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

Head File 8-11-92

AUG 11 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Vinclozolin. Time extension request for Guideline 171-4(k). Chemical #11320. Case #2740. DP Barcode #D180955. CBRS #10277.

FROM: Steven A. Knizner, Chemist *Steven A. Knizner*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

THRU: Andrew Rathman, Section Head *AR*
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

TO: Margarita Collantes, PM Team 53
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508W)

In response to Guideline 171-4(k) data gaps noted in the Phase 4 Review of vinclozolin, BASF Corp. was required to conduct crop field trials for various raw agricultural commodities. In a letter dated 9/27/91, BASF requested a time extension of nine months for completion of field trials (from July 3, 1993 to March 1994).

Because Phase 4 Reviews did not reflect current CBRS policy (adopted 12/6/91, see enclosure) outlining requirements for crop field trials to support aerial applications, some of the data gaps identified in the Phase 4 Review are no longer applicable.

The raw agricultural commodities lettuce, strawberries, and raspberries, were indicated as having

data gaps reflecting the aerial mode of application. BASF is deleting aerial application of vinclozolin on raspberries from its product label, so this data gap no longer exists.

Current CBRS policy regarding aerial application states that "Provided the pesticide product label specifies that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), crop field trials reflecting aerial application will no longer be required in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and preharvest intervals. This data waiver does not apply to aerial applications using diluents other than water (e.g., vegetable oils). In addition we do reserve the right to require aerial data if special circumstances warrant it."

Since the only data gap noted for lettuce and strawberries involved data reflecting aerial application, and since the minimum spray volume for aerial applications of all formulations of vinclozolin on lettuce and strawberries is 20 gallons (with water as the diluent), the data gap concerning residues following aerial application is no longer applicable.

The only other 171-(4)k crop field trail required by the Phase 4 Review pertained to stone fruits (peaches, sweet and sour cherries, and plums). The data gap identified in these commodities required additional cherry residue trials from NY/PA and UT/MT/ID sites. This data gap must still be fulfilled.

Because BASF apparently initiated crop field trials in March 1992, CBRS concludes that there is no scientific reason for granting a time extension for completion of crop field trails.

Conclusions

1. Because of current CBRS policy concerning requirements for crop field trials to support aerial applications, field trials are longer required for lettuce and strawberries.
2. Crop field trials for cherries required in the Phase 4 Review must still be conducted.
3. There is no scientific reason for granting a time extension for completion of crop field trials.

Recommendations

CBRS finds no scientific reason for granting a time extension for completion of crop field trials. CBRS recognizes that the granting of time extensions is under the purview of SRRD.

Enclosure.

cc: Vinclozolin List B File, S.F., circ., R.F., S.Knizner
RDI: A.Rathman, 8/11/92 M.Metzger, 8/11/92, E.Zager, 8/11/92
H7509C:CBRS:SAK:sak:Vincol.tme:CM#2:8/10/92



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

DEC. 6, 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Requirement for Crop Field Trials
to Support Aerial Applications.

FROM: Robert S. Quick, Acting Chief
Chemistry Branch I, HED (H7509C)
and
Edward Zager, Chief
Chemistry Branch II, HED (H7509C)

Robert S. Quick
Edward Zager

TO: Chemistry Branch I Staff
and
Chemistry Branch II Staff

Earlier this year NACA submitted a study entitled "A Comparison of Pesticide Residues Obtained as a Result of Ground and Aerial Application Techniques" along with a request that the crop field trial requirement be waived for aerial applications provided adequate ground data are available and a minimum spray volume of 2 gallons per acre (GPA) is specified for the aerial use. Our review of this study is described in the attached letter to Dr. Richard F. Holt. As noted in that letter, we are granting the requested waiver with a few limitations:

Provided that the pesticide product label specifies that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), crop field trials reflecting aerial application will no longer be required in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and preharvest interval. This data waiver does not apply to aerial applications using diluents other than water (e.g., vegetable oils). In addition, we do reserve the right to require aerial data if special circumstances warrant it.

This change in our data requirements is to be implemented immediately for all types of actions-tolerance petitions, amended registrations, reregistration reviews, etc. Therefore, all reviews and responses to inquiries about crop field trial requirements should follow the above policy.

Attachment: 12/6/91 letter to R. Holt

cc: RF, Petition Review Aids File



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