Memorandum:


FROM: Jerry B. Stokes, Chemist Chemistry Branch/Tolerance Support Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief Chemistry Branch/Tolerance Support Health Effects Division (H7509C)

TO: Susan Lewis, PM-21 Fungicide-Herbicide Branch Registration Division (H7505C)

and

Beth Doyle, Toxicologist Toxicology Branch Health Effects Division (H7509C)

This is an expedited review per the request of RD. The completion date is 5/16/91.

History

ISK Biotech submitted a letter dated March 19, 1991 to RD to request the Agency remove the 12 month rotational crop label restriction. At RD's request, CBTS, along with other OPP personnel met with the company representatives in April 1991 to discuss this proposal.

The company has submitted data for the rotational crop studies to the Agency in July 1990 (MRID #415648-01 to 415648-46) for evaluation. In this meeting, the company affirmed their belief that sufficient data has now been submitted to the Agency to justify removal of the label restriction.
However, EFGWB has completed their review of the above data and found the data to be deficient. TOX also stated that additional toxicological data for the soil metabolite SDS-46851 must be submitted. Based on the data available to the Agency, OPP stated that at this time, it appears that rotational crop tolerances may be needed.

Conclusion/Comments

In this RD expedite, CBTS has been requested to review the residue data for the rotational crops to determine what residue levels would be appropriate to use in a DRES analysis.

CBTS has made a preliminary scan of the data, and has concluded at this time there are too many data variables, and too many unknowns that preclude the calculation of potential residue levels in rotational crops. Furthermore, the registrant's intentions in regard to a rotational crop restriction are not clearly known. Therefore CBTS requests the registrant clarify the following:

1) Is it the intent of the registrant to not only remove the 12 month plantback restriction from the label but also to have no restrictions for plantback times? The data show plantback intervals from as little as 30 days up to 8 months for a variety of crops.

2) Does the registrant intend to allow plantback of any crop or only specified crops?

3) Is there a maximum amount of chlorothalonil that can be applied to a field, growing season after growing season?

4) Do the water soluble soil metabolites, especially the terminal residue SDS-46851, increase in time if the chlorothalonil is applied repeatedly? Does SDS-46851, and other water soluble soil metabolites, dissipate in the soil from season to season?

Recommendation

CBTS needs the above questions answered before we can adequately determine residue levels in any rotational crops. Also EFGWB has expressed concern that the some of the submitted soil sampling studies may not be acceptable, and that new studies will be required. CBTS may need additional data if these studies are inadequate. In addition, the need for other data will depend upon the petitioner's intentions and his response to the above questions.

cc: J. Stokes (CBTS); C. Furlow (PIB/FOD); Chlorothalonil S.F.; R.F.; Circulation (7)
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