentation of Toxicological Endpoints for Dicofol.

Selection	Endpoint	NOEL (mg/kg/day)	Dermal Absorption
Agency	Short-term (oral rabbits, developmental)	4	100 %
Rohm & Haas	Short-term (oral 90-day study of cortisol release in the dog)	20	1.5 %
Agency	Intermediate-term (oral dog, inhibition of ACTH stimulated cortisol release and oligospermatogenesis)	0.3	100 %
Rohm & Haas	Intermediate-term (oral 90-day study of cortisol release in the dog)	20	1.5 %

*Agency Response: The selection of the toxicological endpoints and dermal absorption value will be evaluated by the Hazard ID Committee. The methods in which Rohm and Haas has applied these data in the MOE calculations are acceptable.*

### **Residential Assessment**

The risks to residential **handlers** while mixing/loading and applying dicofol to turf were assessed in the RED using PHED exposure estimates for backpack sprayers, hose-end sprayers, and low pressure handwands. This handler assessment was conducted using the Agency's selected short-term endpoint of 4 mg/kg/day and 100 percent dermal absorption. The RED did not specifically estimate residential turf **postapplication** risks to children. Instead, the following statement was provided: *"based on the findings of the surrogate agricultural assessment, residential postapplication risks are also of concern."* Residential postapplication exposures are associated with intermediate-term durations (i.e., 7 to 90 days), and would have been assessed using the Agency's selected intermediate-term endpoint of 0.3 mg/kg/day and 100 percent dermal absorption.

Rohm and Haas responded to the residential assessment as follows: *"the risk assessment methods currently available for assessing these types of exposures are relatively crude in comparison to those for other types of exposures, and relevant data is under development for the postapplication exposures."* Therefore, *"the Dicofol Task Force agrees that residential uses should be deleted from all Dicofol labels until such time as an acceptable risk assessment can be demonstrated for residential exposures. Dicofol use on residential home lawns has been deleted from the label. This change is reflected in the revised EPA stamped label, dated August 26, 1996."*

*Agency Response: Based on the limited data available for residential exposure, the Agency concurs with Rohm and Haas and will reevaluate residential home lawn treatments when the data are submitted.*

### **Occupational Assessment**

**Handlers.** Rohm and Haas submitted revised short- and intermediate-term occupational handler exposure/risk tables. The changes in the MOEs are attributed to the selection of the toxicological endpoints and dermal absorption value as discussed above. Other changes in the parameters used in the exposure/risk calculations are detailed in the bullets below.

- The maximum application rate for citrus was lowered from 6 to 4 lb ai/A.

*The Agency concurs.*

- All wettable powder formulations will be packaged in water soluble packets and, therefore, open bag packaging was omitted from the submission.

*The Agency concurs.*

- Rohm and Haas added gloves, coveralls, and respirators to the mixer/loaders using water soluble packets for aerial applications.

*The Agency has reservations about adding PPE such as double layers of clothing and respirators in addition to engineering control as a protection factor derived mitigation measure.*

- Rohm and Haas added coveralls, and respirators to the mixer/loaders using closed systems for transferring liquid formulations for aerial applications.

*The Agency has reservations about adding PPE such as double layers of clothing and respirators in addition to engineering control as a protection factor derived mitigation measure.*

- Although Rohm and Haas has deleted the residential turf use from the labels until additional data are collected, the exposure/risk tables in the rebuttal contain handler assessments for "occupational" applications to lawns/ornamentals.

*The Agency requires that all residential turf uses be removed from the labels, even if the residential turf is treated by a PCO, until new data can be collected and the risks evaluated. PCO treated residential turf still has the potential for infant and children*

*postapplication exposures (e.g., playing on lawn and hand-to-mouth activities). Note: Although the occupational lawn/ornamental MOEs presented in the rebuttal are >100 for the high pressure handwand, backpack sprayer, hose-end sprayer, and low pressure handwand sprayer, the Agency's new policies would modify these assessments. The unit exposure for a handgun lawn sprayer would be substituted for the garden hose-end sprayer (resulting in a lower exposure potential). The backpack and low pressure handwand sprayers would only be assessed as a spot treatment, not a full coverage of 5 acres. The high pressure handwand scenario would only be assessed for occupational ornamental uses (i.e., not lawns) and the amount handled would be changed from 20 acres treated to 1,000 gallons of spray solution.*

**Reentry.** The Agency provided a "range finder" surrogate postapplication risk assessment in the RED. This surrogate assessment was conducted using the minimum (0.63 lb ai/A) and maximum (6 lb ai/A) application rates. In lieu of chemical-specific data, the Agency assumed that the initial dislodgeable foliar residue (DFR) values would be equal to 20 percent of the application rate. The Agency characterizes this assumption as representing the high-end of values that may occur. Furthermore, the Agency assumed that 10 percent of these residues would be expected to dissipate each day. The postapplication activities selected ranged from low potential of exposure (e.g., hoeing represented by a transfer coefficient of 500 cm<sup>2</sup>/hr) to high potential of exposure (e.g., citrus harvesting represented by a transfer coefficient of 10,000 cm<sup>2</sup>/hr). Using the Agency's selected intermediate-term endpoint of 0.29 mg/kg/day and 100 percent dermal absorption, the REIs ranged from 44 to 94 days.

Rohm and Haas responded to the Agency's surrogate reentry assessment in the following manner: "*Dislodgeable foliar residue studies, as required by the Agency Data Call-In of October 18, 1995, amended January 10, 1997, are presently in progress. When postapplication exposures are appropriately assessed using the results of these studies and the dermal exposure criteria determined from the 90 day dermal study in the dog and any additional bioavailability studies conducted, it is reasonable to anticipate that adequate (>100-fold) MOEs will be demonstrated for occupational post-application exposure scenarios. It is therefore inappropriate to reevaluate the Reentry Interval at the present time.*" Rohm and Haas also stated in the rebuttal that the DFR data for citrus (representative of orchard crops), cotton (representative of mid level crops), and cucumber (representative of low level crops) are being conducted and will be submitted as per the requirements of the Data Call-In. In addition, the dermal portion of the risk assessment (i.e., transfer coefficients) will be provided by using the results of the Agricultural Reentry Task Force (ARTF). Note: Dicofol registrants have been granted a waiver for inhalation exposure.

*Agency Response: The Agency will reevaluate the reentry exposure and REIs when the data are submitted.*

## Conclusion

The most significant aspect of the rebuttal effecting the MOE calculations was in the selection of the toxicological endpoints and dermal absorption value. The evaluation of these data is the responsibility of the Hazard ID Committee and out of the scope of this review. However, the combined effect of Rohm and Haas' selected short- and intermediate-term dermal endpoints and dermal absorption value results in estimated risks of approximately 330 and 4,400 times lower than that chosen by the Agency, respectively. Other aspects of the rebuttal include:

- Residential turf uses have been voluntarily deleted until new data are collect to evaluate residential risks. The occupational lawn applications at residential sites also need to be removed from the labels because of the postapplication concerns to infants and children.
- In general, the use of maximum PPE (i.e., coveralls over single layer clothing and respirators) is not an option when using engineering controls (i.e., water soluble packets (WSP) for wettable powder formulations and closed loading systems for liquid formulations). The MOEs presented in the rebuttal used PPE in combination with WSP and closed loading of liquid formulations.
- Additional data are currently being collected by Rohm and Haas to evaluate agricultural postapplication exposures.

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RDI: SVH: 6/3/98



13544

**R126056**

**Chemical: Dicolol**

**PC Code:  
010501**

**HED File Code: 11000 Chemistry Reviews**

**Memo Date: 6/3/1998**

**File ID: DPD246346**

**Accession #: 412-06-0194**

**HED Records Reference Center  
8/8/2006**