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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Vinclozolin.** Anticipated Residues for Acute DRES Analysis. Reregistration Case #2740 Chemical #113201 No MRID # DP Barcode D220964 CBRS #16478

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Below find anticipated residues (ARs) for the vinclozolin acute DRES analysis. These ARs have been generated according to guidance found in the "Interim Office Policy for Performing Acute Dietary Risk Assessment" (S.Irene, 7/21/95). Tier 1 of these guidelines calls for DRES use of the highest residue level found in field trials conducted at the maximum label use pattern. CBRS notes that the highest residue level may be lower than the tolerance level because the registrant petitioned for higher tolerance levels in order to harmonize with CODEX Maximum Residue Levels (MRLs).

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Recommendations

CBRS recommends that anticipated residues summarized in Table 1 be used for the vinclozolin acute DRES analysis.

NOTE: For commodities which have import tolerances, only the rac should be included in DRES analysis (processed commodities should not be included).

Table 1. ARs to be used for vinclozolin acute DRES analysis.

Commodity	Import or Domestic Tolerance	AR for Acute Dres Analysis (ppm)
Onions, dry bulb	Domestic	5.84
Belgian Endive	Domestic	1.4
Red chicory (radicchio)	Domestic	1.4
Lettuce, leaf and head	Domestic	4.02
Peppers, bell	Import[a]	1.09
Tomatoes	Import[a]	0.88
Cucumbers	Import[a]	0.27
Grapes	Import[a]	5.8
Raisins	Import[a]	13.3
Raspberries	Domestic	4.6
Strawberries	Domestic	5.91
Kiwifruit	Import[a]	8.4
Cherries	Domestic	3.79
Peaches	Domestic	5.0
Nectarines	Domestic	5.0
Plums	Import[a]	25
Prunes	Import[a]	75

[a] For commodities which have import tolerances, only the rac should be included in DRES analysis (processed commodities should not be included).

Detailed Considerations

Onions, Dry Bulb: Acceptable data on onions are available for purposes of reregistration. In data summarized for the Phase 4 Review (3/91), combined residues of vinclozolin and its 3,5-DCA metabolites were <1.0 ppm in/on all samples of onions treated with 4-9 ground applications of vinclozolin and harvested 18 days after treatment in 19 tests performed in

NY, MI, OR, MN, and TX. BASF subsequently submitted data in which over-tolerance residues of vinclozolin in/on onions were detected from 4 field trials in CA. Combined residues of vinclozolin and its metabolites containing the 3,5-DCA moiety were 0.12-14.93 ppm in/on onions (bulbs and tops) receiving 5 applications of the WP formulation at 1.0 lb ai/A/application (1x) at 14-day intervals and harvested 18 days after the final application. Reanalysis of only bulbs (without tops) showed residues of 3.33-5.84 ppm in/on bulbs from one test in which residues in/on tops plus bulbs were 9-14.93 ppm. CBRS concluded that a petition must be submitted increasing the tolerance for vinclozolin in/on bulb onions from 1.0 ppm to 6.0 ppm. For the RED, CBRS has reassessed the dry bulb onion tolerance at 6.0 ppm.

For onions, dry bulb, a value of 5.84 ppm should be used for the acute DRES analysis.

Belgian Endive (Tops), and Chicory, Red (tops) (Radicchio): In conjunction with PP#8E3620 to establish an import tolerance on Belgian endive and again for PP#9E3808, IR-4 submitted residue data from 4 trials conducted in Europe. Combined residues of vinclozolin and its 3,5-DCA metabolites were 0.09-2.21 ppm in/on samples of Belgian endive (tops) grown from roots receiving applications of vinclozolin at 5-20 g ai/10m^2 (0.5-2x). For the 1x treatment rate (10 g ai/10 m^2) combined residues of vinclozolin and its 3,5-DCA metabolites were 0.10-1.40 ppm (average 0.40 ppm) (W. Chin, CBTS No. 5947, PP#9E3808). The available data that supports the import tolerance for residues of vinclozolin and its 3,5-DCA metabolites in/on Belgian endive (tops) also supports the domestic tolerance on radicchio.

For Belgian endive, a value of 1.4 ppm should be used for the acute DRES analysis.
For red chicory (radicchio), a value of 1.4 ppm should be used for the acute DRES analysis.

Lettuce (leaf and head): Combined residues of vinclozolin and its 3,5-DCA metabolites in untrimmed samples were 0.234-7.01 ppm for head lettuce and 0.303-7.09 ppm for leaf lettuce (3 samples each); residues in trimmed samples were 0.113-1.35 ppm for head lettuce and <0.05-4.02 ppm for leaf lettuce (3 samples each). The samples were harvested 27-28 days following the last of three foliar ground applications of the 50% DF formulation at 1.0 lb ai/A/application (1x) in 6 tests performed in AZ, CA, and FL. In addition, BASF submitted data from 6 additional tests performed in AZ, CA, and FL. Combined residues of vinclozolin and its 3,5-DCA metabolites in untrimmed samples were 0.06-0.33 ppm for head lettuce and 0.07-0.27 ppm for leaf lettuce (3 samples each); residues in trimmed samples were <0.05-0.11 ppm for head lettuce and <0.05-0.11 ppm for leaf lettuce (3 samples each). The samples were harvested 27-28 days following the last of three foliar ground applications of the 50% DF formulation at 1.0 lb ai/A/application (1x).

For leaf and head lettuce, a value of 4.02 ppm should be used for the acute DRES analysis.

Peppers, bell: In conjunction with PP#4E2998 requesting a 3 ppm import tolerance for green peppers, BASF submitted data from 4 trials in the Netherlands. Combined residues of

vinclozolin and its 3,5-DCA metabolites were 0.60-1.09 ppm in samples receiving 3 applications of the WP or FlC formulations at a rate of 0.75 kg ai/ha/application and harvested at PHIs of 3-7 days. CBRS notes that the registrant originally petitioned for the 3 ppm tolerance in order to harmonize with the CODEX MRL.

For bell peppers, a value of 1.09 ppm should be used for the acute DRES analysis.

Tomatoes: In conjunction with PP#8E3688 requesting a 3 ppm import tolerance for tomatoes, BASF submitted data from 8 greenhouse trials in Spain and 2 greenhouse trials in the Netherlands. Combined residues of vinclozolin and its 3,5-DCA metabolites were <0.05-0.88 ppm in samples receiving 3 applications of the WP or FlC formulations at a rate of 0.37 to 1.25 kg ai/ha/application and harvested at PHIs of 0-50 days. The available data support the established 3.0 ppm tolerance for residues of vinclozolin and its 3,5-DCA metabolites in/on imported tomatoes. CBRS notes that the registrant originally petitioned for the 3 ppm tolerance in order to harmonize with the CODEX MRL.

For tomatoes, a value of 0.88 ppm should be used for the acute DRES analysis.

Cucumbers: In conjunction with PP#8E3688 requesting a 1 ppm import tolerance for tomatoes, BASF submitted data from 7 greenhouse trials in Spain and 4 greenhouse trials in the Netherlands. Combined residues of vinclozolin and its 3,5-DCA metabolites were <0.05-0.27 ppm in samples receiving 3 applications of the WP or FlC formulations at a rate of 0.32 to 1.25 kg ai/ha/application and harvested at PHIs of 3-42 days. The available data support the established 1.0 ppm tolerance for residues of vinclozolin and its 3,5-DCA metabolites in/on imported cucumbers. CBRS notes that the registrant originally petitioned for the 1 ppm tolerance in order to harmonize with the CODEX MRL.

For cucumbers, a value of 0.27 ppm should be used for the acute DRES analysis.

Grapes: In conjunction with PP#1E2457 requesting a 6 ppm import tolerance for grapes, BASF submitted data from studies conducted in Canada, France, Germany, England, Italy, Spain, and South Africa. Following 2-5 applications at 0.67 to 1.12 lb ai/A/application, residues ranged from 0.4 to 5.8 ppm in or on grapes harvested at PHIs of 21-22 days. The value of 5.8 ppm resulted from 4 applications at a rate of 0.67 lb ai/A/application.

For grapes, a value of 5.8 ppm should be used for the acute DRES analysis.

Raisins: An import tolerance of 30 ppm is established for raisins (C.Deyrup 2/3/87, PP#1E2457/FAP#7H5529, CB No. 1844 and 1845). This tolerance was originally based on the dry down factor (5x) for grapes processed into raisins (C.Deyrup 2/3/87, PP#1E2457/FAP#7H5529, CB No. 1844 and 1845). Subsequently, a processing study was supplied for grapes (N.Dodd, 1/28/88, PP#7H5529, CB No. 3016, MRID #40403201). Concentration factors of 2.1 and 2.4x were obtained (average concentration factor 2.3X).

Based on the HAFT of 5.8 ppm for grapes and an average concentration factor of 2.3x, for raisins, a value of 13.3 ppm should be used for the acute DRES analysis.

Raspberries: In data submitted in conjunction with PP#3F2934, combined residues of vinclozolin and its 3,5-DCA metabolites were 0.15-4.6 ppm in/on 24 samples of raspberries receiving 4 applications of vinclozolin at 1.0 lb ai/A/application (1x) and harvested 5-11 days after treatment in tests performed in NY, NJ, MI, OH, OR, and WA.

For raspberries, a value of 4.6 ppm should be used for the acute DRES analysis.

Strawberries: In data submitted in conjunction with PP#9F2205, combined residues of vinclozolin and its 3,5-DCA metabolites in/on samples of strawberries in CA receiving 18 or 24 applications of vinclozolin at 1.0 lb ai/A/application (1x), with 11 or 8 days between last two applications respectively, and with a 0 day PHI, were 2.47 and 3.68 ppm respectively. Residues in/on strawberries grown in FL treated 21 times at 0.75 lb ai/A/application (0.75x) with a 0 day PHI (4 days between last two applications) were 5.91 ppm.

For strawberries, a value of 5.91 ppm should be used for the acute DRES analysis.

Kiwifruit: In conjunction with PP#0E2380, BASF submitted data from 9 field trials in New Zealand using the only commercial variety of kiwifruit grown for export, the Hayward. Combined residues of vinclozolin and its 3,5-DCA metabolites were 1.97 to 8.40 ppm in samples receiving 5 applications (3 during blossom plus 2 pre-harvest) at a rate of 50 gm ai/100 L (equals 1.0 lb ai/A based on a spray volume of 2200 L/ha) and harvested at a 3 day PHI (M. Nelson, 10/15/80).

For kiwifruit, a value of 8.4 ppm should be used for the acute DRES analysis.

Stone Fruits

In conjunction with PP#1F3976/FAP#1H5615, BASF Corporation requests that tolerances be reduced for the combined residues of the fungicide vinclozolin, [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroaniline moiety in or on stone fruit due to a decrease in the number of applications per growing season from 5 (3 blossom and 2 fruit) to 4 (3 blossom and 1 fruit) and an increase in the preharvest interval from 3 to 14 days. It is proposed that 40 CFR §180.380 be amended to reduce the established stone fruit tolerance from the current level of 25.0 to 5.0 ppm and it is further proposed that 40 CFR §185.1850 be amended to reduce the established food additive tolerance for prunes from the current level of 75.0 to 15.0 ppm. This petition is currently in reject status (W.Wassell, 8/20/93, CBTS Nos. 11396, 12350, DP Barcodes D188198, D194020) because of deficiencies relating to storage stability, geographic representation of field trials, and several concerns relating to import tolerances for plums/prunes (including a plum/fresh prune processing study). However, CBTS noted that an examination of the currently approved labels for Ronilan® Fungicide (EPA Reg. Nos. 7969-53, -62 and -85)

show that the proposed use pattern included in the Section B of the subject petition is already included on these labels. Therefore, when available, CBRS will only consider data reflecting this type of application for domestic stone fruit in generating ARs for the acute DRES analysis .

Cherries: Combined residues of vinclozolin and its 3,5-DCA metabolites were 0.05 - 3.79 ppm in/on 109 samples of sweet and sour cherries harvested 0-14 days following the last of 4 foliar broadcast applications of the DF or WP formulations at 1 lb ai/A/application (1x) in 12 tests performed in CA, MI, NY, UT, and WA.

For cherries, a value of 3.79 ppm should be used for the acute DRES analysis.

Peaches/Nectarines: CBTS in their review of PP#1F3976/FAP#1H5615 (W.Wassell, 8/20/93, CBTS Nos. 11396, 12350, DP Barcodes D188198, D194020), noted that no data are available exactly reflecting the new use pattern for peaches or nectarines. CBTS also noted that the residue levels exhibited in the studies having PHI's of 7 days or greater show that the residue levels are not above the proposed reduced tolerance level of 5.0 ppm

For peaches and nectarines, a value of 5.0 ppm should be used for the acute DRES analysis.

Plums: In conjunction with the pending petition (PP#1F3976/FAP#1H5615) to lower tolerances on stone fruit, BASF stated that they wish to retain the current tolerance on plums for import purposes only. Numerous deficiencies relating to this import tolerance exist (W.Wassell, 8/20/93, CBTS Nos. 11396, 12350, DP Barcodes D188198, D194020). These deficiencies include lack of foreign labels (CBTS does not know application rates, timings, or PHIs), field trial data, and a plum processing study.

For plums and prunes, values of 25.0 ppm and 75 ppm respectively (tolerance levels) should continue to be used for the acute DRES analysis.

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