1 cy.

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

CASWELL FILE

JUN 13 1984

7548

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Accession No. 072376

Subject: PP#2F2716/2H5359. Dyfonate in or on potatoes. Amendment of 2/21/84.

From: Martha J. Bradley, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: William Miller, PM 16
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Stauffer Chemical Company has submitted this amendment in response to our (M. Nelson) memo of 9/15/82. The deficiencies listed in the above memo are repeated below with the response and our comments/conclusion.

Deficiency 1b. A large animal (lactating ruminant) metabolism study, presently lacking, is needed. Pending receipt and review of such a study, we can not consider the nture of the residue in animals to be adequately delineated for purposes of this petition.

Response 1. The petitioner has submitted a metabolism study in the lactating goat using phenyl-$^{14}C$ labeled Dyfonate. Two goats received a single oral dose of ca. 2 mg/kg, (one labeled and one unlabeled) and two goats received ca. 2 mg/kg in four doses spaced at 48 hour intervals (one labeled and one unlabeled). Nine days after the last dosing, three of the goats were sacrificed, the animal receiving the single unlabeled dose was not sacrificed but used in an additional study after receiving a single labeled dose of ca. 2 mg/kg. It is unclear whether the animal that received the labeled single oral dose was sacrificed nine days after receiving the dose or was held until nine days after the last of the multiple doses were given. Recovery of $^{14}C$ nine days after dosing, as

percent of administered dose, ranged from 45 to 77% in urine, 16-21% in feces, 0.7 to 2% in milk and 0.2-0.3% in tissues. The radio-labeled residue in milk, blood and urine was characterized, however the tissue residue was not. The primary metabolites found were the phenyl methyl sulfone in milk and blood and the 3- and 4-hydroxyphenyl methyl sulfone in urine.

Comments/Conclusion 1. The submitted metabolism study was apparently designed to study the absorption and elimination of Dyfonate, and does not identify the tissue residues which are our greatest concern. The petitioner should conduct a new lactating ruminant metabolism study and should consult the Residue Chemistry Guidelines for the nature of the residue in livestock for the proper procedures (such as animals should be dosed daily for at least three days and animals should be sacrificed within 24 hours of cessation of dosing).

This deficiency has not been resolved.

In addition, the poultry metabolism study required by the fonofos (Dyfonate) Registration Standard issued March, 1984, should be submitted for this petition.

Deficiency 2b. The potato field trial data were reportedly analyzed by methods WRC-71-26 and RRC-72-35. We request information on those methodologies (extraction and clean-up procedures, determinative conditions, etc.) so we can determine if they are adequate for purposes of providing residue data.

Response 2b. The petitioner has submitted the residue method WRC 72-35 and states that all residue samples submitted in this petition were analyzed with this method and any reference to other methods in the subject studies is an error.

Comments/Conclusion 2b.

Method WRC (or RRC) 72-35 is the same as and supercedes WRC 70-39 and is summarized in our (M. Nelson) memo of 9/15/82. The method is a revised version of RR-67-2 submitted in PP#7F0548 and published in PAM II as Method A, although successful method trials were conducted on asparagus and peanuts. The revisions are the use of a rubidium sulfate tip in the flame detector, 8% DC-200 column, larger volumn of elution solvents for the silicic acid column clean-up, omission of TLC clean-up for the metabolite and slightly higher GLC temperatures for faster elution times. These revisions should be added as a supplement to Method A and Method A should be changed to Method I since method trials were conducted.

This deficiency has been resolved.

Deficiency 2c. Depending on the outcome of the requested feeding studies (see Conclusions 4a and 4b), enforcement methodology may be needed for meat, milk, poultry, and eggs. (If this is the case, the methodology would need to be validated, and method trial (s) conducted in EPA laboratories.)

Response 2c. See Response 4a and 4b.

Comments/Conclusion 2c. Depending on the outcome of the requested metabolism (Conclusion 1) and feeding (Conclusion 4a and 4b) studies, enforcement methodology may be needed for meat, milk, poultry, and eggs.

This deficiency has not been resolved.

Deficiency 3a. Based on the information provided by the petitioner, and contingent upon satisfactory resolution of Conclusion 2b, we conclude that the proposed 3 ppm food additive tolerance for potato waste (peels) is appropriate.

For consistency within the Regulations, we suggest that the tolerance if/when established be expressed in terms of "processed potato waste".

