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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP OFFICE OF PESTICIDES
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

DATE: February 14, 2007

SUBJECT: IR5878 Technical (Orthosulfamuron)
DP Barcode: D336629 PC Code: 108209

Waiver Request for Acute and 90-Day Neurotoxicity Studies
HED TXR No.: 0054041

TO: James Tompkins, RM 25
Herbicide Branch
Registration Division

FROM: Karlyn J. Bailey, Toxicologist *K. Bailey*
Registration Action Branch 2
Health Effects Division (7509 P)

THRU: Richard Loranger, Branch Senior Scientist *R. Loranger*
Registration Action Branch 2
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ACTION REQUESTED: Review Submitted Waiver Request for Acute and 90-Day Neurotoxicity Studies.

BACKGROUND: ISAGRO S.p.A (Centro Uffici San Siro-Edificio D-ala 3, Via Caldera, 21-20153 Milan, Italy), has submitted a request (MRID 46578930), dated May 25, 2005, to waive the requirement for Acute and 90-Day Neurotoxicity studies for the following pesticide technical active ingredient: IR5878 Technical (Orthosulfamuron), PC Code 108209.

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CONCLUSION: The Health Effects Division (HED) has reviewed the rationale submitted by ISAGRO S.p.A in support of waiving the Acute and 90-Day Neurotoxicity studies. The request to waive the studies has been accepted based on the following:

- Although there were marked decreases in motor activity seen in a 2-generation reproduction study (rat) incorporated with Functional Observational Battery (FOB) observations, these decreases were seen in F1 males only, at the highest dose tested of 5600 ppm (approximately equivalent to 354.5 mg/kg/day). In addition, 90-day and carcinogenicity studies in the rat, also with FOB observations, did not reveal signs of neurotoxicity when tested near (706 mg/kg/day) or up to the limit dose (1000 mg/kg/day).
- There were no other treatment-related signs of neurotoxicity observed in the database, including toxicity studies in mice and dogs.
- IR5878 belongs to the sulfamoylurea chemical class, which is very closely related to the sulfonylurea class of chemicals. Sulfonylureas do not typically exhibit neurotoxicity; therefore, it is unlikely that IR5878 is a neurotoxicant.



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Chemical: Orthosulfamuron

PC Code:
108209

HED File Code: 13000 Tox Reviews

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