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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

TXR 0050375

11/28/2001

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

MEMORANDUM

SUBJECT: PP#0F6139; Pyraclostrobin on various commodities.

DP Barcode:	D267732 D279220	PRAT Case:	292946
Submission No.:	S583112	Caswell No.:	None
Chemical No.:	099100	Class:	Fungicide
Trade Name:	Cabrio	EPA Reg No.:	7969-xxx
	Headline		
40 CFR:	Not established		
MRID No.:	None		

TO: Richard Keigwin
RD (7505C)

and

Cynthia Giles-Parker/John Bazuin, PM Team 22
RD (7505C)

FROM: William D. Wassell, Chemist *Will Wassell*
Ghazi A. Dannan, Ph. D., Toxicologist
Kelly M. O'Rourke, Biologist *Kelly O'Rourke*
RAB3/HED (7509C)

THRU: Stephen C. Dapson, Branch Senior Scientist *Stephen C. Dapson*
RAB3/HED (7509C) *12/06/2001* (1)

Introduction:

Richard Keigwin of RD has asked RAB3 to outline the data deficiencies associated with PP#0F6139.

Data Deficiencies Identified by the HIARC:

The 28-Day Dermal Toxicity Study (MRID No. 45118324) was deemed to be unacceptable because no systemic effects were seen at the highest tested dermal dose of 250 mg/kg/day which is well below the limit dose of 1000 mg/kg/day. According to the OPPTS GL # 870.3200, the highest tested dose should

result in definite systemic toxicity unless the limit dose (1000 mg/kg/day) is used or there is severe irritation to the skin. The skin effects in this study were very minimal.

Multigeneration Reproduction Study in rats (MRID No. 45118327) was deemed to be unacceptable. The HIARC noted that a new study with higher dose levels is required to assess the potential of pyraclostrobin to cause reproductive toxicity.

The Carcinogenicity Study in mice (MRID No. 45118330) was deemed to be unacceptable by the HIARC because the dose levels were too low.

The HIARC noted that there is no inhalation toxicity study available for pyraclostrobin. The HIARC recommended the submission of a 28-day Inhalation Toxicity study using the same form of pyraclostrobin to which workers are exposed. The HIARC noted that the active ingredient should not be diluted in acetone as was done in the acute inhalation study.

Data Deficiencies Identified by the CARC:

The CARC agreed with the assessment of the HIARC concerning the Carcinogenicity Study in mice (MRID No. 45118330). The study is unacceptable due low dose levels. The study must be repeated with higher dose levels.

The CARC also classified the Carcinogenicity Study in Rats (MRID No. 45118331) as unacceptable due to low dose levels. This study must be repeated with higher dose levels.

The CARC concurred with the HED reviewers of the chronic toxicity study in rats (MRID 45118329) that the study is unacceptable because the highest tested dose did not produce any toxicological effects.

The CARC also concluded that the carcinogenic potential of pyraclostrobin could not be classified, based upon the currently available data. This finding will make it not possible for HED to make a safety finding for pyraclostrobin with respect to cancer risk.

Concerning approval of a turf or Golf Course use:

There will be recreational exposure from golf course use by adults and children (we now assume the 5-yr olds and older golf). An assessment conducted without consideration for cancer would be incomplete - and may be misleading. The exposure from the golf course or turf use may result in anticipated residues estimates being needed in order to make a safety finding for short- and intermediate-term aggregate exposure when the pyraclostrobin food uses are registered.

Significant occupational exposure is expected for golf course maintenance workers (new data indicate that the exposure is at least an order of magnitude higher than had been assumed in the standard assumptions). This is a concern for the same reason given above.

cc: WDWassell, RAB3 Reading File

RDI: SDapson: 11/14/01; CSwentzel: 11/14/01.

(2)