Deficiency 3b. Taking into consideration that up to 3 ppm residue will be permissible in peels and that peeling losses reportedly average 10-15%, we conclude that a 0.2 ppm tolerance level for whole potatoes may not be adequate. We suggest 0.5 ppm as a more appropriate level and request a revised Section F to reflect this. Alternately, the petitioner can provide actual data demonstrating what residue levels in whole potatoes (representative varieties, immature and mature, new and old, etc.) will be when ca 3 ppm residue is present in/on the peels, and propose an appropriate tolerance for whole potatoes based on that.

Response 3a and 3b. The petitioner has revised Section F and now requests a 1.0 ppm Food Additive tolerance on processed potato waste and has not changed the proposed tolerance on whole potatoes from 0.2 ppm. The petitioner states that few whole potato samples exceeding the existing tolerance of 0.1 ppm have been reported since 1981 and that random sampling of potato peelings from processing operations in 1982 and 1983 further support the revised proposed tolerances.

Comments/Conclusion 3a and 3b. The petitioner originally stated that over-tolerance residues were occuring in potatoes and could cause an economic hardship because the potatoes had to be stored while the residue degraded to acceptable limits. The petitioner's 1980 residue studies showed that residues concentrate in the potato peel and that random samples of peelings taken from potato processing operations, although the data are not submitted, were as high as 1.8 ppm.

In view of the above information, the submitted residue data for peels, pulp and whole tubers (one study consisting of 5 different modes of application at 1X and 2X) are inadequate to support a 1 ppm tolerance on processed potato waste (peels). The residue field trials are apparently not reflective of commercial agricultural practice and are definitely lacking in geographical representation of potato growing areas. In addition, residues on whole tubers approach the proposed 0.2 ppm tolerance level at 1/2X and 3/4X application rate and reach that level when the data are normalized to 1X rate.

Additional residue data are needed for whole tubers, peel and pulp reflecting maximum application rates and representing the geographic potato growing areas in the U.S. in order to determine adequate tolerance levels in whole potatoes and processed potato waste (peels). A potato processing study with potatos bearing detectable residues is also needed to determine residue levels on the processed human and animal feed items, including dried products.

This deficiency has not been resolved.

Deficiency 3c. Depending on the outcome of the requested feeding studies (see Conclusions 4a and 4b), tolerance proposals may be needed for meat, milk, poultry, and eggs.

Response 3c. See Response 4a and 4b.

Comments/Conclusion 3c. This deficiency has not been resolved.

Deficiency 4a. A new lactating ruminant feeding study, run at higher levels, is needed. We suggest dosing levels of 0, 1.5, 5 and 15 ppm as suitable.

Response 4a. Since the petitioner is now proposing a reduced food additive tolerance of 1 ppm, a higher level feeding study was not conducted.

Comments/Conclusion 4a. Depending on the residue levels on whole potatoes and processed products, the requested new lactating ruminant feeding study may be needed. This deficiency has not been resolved.

Deficiency 4b. A poultry feeding study, presently lacking (except for quail), is needed. We suggest dosing levels of 0, 0.3, 1.0 and 3.0 ppm. (Other levels might be preferable to the petitioner if there are future plans involving other poultry feed items).

Response 4b. A letter from the Northwest Food Processors Association is submitted stating that a survey of their 11 members and an unknown number of non-members revealed that none of the potato by-products generated by the potato processing industry in Oregon, Idaho and Washington are being used for poultry feed. Therefore, a poultry feeding study is not submitted.

Comments/Conclusion 4b. According to Harris (Guide for Estimating Toxic Residues in Animal Feeds or Diets) and Morrison (Feeds and Feeding, Abridged, 9th Ed.), potatoes and their by-products are considered to be poultry feed items. Therefore, the requested poultry feeding study should be submitted.

This deficiency has not been resolved.

Deficiency 4c. We defer classification of the proposed uses as to 40 CFR 180.6(a) pending receipt and review of the requested feeding studies (see Conclusions 4a and 4b).

Response 4c. See Response 4a and 4b.

Comments/Conclusion 4c. This deficiency has not been resolved.

Conclusions

1a. The submitted metabolism study was apparently designed to study the absorption and elimination of Dyfonate, and does not identify the tissue residues which are our greatest concern. The petitioner should conduct a new lactating ruminant metabolism study and should consult the Residue Chemistry Guidelines for the nature of the residue in livestock for the proper procedures (such as animals should be dosed daily for at least three days and animals should be sacrificed within 24 hours of cessation of dosing). The study should identify the residues in milk and tissues.

