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

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

12/AUG/2002

MEMORANDUM

Subject: EPA Reg. No: ID #0F06139
DP Barcode: D283002
Case No: 292946
PC Code: 099100

From: Masih Hashim, Toxicologist
Technical Review Branch
Registration Division (7505C)

To: John Bazuin, PM Team 22
Fungicide Branch
Registration Division

Applicant: BASF Corporation
P.O. Box 13528
Research Triangle Park, NC 27709-3528

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Pyraclostrobin	38.1
Inert Ingredients/related derivatives	61.9
Total:	100.0

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DATA EVALUATION RECORD

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Reviewer: Michael Honeyman Date October 22, 2001
Secondary Reviewer: Masih Hashim Date August 12, 2002

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403.

TEST MATERIAL (PURITY): BAS 500 .. F (40% in [redacted]

SYNONYMS: Pyraclostrobin

CITATION: Gamer, A., Leibold, E., Hoffman, H.D. (2001) "BAS 500 F 40% in Solvesso (Technical Active Ingredient) Acute Inhalation Toxicity Study in Wistar rats." Department of Toxicology of BASF Aktiengesellschaft. Lab report no.13I0283/017002. June 21, 2001, Unpublished.

SPONSOR: BASF Corporation.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study, groups of young adult Wistar rats (5/sex) were exposed by inhalation route to pyraclostrobin (38.1% a.i. by HPLC) in Solvesso for 4 hours head-nose only at concentrations of 0.89, 1.96, 4.07, or 7.3 mg/L. Animals then were observed for 14 days.

The LC_{50} for males is $4.07 < LC_{50} < 7.3$ mg/L.
The LC_{50} for females is $4.07 < LC_{50} < 7.3$ mg/L.
The LC_{50} for combined sexes is $4.07 < LC_{50} < 7.3$ mg/L.

Pyraclostrobin is classified as being of **Low Toxicity** based on the combined LC_{50} of greater than 4.07 and less than 7.3 mg/L.

Clinical findings included piloerection, gasping, respiratory sounds, eyelid closure, squatting posture, and wet-smeared fur. All animals showed accelerated breathing. Mean body weight gain in group 3 females decreased for the first week, but increased during the second week. All other groups gained weight over the 14 days.

Necropsy findings included varying degrees of discoloured lungs and wet, contaminated fur among the high dose decedents.

This acute inhalation study is classified as acceptable. This study satisfies the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS: (see citation)

1.		
	BAS 500 F in Solvesso	Registration No. 304428 Pyraclostrobin, BAS 500 F, 38.1%
		Batch No. 2001-1
		Viscous melt, red-brown, store at room temp

2. Vehicle and/or positive control: None used.

B. STUDY DESIGN and METHODS:

1. In life dates - Start: April 11, 2001 End: June 13, 2001

2. Exposure conditions - Head-nose exposure to homogenous aerosol, 55 L, glass-steel construction. The technical equipment included a piston metering pump KP 2000 and a two-component atomizer Mod. 970. Aerosol was produced by compressed air. Compressed supply air flow was 2000 L/h and exhaust air flows were 1800 L/h. Air change occurred approximately 36 times per hour. Temperature and humidity were measured at 1 hour intervals.

3. Animal assignment and treatment - Animals were assigned to the test groups noted in Table 1. Rats were exposed to the test formulation by head-nose only exposure for 4 hours. Animals were observed daily (detailed observations on weekdays) and were weighed weekly (first measurement just prior to exposure) for 14 days after dosing. Survivors were sacrificed and a necropsy was performed.

Table 1. Concentrations, Exposure conditions, mortality, animals treated

Group	Substance flow ml/h	Nominal conc. mg/l	Analytical Conc. mg/l	MMAD µm	GSD			
						male	female	combined
1	150	81.8	0.89	4.0, 4.3	2.5, 2.6	0/5	0/5	0/10
2	277.5	151.2	1.96	3.5	2.6	1/5	0/5	1/10
3	550	299.8	4.07	3.8	2.7	0/5	1/5	1/10
4	400	218.0	7.3	2.7	2.7	5/5	4/5	9/10

4. **Generation of the test atmosphere** - Time to equilibrium was 10 minutes.

Test atmosphere concentration - Concentration was calculated by taking a known volume from the exposure system and running an HPLC (HP 1050). Results are in table 1 above.

Particle size determination - Gravimetric determination was performed with an HPLC. Metered volumes of the aerosol were drawn through a filter by vacuum pump. For particle size analysis, the equipment included a Stack Sampler Mark III, a Vacuum Compressed Air Pump (Millipore), a Sampling probe (internal d = 6.9 mm), a limiting orifice at 3 L/min, and filters. Before sampling, the impactor was assembled with a backup particle filter. The impactor was connected to the vacuum pump and samples were taken from the breathing zone of the animals starting not earlier than 30 minutes after the beginning of the exposure. After sampling, collected particles were eluted from the filters with acetonitrile and analyzed by HPLC. Wall losses were determined quantitatively. Results are in Table 1 above.

5. **Statistics** - Calculations were limited to standard deviations and means.

II. RESULTS AND DISCUSSION:

A. Mortality is given in Table 1. Deaths from groups 2 and 3 occurred on the day of exposure. Four Group 4 males died during exposure while the fifth died on the following day. Among the high-dose females, two died during exposure and another two expired later that day.

The LC_{50} for males is $4.07 < LC_{50} < 7.3$ mg/L.
The LC_{50} for females is $4.07 < LC_{50} < 7.3$ mg/L.
The LC_{50} for combined sexes is $4.07 < LC_{50} < 7.3$ mg/L.

B. Clinical observations - Findings were similar between males and females. Accelerated breathing was seen in all animals. Piloerection, gasping, respiratory sounds, eyelid closure, squatting posture, and smeared fur were present to varying degrees. See Table 2.

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Body Weight - Mean body weight gain in group 3 females decreased for the first week, but increased during the second week. All other surviving animals gained weight over the 14 days.

D. Necropsy - Discolouration of the lungs was the most common finding during necropsy. Wet, contaminated fur was seen in the high dose group animals that died before study end. See Table 4.

E. Reviewer's Conclusions: The authors present a valid study. For males, females, and both sexes combined, $4.07 < LC_{50} < 7.3$ mg/L. No label comments are required. The Toxicity Category is IV.

F. Deficiencies - None.

The study is Acceptable to US EPA (Technical Review Branch).

ACUTE TOX ONE-LINERS

1. DP BARCODE: D283002
2. PC CODE: 099100
3. CURRENT DATE: 8-12-02
4. TEST MATERIAL: Pyraclostrobin 38.1%

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute Inhalation Study/ rat/ BSF Lab/ Study Code # 1310283/017002/ 6-21-01	454551-01	LC_{50} is 4.07 < LC_{50} <7.3 mg/L	IV	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated