

US EPA ARCHIVE DOCUMENT

8-20-91



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

008556  
008556

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

MEMORANDUM

SUBJECT: Vinclozolin - Submission of Stability Data (EPA Reg. No. 7969-53)

Shaughnessy No.: 113201  
Tox Chem No.: 323C  
Project No.: 1-0529  
Submission No.: S389256

FROM: William B. Greear, M.P.H. *William B. Greear 8/20/91*  
Review Section IV, Toxicology Branch I  
Health Effects Division (H7509C)

TO: James Stone/Susan Lewis, PM Team #21  
Fungicide-Herbicide Branch  
Registration Division (H7505C)

THRU: Marion P. Copley, D.V.M., Section Head *Marion Copley 8/20/91*  
Review Section IV, Toxicology Branch I  
Health Effects Division (H7509C)

I. CONCLUSIONS

The stability data are acceptable and the oral (gavage) developmental toxicity study [BASF# 89/0190] and dermal [BASF# 90/0025] developmental toxicity study are upgraded to core-Minimum. The study conclusions remain unchanged. This memo is in place of supplemental data evaluation records (DERS).

II. REQUESTED ACTION

Under a cover letter dated January 3, 1991, Rodney C. Akers of the BASF Corporation has submitted stability data on vinclozolin in carboxymethylcellulose, as requested by TB-I, in order to upgrade the following studies:

- o Study of the Prenatal Toxicity of Reg. No. 33258 (Vinclozolin) in Rats after Dermal Application, Project No. 34R0375/88074. BASF Reg. Doc. No. 90/0025; Submitted March 1990. MRID# 41413001. (Original DER in HED Doc. # 007370)

- o Report on the Prenatal Toxicity of Reg. No. 83258 (Vinclozolin) in Rats after Oral Administration (Gavage). BASF Reg. Doc.No. 89/0190; Submitted June 1989. MRID# 41132201. (Original DER in HED Doc. #s 007228, and 007909).

The stability data were submitted in the following report:

- o Stability of Vinclozolin (Reg. No. 83258) in Carboxymethylcellulose (CMC) - Suspension and in Water, Becker, Reg. Doc. No. BASF 90/0532, 16 pages. MRID No. 417375-01.

BASF conducted stability tests for 3% vinclozolin in bidistilled water and in CMC-suspension after storage for 24 hours at room temperature and at 40°C. The 3% concentration was used because it was stated to be the average concentration used in the toxicity studies. The actual concentrations used in the toxicity studies ranged from 0.3 to 10%. At room temperature, the concentration ranged from 100.6 to 103.0% of the theoretical value when sampled at 0, 1.0, 22.5 and 24.0 hrs in bidistilled water. At 40°C, the concentrations ranged from 99.3 to 103.0% of the theoretical value when sampled at 0, 1.0, 22.5 and 24.0 hours in bidistilled water. At room temperature, the concentration ranged from 98.5 to 101.2% of the theoretical value when sampled at 0, 2.3, 21.5 and 24.0 hours in CMC. At 40°C, the concentration ranged from 97.3 to 103.2% of the theoretical value in CMC.

The data are acceptable and the oral (gavage) and dermal developmental toxicity studies in the rat are upgraded to Minimum Data.

---

The sponsor indicated MRID# 49709301 and Submission Date of 1990.