1b. In addition, the poultry metabolism study required by the fonofos (Dyfonate) Registration Standard issued March, 1984, should be submitted for this petition. The residues in eggs and tissues should be identified.

2b. Method WRC (or RRC) 72-35 is the same as and supercedes WRC 70-39 and is summarized in our (M. Nelson) memo of 9/15/82. The method is a revised version of RR-67-2 submitted in PP#7F0548 and published in PAM II as Method A, although successful method trials were conducted on asparagus and peanuts. The revisions are the use of a rubidium sulfate tip in the flame detector, 8% DC-200 column, larger volumn of elution solvents for the silicic acid column clean-up, omission of TLC clean-up for the metabolite and slightly higher GLC temperatures for faster elution times. These revisions should be added as a supplement to Method A and Method A should be changed to Method I since method trials were conducted.

2c. Depending on the outcome of the requested metabolism (Conclusion 1) and feeding (Conclusion 4a and 4b) studies, enforcement methodology may be needed for meat, milk, poultry, and eggs.

3a and 3b. The petitioner originally stated that over-tolerance residues were occuring in potatoes and could cause an economic hardship because the potatoes had to be stored while the residue degraded to acceptable limits. The petitioner's 1980 residue studies showed that residues concentrate in the potato peel and that random samples of peelings taken from potato processing operations, although the data are not submitted, were as high as 1.8 ppm.

In view of the above information, the submitted residue data for peels, pulp and whole tubers (one study consisting of 5 different modes of application at 1X and 2X) are inadequate to support a 1 ppm tolerance on processed potato waste (peels). The residue field trials are apparently not reflective of commercial agricultural practice and are definitely lacking in geographical representation of potato growing areas. In

addition, residues on whole tubers approach the proposed 0.2 ppm tolerance level at 1/2X and 3/4X application rate and reach that level when the data are normalized to 1X rate.

Additional residue data are needed for whole tubers, peel and pulp reflecting maximum application rates and representing the geographic potato growing areas in the U.S. in order to determine adequate tolerance levels in whole potatoes and processed potato waste (peels). A potato processing study with potatos bearing detectable residues is also needed to determine residue levels on the processed human and animal feed items, including dried products.

3c. Depending on the outcome of the requested feeding studies (see Conclusions 4a and 4b), tolerance proposals may be needed for meat, milk, poultry, and eggs.

4a. Depending on the residue levels on whole potatoes and processed products, the requested new lactating ruminant feeding study may be needed.

4b. According to Harris (Guide for Estimating Toxic Residues in Animal Feeds or Diets) and Morrison (Feeds and Feeding, Abridged, 9th Ed.), potatoes and their by-products are considered to be poultry feed items. Therefore, the requested poultry feeding study should be submitted.

4c. We defer classification of the proposed uses as to 40 CFR 180.6(a) pending receipt and review of the requested feeding studies (see Conclusions 4a and 4b).

5. A revised International Residue Limit Status sheet is attached. When the potato tolerances are revised, there will be an unavoidable conflict with Canadian limits. The U.S. data indicate the need for a higher tolerance level for potatoes. There will be no conflict with Codex because no Codex tolerance exists for potatoes.

Recommendations

We recommend against the proposed tolerance requests at this time because of Conclusions 1a, 1b, 2c, 3a, 3b, 3c, 4a, 4b and 4c.

cc: R.F., Circu, Reviewer, TOX, EAB EEB, PP#2F2716/2H5359
RDI:R. Quick:6/11/84
TS-769:RCB:M. Bradley:edited:wh:6/13/84:CM#2:RM810:X7484

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Dyfonate (fonofos) PETITION NO. 2F2716/2H5359

CCPR NO. _____

Codex Status

|X| No Codex Proposal Step 6 or above

Proposed U.S. Tolerances

180.221

Residue (if Step 9):

_____

Crop(s) Limit (mg/kg)

Residue: Dyfonate and its oxygen analog

| Crop(s) | Tol. (ppm) | |
|---|---|---|
| potatoes | 0.2 | |
| potato waste (peels) | 1.0 | FA |

CANADIAN LIMIT

Residue: _____

parent presumably

| Crop | Limit (ppm) |
|---|---|
| potatoes | 0.1 |

MEXICAN TOLERANCIA

Residue: _____

parent presumably

| Crop | Tolerancia (ppm) |
|---|---|
| none (on potatoes) | |

Notes: