



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

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MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: 23 SEPTEMBER 2004

SUBJECT: TRIFLUMIZOLE - Waiver Request for 28-day Inhalation Study.

PC Code: 128879 DP Code: 306593

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INTRODUCTION

The Crompton Corporation, Crompton Uniroyal Chemical has requested a waiver from the requirement of conducting a 28-day rat inhalation study (Correspondence, W. Cummings [Crompton] to M. Waller [EPA/OPP], 18 November 2003, pinpunch received 21 November 2003, MRID 462603-00). Crompton sites the EPA guidance document "Guidance: Waiver Criteria for Multiple-Exposure Inhalation Toxicity Studies, August 15, 2002" as the bases for the waiver request.

DISCUSSION

The aforementioned guidance document lists four criteria for use in the consideration of waiver requests:

- > severe irritation and corrosivity
- > low volatility
- > large particle size
- > inhalation Toxicity Category IV and an extrapolated Margin of Exposure (MOE).

Relative to these criteria, triflumizole is not volatile having a vapor pressure of 1.4×10^{-6} mm Hg at standard temperature and pressure. It is classified in Acute Inhalation Toxicity Category IV. Inhalation MOEs far exceed 1000 (Memo, M. Dow, DP 282644, 26 April 2002). Triflumizole is

not formulated to be used as an aerosol i.e. fog, smoke, dust, fume or mist). Crompton sponsored a study designed to measure droplet size as developed from conventional ground and aerial spray systems (MRID 46260301, "Atomization Droplet Size Spectra for Procure[®]", A. Hewitt, Stewart Agricult. Res. Serv. Inc, 3 July 2002). For ground applications the study indicates nominally 0% of the droplet size spectrum was 3 - 11.6 μm . For rotary and fixed wing aircraft the spray volume contained in droplets with a diameter less than 100 μm was less than 1 %.

CONCLUSION

Since triflumizole is not volatile, is classified in Inhalation Toxicity Category IV, has very large estimated inhalation MOEs and exhibits essentially negligible inhalable droplet size under normal agricultural conditions, HED agrees that in this case a waiver should be granted from the requirement of a 28-day rat inhalation toxicity study.



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