



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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JUN 2 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

MEMORANDUM:

SUBJECT: PP9F3758: Propiconazole (Tilt®, Orbit®) in Wild Rice, Apricots, Nectarines, Peaches, Plums, and Prunes. Amendment of April 20, 1993.
CBTS #11773
DP Barcode #D190499
EPA Reg. No.'s 100-618, 100-617, 100-702
No MRID #

FROM: María Isabel Rodríguez, Chemist *María Isabel Rodríguez*
Tolerance Petition Section III *June 2, 1993.*
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

THROUGH: Philip V. Errico, Section Head *P.V. Errico*
Tolerance Petition Section III
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

TO: Susan Lewis/Sidney Jackson
Product Manager Team #21
Registration Division (H7505C)

and

Albin Kocialski
Registration Section
Chemical Coordination Branch
Health Effects Division (H7509C)

In response to CBTS Review #10742 (M.I. Rodríguez, April 8, 1993, PP9F3758, #D183633, MRID #425114-01), Ciba-Geigy Corporation submitted a letter dated April 20, 1993 from Dr. Gregory R. Watson, Regulatory Manager. The package contains a Confidential Statement of Formula (CSF) for propiconazole {1-[(2-{2,4-dichlorophenyl}-4-propyl-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole} formulated as Tilt®.



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Discussion:

Since propiconazole has two optically active carbons and possible *cis/trans* configurations, the registrant was requested (CBTS Review 10742) to identify the active isomer(s) and, if necessary, provide a revised Confidential Statement of Formula listing them separate from the inactive isomer(s). They were also requested to provide a chemical name which illustrates the stereo configuration of their compound. The R,S or Cahn-Ingold-Prelog convention could be used for this purpose.

The registrant explained that propiconazole is a racemic mixture of four isomers; two optical isomers where both *cis* and *trans* configurations are present. The racemic mixture consists of [(2S,4R)/(2R,4S)]/[(2R,4R)/(2S,4S)]-1-[(2-{2,4-dichlorophenyl}-4-propyl-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole (88% ai); *cis,trans* isomers typically at a ratio of 1:1, all isomers show fungicidal activity. The registrant explained that none of the isomers have shown any significant biological activity advantage over the racemic mixture.

The registrant submitted a CSF for Tilt®, identifying the active ingredient as a racemic mixture and including stereochemical configuration (RS) notation in the scientific name of the active ingredient. See the Confidential Appendix to this memorandum for details.

All deficiencies listed in CBTS Review #10742, have been resolved.

Recommendations:

TOXicological considerations permitting, CBTS has no objections to the establishment of food tolerances for residues of the fungicide propiconazole {1-[(2-{2,4-dichlorophenyl}-4-propyl-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole} and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalents in or on wild rice for use in Minnesota only (regional tolerance) at 0.5 ppm and for use in/on apricots, nectarines, peaches, plums, and fresh prunes at 1.0 ppm.

Note to the PM:

Whenever 40 CFR § 180.434 is modified, the chemical name should be written to reflect that this tolerance applies to all isomers of a racemic mixture.

cc (with Confidential Appendix): MIRodriguez, PP9F3758, Reading File.

cc (without Confidential Appendix): Circulation

RDI: P. V. Errico (6-2-1993), R. A. Loranger (6-2-1993)

M. I. Rodriguez: Draft (6-1-1993), Edited (6-2-1993): H7509C/CBTS/CW2, Room 804-T/703-305-6710

Branch File: F:\USER\CB\PRPCONZL.005

2

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Pages ____ through ____ are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☒ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
