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

MAR 27 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 55947-UE (Endurance 65WDG Herbicide) on Non-bearing Orchards of Fruit, Nuts and Vines crops; 55947- UG (Prodiamine 65WDG Herbicide) for use on Turf and Ornamentals; Response to Product Chemistry Review of Prodiamine 11/26/86. (MRID # 402293-13 ; DEB # 4957 and 4958).

FROM: Freshteh Toghrol Ph.D., Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effect Division (H7509C)

THRU: Francis B. Suhre, Acting Section Head
Special Registration Section II
Dietary Exposure Branch
Health Effect Division (H7509C)

TO: Larry Schnaubelt, Acting PM-23
Herbicide-fungicide Branch
Registration Division (H7505C)

Sandoz Crop Protection Crop., Chicago, Illinois, has submitted residue data, to support the registration of Endurance 65WDG Herbicide [N^3, N^3 - Di- n- propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine] on non-bearing orchards of fruits, nut and vine crops. The petitioner has also responded to deficiencies cited in our previous review on prodiamine product chemistry (F.B. Suhre memo dated 11/21/86,).

There are no established permanent tolerances for prodiamine (other names Endurance, Blockade, USB 3153).

Temporary tolerances were established for prodiamine (USB 3153) residues in a number of raw agricultural commodities, such as almond hulls, cottonseed, cottonseed forage, grapes, nuts, soybeans, soybeans hay and forage and stone fruit at 0.1 ppm (PP#6G1659 and PP#6G1660). These temporary tolerances expired on 4/21/78 and 10/2/80, respectively.

A permanent tolerances petition is pending (PP#9F2236, A. Smith, memo dated 9/16/80) for prodiamine residues in or on almond hulls, almonds, cottonseed, cottonseed forage, grapes, soybeans, soybean hay, soybean forage and walnuts at 0.1 ppm.

The deficiencies cited in our previous review (F. B. Suhre memo dated 11/21/86) on the product chemistry of Technical Prodiamine are restated below, followed by the petitioner's response and DEB's comments.

Deficiency #1, Restated from Review dated 11/21/86.

"The Confidential Statement of Formula(CSF) for Endurance 65WDG, prodiamine 65WDG and Prodiamine (technical) were submitted on EPA Form 8570-4 (revised 10-81). The registrant must resubmit the CSF's for each product on EPA Form 8570-4 (revised 2-85). The 2-85 revised Form requires that a certified upper and lower limit be provided for the active ingredient and that a certified upper limit be provided for all other components. This information was not required on the earlier Form (revised 10-81)."

Petitioner's response to deficiency #1:

The petitioner has provided a Form 8570-4 (revised 2-85) for Prodiamine 65WDG Herbicide (55947-UG).

DEB's Comment #1:

This deficiency is resolved. Endurance 65WDG and Prodiamine 65WDG are identical formulations; but, each product is labeled for a different non-food use.

Deficiency #2, Restated from Review dated 11/21/86.

" Prodiamine is a dinitroaniline; therefore, the technical product must be analyzed for nitrosamine contaminants. The registrant has provided nitrosamine data on laboratory and pilot plant production runs of Prodiamine. The data indicate that the

levels of nitrosamine in the technical product can be controlled (kept below 1.0 ppm) by adjusting the manufacturing process. At the time of commercial production (technical prodiamine) the registrant must analyze samples, from at least 5 production runs, for the presence of nitrosamine contaminants. The nitrosamine sampling requirements appear in Appendix A of the 6-25-80 Federal Register Notice; 42854 FR No. 125."

Petitioner Response to #2

The petitioner has noted a typographical error in our memo of 11/21/86 on the bottom of page 4 (Attachment 1); the statement "... the level of nitrosamine in prodiamine can be controlled by adjusting the manufacturing variables and the level of nitrosamine in the commercial produced technical prodiamine will not exceed [REDACTED]

DEB's Comments #2

This deficiency is not resolved.

DEB agrees with the petitioner that there was a typographical error on the level of nitrosamine. The level of nitrosamine should be kept at [REDACTED]

(memo dated 11/21/86, Confidential Appendix) this should be controlled at less than 1 ppm. The nitrosamine data should be sent to the Agency for review.

Deficiency #3 and #4, Restated from Review dated 11/21/86.

" The registrant has not adequately described the manufacturing process for technical prodiamine" (40 CFR 158.120, 61-2(b)).

" The data submitted for the preliminary analysis of technical prodiamine is not adequate to support registration. The registrant must analyze 5 or more representative samples and must submit the data for each sample. In addition, the registrant must chemically elucidate the structure of each impurity present at >0.1% in the technical product."

Petitioner Response #3 and #4

The petitioner has not responded to these deficiencies in this package.

DEB's Comments #3 and #4

PRODUCT IMPURITY INFORMATION IS NOT INCLUDED

These deficiencies are not resolved.

Magnitude of the Residue:

In addition the registrant has re-submitted data previously reviewed by DEB in connection with PP#6G1659 and PP#6G1660 (prodiamine on nuts, stone fruits and grapes). These data indicate no significant likelihood that prodiamine residues will occur in food or feed items as a result of this proposed use on non-bearing orchards. A possible exception involves prodiamine residues ranging from <0.01 to 0.03 ppm on almond hulls harvested (10 months after treatment) after contacting the orchard floor. Residues of prodiamine on almond hulls ranged from <0.01 to 0.03 ppm. A tree, nut and vine terrestrial dissipation study is currently in process to determine whether residues of prodiamine could transfer to food or feed items contacting the ground (in treated orchards) prior to or during harvest (Sandoz letter dated 4/14/88).

Conclusions:

1. The product chemistry of technical prodiamine is not adequately understood (see deficiencies 2, 3, and 4 in this memo).
2. No permanent tolerances are currently established for prodiamine.
3. The available residue data indicate that the proposed use of Endurance 65WDG Herbicide on non-bearing orchards is a non-food use, however, we withhold our final decision on this issue pending a review of the terrestrial dissipation study currently in progress.

Recommendation:

DEB recommends against the registration of technical prodiamine, for the reasons cited in conclusion 1 of this memo.

We further recommend that the terrestrial dissipation study

for prodiamine be reviewed by the Environmental Fate and Ground Water Branch, when it is received. A copy of their review should be provided to DEB to aid us in reaching a decision on whether the proposed use of Endurance 65WDG Herbicide on non-bearing orchard reflect a non-food use.

cc: Circ, R.F., Prodiamine S.f., F. Toghrol PMSD/ISB
RDI: F.B. Suhre Acting Section Head: 3/10/89: E. Zager Acting
Deputy Branch Chief: 3/10/89
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