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

MAR 17 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Captan - EPA Registration No. 239-1246 - Review of Protocols for Apple and Grape Crop Field Trial Data and Processing Study Data.
(No MRID Number) [DEB No. 4925] [HED Project No. 9-0786]

FROM: Francis D. Griffith, Jr., Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Richard F. Mountfort, PM 23
Herbicide-Fungicide Branch
Registration Division (H7505C)

THRU: Andrew R. Rathman, Section Head
Dietary Exposure Branch
Health Effects Division (H7509C)

BACKGROUND

ICI Americas, Inc., in conjunction with the Captan Task Force, has submitted four protocols for Captan on grape and apple crop field trial residue data and processing study residue data to determine if a "no detectable residue" situation exists. RD requests DEB review these protocols for data development for tolerance reduction in the raw agricultural commodity (RAC) and to see if the need for food and feed additive tolerances can be eliminated.

CONCLUSIONS

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

DEB has no objections to either the apple or grape protocol for gathering captan and THPI residue data on crop field trials. DEB does suggest the petitioner also obtain total captan residue data from all test sites using exaggerated rates, i.e., 2X, 3X, etc., applications. In both instances, DEB suggests increasing sample size for a more representative sample and to have an adequate reserve sample for unforeseen analytical problems. The registrant is reminded to follow

the Agency's current policy on documenting the handling and storage stability of all samples.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

DEB has no objections to either protocol for gathering captan and THPI residue data on apple and grape processed commodities from the proposed use rate. If exaggerated application rate studies are not conducted, then additional proposed use application rate processing studies may be necessary. In both cases, DEB suggests increasing the initial sample size of the RAC from all test sites for more representative sampling and adequate reserve for unforeseen processing or analytical problems. Analytical method and storage stability concerns on processed commodities are the same as those expressed for the RAC above.

Since the registrant's intent is to establish a "no detectable residue" spray program for captan on apples and grapes which will lead to a reduction of tolerances on the RACs and hopefully no food additive tolerances (FATs), the registrant is provided with a copy of current DEB policy on requirements for processing studies where the RAC contains no detectable residue. The registrant's final report should present all of the data as required by the Data Reporting Guidelines (DRGs) for crop field trials analytical methods, storage stability, and processing studies.

DETAILED CONSIDERATIONS

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

The petitioner has submitted a protocol for use of captan on apples titled "Apple Field Trials with Captan 50-WP to Provide Samples for Use in Residue Analyses" and is coded CAPT-89-MR-02.

The petitioner has submitted a protocol for use of captan on grapes titled "Grape Field Trials with Captan 50-WP to Provide Samples for Use in Residue Analyses" and is coded CAPT-89-M-07.

DEB Comments

The registrant proposes to conduct on apples in the crop year 1989. Five field trials one each in New York, Michigan, West Virginia, California, and Washington will be conducted using captan at 4 lbs ai/acre as a ground foliar spray (50 to 400 gal/acre) with up to a total of seven sprays per season. The geographic representation is adequate for supplementary crop field trial residue data. While the 4.0 lbs ai/acre

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application on apples is acceptable, DEB suggests the registrant consider additional trials as the same site using exaggerated rate applications such as 8 lbs (2X) ai/acre, 12 lbs (3X) ai/acre, etc. The registrant proposes a four-spray schedule of captan on apples at delayed dormant, prepink, pink, and bloom then sampled at maturity. Other plots at the same site will have a fifth spray at petal fall then harvested at maturity, a fifth and sixth spray of petal fall and 1st cover, and a final plot that will have an additional 7th spray at second cover. The registrant will have a control plot at each crop field trial. Control samples are also harvested at maturity. DEB has no objections to this protocol to establish the point where no detectable residues will result on apples.

The registrant proposes collecting a sample of 36 apples (minimum) per plot. While this is acceptable for one (or duplicate) analyses, DEB suggests increasing the sample size to obtain better representative samples, plus have an adequate reserve sample for unforeseen analytical problems.

The registrant proposes to conduct on grapes in the crop year 1989. Five crop field trials one each in California, New York, Washington, West Virginia, and Michigan will be conducted using captan at 2 lbs ai/acre as a ground foliar spray (20 to 200 gal/acre) with up to a total of four sprays per growing season. The geographic representation is adequate for supplementary crop field trial data. While 2 lbs ai/acre application on grapes is acceptable, DEB suggests the registrant consider additional trials at the same sites using exaggerated rate applications such as 4 lbs (2X) ai/acre, 6 lbs (3X) ai/acre, etc. The registrant propose a two-spray schedule of captan on grapes at flower cluster and late prebloom. Other plots at the same site will have an additional 3rd spray at the postbloom stage and a final plot will have an additional 4th spray at a 10- to 14-day cover/postbloom. Harvest of all samples from each of the four plots will be at maturity. There will be a 5th plot to serve as a control plot at each field trial. The samples from each of these plots will be harvested at maturity for residue analysis. DEB has no objection to this protocol to establish the point where no detectable residues will result on grapes.

The registrant proposes collecting a 4 lbs sample from each test plot. While this is acceptable for one (or duplicate) analyses DEB suggests increasing the sample size to obtain a better representative sample plus have an adequate reserve sample for unforeseen analytical problems.

For both apples and grapes the petitioner proposes using the analytical method "Determination of Captan Residues and

its Primary Metabolite THPI in Crops"; Chevron method coded MR-IK-2 (December 29, 1982) as modified by Morse Laboratories. This method is suitable to gather crop field trial residue data.

DEB has no objections to the registrant's proposed sampling and shipping of samples of both apples and grapes. DEB reminds the registrant to document fully the handling of all samples from harvest to analysis. The registrant is referred to the Agency's Position Document titled "Effects of Storage (Storage Stability) on Validity of Pesticide Residue Data" for our current policy and requirements for storage stability data.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

The registrant has presented a protocol to provide residue data on apple processed commodities titled "Apple Trials with Captan 50-WP to Provide Samples of Processed Products for Use in Residue Analyses" and coded CAPT-89-PR-01.

The registrant has presented a protocol to provide residue data on grape processed commodities titled "Grape Trials with Captan 50-WP to Provide Samples of Processed Products for Use in Residue Analyses" and coded CAPT-89-PR-02.

DEB Comments

The registrant proposes using apples from the California and New York field trials discussed above in Magnitude of the Residue - Crop Field Trials in processing studies. DEB reiterates its comments above for apple crop field trials. In the protocol the registrant proposes adding a 6th plot to the California and New York crop field trials in 1989 with Captan 50-WP being used at a 24 lbs ai (6X)/acre application rate for all seven sprays (from delayed dormant through 2nd cover). DEB has no objections to this protocol to generate processing study residue data on apple commodities. However in his cover letter the registrant proposes deleting the exaggerated application rate processing study. DEB suggests the registrant reconsider this course of action in view of the DEB memorandum dated 17 November 1988 on requirements for processing studies when the raw agricultural commodity contains no detectable residues (see attached copy). The registrant should conduct an exaggerated application rate processing study. If exaggerated application rate processing studies are not conducted, then additional proposed use application rate studies may be necessary.

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A 50 lb sample of grapes will be collected for processing. As above, DEB encourages taking extra samples to ensure better representative samples and adequate reserves for unforeseen processing or analytical problems.

The registrant proposes using grapes from California and New York (3 trials total) crop field trials discussed above in Magnitude of the Residue - Crop Field Trials in the processing studies. DEB reiterates its comments above for grape crop field trials. The petitioner is proposing to add a 5th plot to the California (2) and New York crop field trials in 1989 using Captan 50-WP at 10 lbs ai (5X)/acre application rate for all four sprays (from flower cluster through cover). DEB has no objections to this protocol to generate processing study residue data on grape commodities. However in his cover letter the registrant proposes deleting the exaggerated application rate processing study. DEB suggests the registrant reconsider this course of action in view of the DEB memorandum dated 17 November 1988 on requirements for processing studies when the raw agricultural commodity contains no detectable residues (see attached copy). If exaggerated application rate processing studies are not conducted, then additional proposed use application rate studies may be necessary.

A 50 lb sample of grapes will be to collected for processing and at least 10 lbs of dried grapes (raisins) in California only. The registrant proposes using standard grape agricultural practices in California for drying the fresh grapes. As above, the petitioner is encouraged to increase the size of all samples.

Storage stability data for processed apple and grape commodities are the same as for the fresh RAC. DEB reiterates its comments above.

Prior to submitting a final report to the Agency with all of the data generated from these protocols, the registrant is encouraged to review the Pesticide Assessment Guidelines, Addenda on Data Reporting on Magnitude of the Residue--Processed Food/Feed Study, Analytical Method and Storage Stability Study to ensure all data requirements are addressed. These DRGs are available from NTIS.

Attachment:

H7509C:DEB:Reviewer(FDG):CM#2:RM814B:5570826:JOB:56541:
I/WP:Griffith:C.Disk:KENCO:3/8/89:SG:vo:de:Edited:fdg:3/13/89

cc: RF, Circu(7), Reviewer (FDG):Captan Special Review File,
ISB/PMSD:Eldredge
RDI Section Head:A.Rathman:3/15/89:Ed Zager:3/16/89

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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17 NOV 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Clarification of the Requirement for Processing Studies when the RAC Contains No Detectable Residue

FROM: Charles L. Trichilo, PhD., Chief
Dietary Exposure Branch
Health Effects Division

TO: Dietary Exposure Branch Staff

The Residue Chemistry Guidelines state that "Whenever there is a possibility of residue levels in processed foods or feeds exceeding the levels in the raw agricultural commodity (RAC), processing studies are required." The Guidelines also state that "RAC samples used in the processing studies must contain field-treated detectable residues, preferably at or near the proposed tolerance level, so that concentration factors for the various byproducts can be determined."

The purpose of this memorandum is to clarify the branch policy concerning the need for processing studies when no detectable residues are found in the RAC.

If detectable residues are found on a crop for which Table II of the Guidelines lists a processed commodity, then a processing study is required, and if the data show a concentration of residues, then a Food Additive Tolerance (FAT) is required. The processing study should use RAC samples bearing detectable residues. However, if all RAC samples show no detectable residues as a result of the proposed use, then the reviewer may be able to make a conclusion as to the need for processing studies and FATs based on results of field trials carried out at exaggerated rates.

If exaggerated rate data are available and these result in detectable residues, then these samples should be used for a processing study. If residues concentrate on processing, then the concentration factor should be applied to the RAC tolerance level to arrive at the FAT level.

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If exaggerated rate residue data are available and these result in no detectable residues, then no FAT is required provided that: 1) the rate was exaggerated by at least the theoretical concentration factor, 2) the data are sufficiently representative of important growing regions so that any reasonable potential for detectable residues has been realized, and 3) the exaggerated rate was not unrealistically high. This latter requirement arises over concern that if highly exaggerated rates are used the residue would not be distributed in the same proportion as if a 1X rate were used. For example, a 10X application of a granular formulation may result in a larger proportion of the pesticide falling to the ground. The level of exaggeration acceptable will depend on the use. For foliar application, a 5X exaggeration is likely to be an upper limit, but for other types of application, e.g., pre-emergent, a greater exaggeration may be acceptable.

If application of the highest practical exaggerated rate results in no detectable residues and the level of exaggeration is less than the theoretical concentration factor, then samples from this exaggerated rate can be the basis of a processing study. If no detectable residues are found in the processed product, then no FAT is required. If the processed commodity contains detectable residues, then a FAT is needed.

In cases where the RAC contains no detectable residues, the processing study will indicate only that the minimum concentration factor is the ratio of the concentration in the processed commodity to the limit of detection (LOD) in the RAC. The reviewer should evaluate all available data in determining the appropriate concentration factor. This will include, at a minimum, the metabolism studies and the chromatograms (or other raw analytical data) for the RAC samples. In some cases it may be possible to estimate residue levels from chromatograms where the response is below the limit of reliable quantitation but indicative of a "true" residue.

When using exaggerated rate data for consideration of FATs, reviewers should be careful not to set a FAT that is too high based on data not reflective of real-world use. Reviewers should also be careful not to require a FAT if there is no reasonable possibility that the processed product will bear residues higher than the RAC. Occasionally, use of exaggerated rate data will result in no clear indication of whether a FAT is needed, or if it is needed, what level it should be. In these situations, considerable judgment, based on all pertinent data, will be required. For further guidance, please consult your section head.

cc: Petition Review Aids File, RF

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