

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

8/19/87

DATE: March 24, 1982

SUBJECT: EPA Registration No. 7969-53
Ronilan - PP 9F 2205

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FROM: Deloris F. Graham *DFG 3/29/82*
FHB/TSS *F 3/29/82*TO: Henry Jacoby
Product Manager (21)Applicant: BASF Wyandotte Corporation
100 Cherry Hill Road
P.O. Box 181
Parsippany, NJ 07054Active Ingredient:

Vinclozolin50%

Inert Ingredient50%

Background: Submitted information pertaining to the Dermal Sensitization Study initially submitted as requested by the Agency in a letter dated September, 1981.

Recommendations:

1. Based on the data submitted, the 3/12 animals not accounted for in the initial Dermal Sensitization Study died of pneumonia. Therefore the initial study submitted can be upgraded from Core Supplementary Data to Core Guideline Data.
2. The label must declare this product as a potential skin sensitizer.

Review:

1. Dermal Sensitization Study: BASF; Report #79/89; September 7, 1979.

Procedure: Six intradermal injections using active ingredient only are made in groups of two. Front row - 2 injections each of 0.1 ml of Freund Complete adjuvant/aquatest (1:1) without test compound. Middle row - 2 injections of 0.1 ml of test allergen in suitable solvent without Freund adjuvant. Back row - 2 injections each of 0.1 ml of test allergen in Freund adjuvant 24 hours after the intradermal application. The skin findings are scored at each application site.

One week after the intracutaneous induction in exactly the same area, 24 hours before, the local application of a 10% formulation of sodium laurylsulphate in white vaseline is massaged into this area with a glass rod without a dressing applied.

For the actual induction, the test allergen is applied to the skin with a 2x4 cm filter paper. Solid compounds are applied as a paste in white vaseline.

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In case of liquid, filter paper is impregnated with undiluted compound or appropriate formulation. The dressing is removed after 48 hours and the dermal irritation effects are read. The challenge is carried out about 10-14 days after percutaneous induction.

Evaluations are made 24, 48, and 72 hours after the beginning of the contact period. About a week later, a second challenge was carried out with another solvent.

Results: After the intracutaneous induction, some distinct erythema and some necrosis and edema with suppurating ulceration were noted.

The first challenge was carried out with a compound formulation in white vaseline. Seven of 12 test animals were found to have skin changes, the intensity and course of which indicated previous sensitization. Vaseline on its own caused slight skin changes not only in the test group, but also in controls.

In the second challenge, skin changes were detectable in four of nine surviving test animals, which unequivocally indicated sensitization. No skin effects were detected in the control group. The remaining three of the twelve animals died of pneumonia.

On the basis of the test results, vinclozolin has sensitization effects on skin of a guinea pig.

Study Classification: Core Guideline Data.

Toxicity Category: Potential Sensitizer

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Vinclozalin Toxicology Review 3/24/82

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Pages 3 through 6 are not included in this copy.

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