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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 29, 2004

MEMORANDUM

Subject:	Name of Pesticide Product:	RH-7592 Technical	
	EPA File Symbol:	62719-415	
	DP Barcode:	D311108	
	Decision No.:	335747	
	PC Code:	129011	Fenbuconazole

From: Breann Hanson, Toxicologist
Technical Review Branch
Registration Division (7505C)

To: Dennis McNeilly, RM Team 22
Fungicide Branch
Registration Division (7505C)

Applicant: Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

FORMULATION FROM LABEL:

Active Ingredient:			% by wt.
129011	Fenbuconazole	CAS No. 119611-00-6	99.0%
Inert Ingredients:			1.0 %
		Total:	100.0%

ACTION REQUESTED:

The Product Manager requests:

> "This was submitted as 6(a)(2) but I can find no evidence that it was ever put into review. Please review."

BACKGROUND: Dow AgroSciences LLC has submitted an acute oral toxicity study in support of registration for RH-7592 Technical, EPA File Symbol: 62719-415. The submission included a CSF, letter and label for the already registered product. The letter states that the study is being submitted due to an internal company review process, of previous R&H Company records, that uncovered several studies that were never submitted to the Agency. The study was conducted at Rohm and Haas Company's Toxicology Department, Spring House, PA, with assigned MRID number 46081401.

RECOMMENDATIONS: The study has been reviewed and is classified as acceptable. The study was performed with an EUP containing 26% AI, not the MUP RH-7592 Technical. Therefore, although the study is acceptable it cannot support registration of 62719-415. The labeling and acute toxicity profile for the technical product, 62719-415, remains unchanged. The acute oral toxicity for the EUP is:

Acute oral toxicity	II	Acceptable	MRID 46081401 [a]

[a] The incorrect protocol (OECD 401: Acute Oral LD50) was used for this test. Although, we accepted the study in this case, our guidance is that OECD 401 is an unacceptable protocol. Please inform the Registrant that the preferred protocol is OECD 425: Acute Oral Toxicity-Up-and-Down Procedure.

Reviewer: Breann Hanson **Date:** Dec. 29, 2004
Risk Manager (EPA): Dennis McNeilly, RM 22

STUDY TYPE: Acute Oral Toxicity - BR rat; OPPTS 870.1100; OECD 401

TEST MATERIAL: Indar® 2-OS (Fenbuconazole: 26%; Lot. No.: SS4117; tan liquid)

CITATION: Vandenberghe, Y.L. (1995) Indar® 2-OS Acute Oral Toxicity Study in Male and Female Rats. Report No.: 94R-103. Unpublished study prepared by Rohm and Haas Company. March 10, 1995. MRID 46081401.

SPONSOR: Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46081401), 6/sex young adult BR rats (Weight: 197-212 g males, 190-210 g females; Source: Charles River Kingston, Stone Ridge, NY) were given a single oral dose of Indar® 2-OS (Fenbuconazole: 26%; Lot. No.: SS4117; tan liquid) by oral gavage at 5,000 mg/kg. The test substance was administered undiluted. Individual animal body weights were recorded prior to test substance administration and on days 7 and 14.. Clinical checks for toxicity were made at 1,2 and 4 hours post-dosing on the initial study day, and once daily thereafter for 14 days. All animals were necropsied on study day 14.

All animals survived and gained weight during the study. Signs of toxicity included ataxia, passiveness, salivation, unusual gait, hypersensitivity to touch, prostration, arched back, emaciation, soft feces, irregular breathing, red stained eyes and/or paws and/or muzzle, yellow stained anal genital area, scant feces and corneal opacity. Symptoms were noted in males by study day 2, while females developed symptoms by study day 3. These signs were transient, lasting usually less than 48 hours. Corneal opacity was noted in one animal through the end of the study period. No gross internal findings were noted at necropsy.

Oral LD_{50} Males => 5,000 mg/kg
Females => 5,000 mg/kg
Combined => 5,000 mg/kg

Based on the LD_{50} in rats, Indar® 2-OS is classified as EPA Toxicity Category IV.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 401) in the rat.

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

RESULTS and DISCUSSION:

Individual animals were dosed as follows:

Limit Test

Animal No.	Sex	Dose level (mg/kg)	Sort-Term Outcome	Long-Term Outcome
94-01675	M	5000	S	S
94-01666			S	S
94-01665			S	S
94-01671			S	S
94-01670			S	S
94-01668			S	S
94-01688	F		S	S
94-01679			S	S
94-0178			S	S
94-01684			S	S
94-01683			S	S
94-01681			S	S

S = survival D = death

A. **Mortality** - None, as noted in table.

B. **Clinical observations** - All animals survived and gained weight during the study. Signs of toxicity included ataxia, passiveness, salivation, unusual gait, hypersensitivity to touch, prostration, arched back, emaciation, soft feces, irregular breathing, red stained eyes and/or paws and/or muzzle, yellow stained anal genital area, scant feces and corneal opacity. Symptoms were noted in males by study day 2, while females developed symptoms by study day 3. These signs were transient, lasting usually less than 48 hours. Corneal opacity was noted in one animal through the end of the study period.

C. **Gross Necropsy** - No gross internal findings were noted at necropsy.

D. **Reviewer's Conclusions:** Agree with study author.

1. **DP BARCODE:** D311108
2. **PC CODE:** 019011
3. **CURRENT DATE:** 29/DEC/2004
4. **TEST MATERIAL:** Indar® 2-OS (Fenbuconazole: 26%; Lot. No.: SS4117; tan liquid)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Rohm and Haas Company 94R-103/03-10-1995	46081401	LD_{50} => 5,000 mg/kg (males, females combined)	IV	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived**