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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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

P.C. #
020503

JUN 29 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3666 - Chlorine Dioxide Generator Pads on
Fresh Grapes.
Evaluation of the February 21, 1990 Amendment.
(MRID No. 413970-01) [DEB No. 6564]
{HED Project No. 0-1049}

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TO: Jeff Kempter/Walter Francis, PM Team 32
Antimicrobial Program Branch
Registration Division (H7505C)

and

Toxicology Branch II - Herbicide, Fungicide
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Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C)

by m/n

David O. Holzworth, Counsel and U.S. Agent for Frupac International Corporation has submitted this amendment consisting of a cover letter and a supplementary Section D (method validation data) in response to a deficiency outlined and summarized in our review of August 17, 1989 by E.T. Haeberer. The deficiencies are repeated in the body of this review followed by the petitioner's responses, then DEB comments. Our conclusions and recommendation follow.

①

CONCLUSIONS1. **DEB Conclusion on Residue Analytical Method**

The petitioner has presented the minimum amount of acceptable method validation data for inorganic chloride analysis. This residue analytical method is suitable to gather inorganic chloride residue data in/on grapes. The deficiency is resolved.

2. **DEB Conclusion on Proposed Tolerance**

The petitioner has presented a formal petition with a Section F that proposes an exemption from the requirement of a calcium hypochlorite tolerance on table grapes when the chlorine generator pads are used in postharvest application as directed (see 40 CFR 180.1054). The deficiency is resolved.

RECOMMENDATION

There being no further residue chemistry deficiencies associated with this petition and with Toxicology Branch considerations permitting, DEB recommends that 40 CFR 180.1054 be amended to grant an exemption from the requirement of a tolerance for calcium hypochlorite when used as directed in postharvest application on table grapes.

DETAILED CONSIDERATIONS**RESIDUE ANALYTICAL METHOD**

Deficiency from our August 17, 1989 review.

- 1b. Validation data have not been submitted for the inorganic chloride analysis. The registrant claims recoveries of 100 to 117 percent at the 25 to 35 ppm fortification level. Pending receipt of method validation data, we tentatively conclude that the analytical method is adequate for its intended purpose.

Petitioner's Response (See MRID No. 413970-01)

The petitioner has supplied additional method validation data showing recovery of inorganic chloride in fresh grapes. The summary of the data is in a report titled "Supplement to Study" by T.E. Valstrom and dated February 2, 1990.

DEB Comments

The petitioner completed this work in 1988 as part of the initial validation work. In summary, approximately 10 grams of homogenized grapes were adjusted to 10 mL with deionized water, then 10 mL of Chloride Ionic Strength Adjustment solution was added. An initial inorganic chloride reading was taken of each aliquot to determine background inorganic chloride concentration. Values reported were 42, 65, and 55 ppm. To these samples, the petitioner added 53, 27, and 16 ppm inorganic chloride, respectively. Recovery ranged from 93 percent (88 ppm out of an expected 95 ppm for the 53 ppm spike) to 98 percent (90 ppm out of an expected 92 ppm for the 27 ppm spike), and the middle recovery was 98 percent (68 ppm out of an expected 71 ppm for the 16 ppm spike).

The method was further validated using an EPA Standard Water certified to contain 52 ppm inorganic chloride. The petitioner obtained a recovery of 55 ppm (105% recovery).

While the recovery values reported are not those claimed in the initial review, they nonetheless are the minimum amount of data adequate to validate the method. We conclude the method is suitable to gather inorganic chloride residue data for table grapes. The deficiency is resolved.

PROPOSED TOLERANCE

Deficiency from our August 17, 1989 review.

A formal petition should be submitted proposing an exemption.

Petitioner's Response

The PM has now forwarded a copy of the calcium hypochlorite on grapes petition dated July 12, 1988. In the petition, Section F is as follows:

The petitioner proposes to exempt from tolerance calcium hypochlorite when applied to table grapes in accordance with use directions and good agricultural practices for the fungicidal control of botrytis cinerea during storage or transit.

DEB Comments

In our August 17, 1989 review, DEB recommended in favor of an exemption from tolerances for postharvest use of calcium hypochlorite pads on grapes. Review of the petition shows the Section B or Directions for Use proposes a postharvest application use and the Section F proposes an exemption from the requirement of tolerance. The petitioner has submitted a formal petition with a Section F that proposes an exemption from a tolerance. The deficiency is resolved.

DEB reiterates that 40 CFR 180.1054 be amended to add table grapes to the exemptions from the requirement of a tolerance.

cc: R.F., Circu (7), Reviewer (FDG), PP#8F3666, E.T. Haebener, PIB/FOD (Furlow), R. Schmitt, DRES/SCAB (J. Kariya), FDA.

H7509C:DEB:Reviewer(FDG):CM#2:Rm 814B:557-0826:JOB:53482:
I:WP5.0:C.Disk:KENCO:06/19/90:DD:SW:VO:EK:DD:ed:fdg:6/25/90.

RDI:SecHd:RSQuick(by MJN):06/29/90:BrSrSc:RALoranger:06/29/90.