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73/OPV-T14-120

5-23-97

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L. J. [Signature]



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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 5/23/97

SUBJECT: PP# 9F03762. SECTION 3 REGISTRATION AND TOLERANCE
PETITION FOR USE OF VINCLOZOLIN ON SNAP BEANS.

TO: Sidney Jackson, PM Team 21
Luis Suguiyama, Chief
Fungicide-Herbicide Branch
Registration Division (7505C)

and

Mark Wilhite, PM Team 53
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

FROM: G. Jeffrey Herndon
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)

THRU: Michael S. Metzger, Chief
RCAB/HED (7509C)

Michael S. Metzger

INTRODUCTION

The registrant, BASF, is requesting a Section 3 registration and establishment of a tolerance for use of vinclozolin on snap beans to control white mold (Sclerotinia sclerotiorum) and grey mold (Botrytis cinerea).

In a meeting with BASF held on 4/17/97, the company representative, Dr. Abraham Tobia, agreed that BASF would be willing to delete certain uses/tolerances in order to get a Section 3 registration and tolerance on snap beans (see memo of G.J. Herndon dated 5/14/97).

ACTION REQUESTED

HED has been requested to estimate the acute dietary risk from vinclozolin from tolerances which currently appear in the CFR, including the existing tolerances that BASF wished to delete. At the current time, HED does not have the capability to perform a Monte Carlo dietary analysis. Therefore, we have qualitatively

examined the TAS Monte Carlo run dated 3/29/96 (MRID# 439835-01).

In response to the acute dietary assessment performed by HED (Tier 1 modeling as outlined in "Final Office Policy for Performing Acute Dietary Exposure Assessment, D. Edwards, 6/13/96) and documented in the HED Chapter of the Vinclozolin RED (memo of K. Boyle signed 4/8/96), BASF submitted "Acute Dietary Exposure: Vinclozolin" (document dated 3/29/96 - MRID# 439835-01), BASF's consultant TAS (Technical Assessment Systems, Inc.) performed an acute dietary assessment using TAS EXPOSURE 4 software with the Monte Carlo option (Tier 3 modeling as outlined in "Final Office Policy for Performing Acute Dietary Exposure Assessment, D. Edwards, 6/13/96). TAS's acute dietary assessment was performed using the acute anticipated residues outlined in the memo of S. Knizner dated 11/15/95, along with percent crop treated (supplied by BEAD) and percent imported data (supplied by USDA) that were used in the HED RED Chapter. The results of the TAS analysis resulted in an MOE = 90 at the 99.9th percentile for the subgroup of concern, females 13+ years of age (exposure = 0.0608848 mg/kg/day).

The Monte Carlo analysis used in TAS's 3/29/96 run used discrete distribution in their Monte Carlo modeling. Rather than using a range of field trial residue data which reflected the current labeled use pattern and PHI, the run incorporated only two possibilities of residue values - either residues were at the highest field trial level (as outlined in the memo of S. Knizner dated 11/15/95)/tolerance or they were zero (reflecting the percentage of the crop which would not have been treated or percentage of the crop which would not have been imported for crops which have tolerances but no U.S. registrations).

Table 1 outlines what currently appears for tolerances for vinclozolin in 40 CFR and the value used in the 3/29/96 Monte Carlo analysis

<u>40 CFR 180.380</u> <u>commodity</u>	<u>tolerance</u>	<u>Value Used in 3/29/96 Analysis</u>
Belgian endive, tops	5.0	1.40 (HFT)
cucumbers	1.0	0.27 (HFT)
grapes	6.0	5.8 (HFTI)
kiwifruit	10.0	8.4 (HFTI)
lettuce, head	10.0	4.02 (HFT)
lettuce, leaf	10.0	4.02 (HFT)
onions, dry bulb	1.0	5.84 (HFT)
peppers, bell	3.0	1.09 (HFTI)
raspberries	10.0	4.6 (HFT)
stonefruits (to include:)		
apricots	25.0	5.0 (HFT)
cherries	25.0	3.79 (HFT)
nectarines	25.0	5.0 (HFT)
peaches	25.0	5.0 (HFT)

plums	25.0	(DNU)
strawberries	10.0	5.91 (HFT)
tomatoes	3.0	0.88 (HFT)
<u>40 CFR 185.1850</u>		
prunes	75	(DNU)
raisins	30	13.3 (HFTI)
<u>40 CFR 186.1850</u>		
grape pomace, dry	42	NA

HFT - These values were recommended to be used in the memo of S. Knizner dated 11/15/95.

HFTI - These values were based on review of import data, even though these are not designated as having no U.S. registration in 40 CFR.

DNU - This commodity was not input into the 1996 TAS Monte Carlo analysis, even though a tolerance exists in the CFR.

Items Incorporated Into The 3/29/96 Monte Carlo Analysis Which HED Believes Underestimates The Actual Risk

- Currently the only "import only" tolerances for vinclozolin noted in the CFR are cucumbers and tomatoes. The TAS analysis assumed that grapes and raisins and peppers were also "import only" and used 40 and 20 percent of crop-treated respectively for these commodities.
- With the exception of raisins, the analysis did not account for the processed commodities associated with those RACs for which "import" only tolerances are established.
- The commodities plums and prunes are included under the current stonefruits crop group, yet were not included in the analysis (a value of 25 ppm for plums and 75 ppm for prunes was recommended to be used for the analysis in the memo of S. Knizner dated 11/15/95).

Items Incorporated Into The 3/29/96 Monte Carlo Analysis Which HED Believes Overestimates The Actual Risk

- The TAS analysis incorporates only two possibilities of residue values - either residues were at the highest field trial level (as outlined in the memo of S. Knizner dated 11/15/95)/tolerance or they were zero (reflecting the percentage of the crop which would not have been treated or percentage of the crop which would not have been imported for crops which have tolerances but no U.S. registrations). A more realistic and refined calculation of dietary exposure would include Monte Carlo modeling using the entire distribution of residue data which reflect the current labeled use pattern and PHI. This approach was recommended by the National Research Council in their publication Pesticides in the Diets of Infants and Children, National Academy Press,

1993.

- The analysis included blackberries, boysenberries, blueberries, cranberries, and garlic for which tolerances have not been established in the current CFR.
- A residue value of 3.0 ppm for snap beans was used in the 3/29/96 analysis. HED has recommended in favor of a 2.0 ppm tolerance (see memo of G.J. Herndon dated 5/14/97).
- Commodities which are typically blended (juices and wines) were entered into the 3/29/96 analysis using the highest field trial residue value. Under current HED policy, an average of the field trial residue values would be used.

CONCLUSIONS/RECOMMENDATION

In the best scientific judgement of HED, if a new Tier 3 acute dietary analysis were performed using all commodities for which vinclozolin tolerances are currently established under 40 CFR 180.380, 185.1850, and 186.1850, in addition to the proposed new use on snap beans, the acute dietary risk would not exceed HED's level of concern.

cc: Herndon, PIRAT; Chemistry PP#9F3763, K. Boyle (RCAB),
Robert Perlis (OGC, 2333), J. Fleuchaus (OGC, 2333).