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

JUN 19 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 8F3603 - Pyridate (Tough®) on Cabbage, Corn and Peanuts.
Evaluation of the April 10, 1991 Amendment.
(No MRID #) [DEB #7919, 7920 and 7921]
(HED Project # 1-1144, 1-1145 and 1-1146)

FROM: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (H-7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (H-7509C)

TO: Robert J. Taylor, PM-25
Fungicide-Herbicide Branch
Registration Division (H-7505C

and

Toxicology Branch
HFA Support
Health Effects Division -7509C)

Agrolinz, Inc. has submitted this amendment consisting of a revised Section B (new labels for two formulations of Tough®) and a supplementary Section A (additional product chemistry data) in response to deficiencies outlined and summarized in our reviews of April 25, 1990, and February 6, 1991, by F. D. Griffith, Jr. The deficiencies are listed and repeated in the body of this review followed by the petitioner's response, then CBTS comments. Our conclusions and recommendations follow.

EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES REMAINING

None

CONCLUSIONS

1. CB Conclusion on **Product Identity/Product Chemistry**

The petitioner has submitted a revised Confidential Statement of Formula (CSF) dated April 1, 1991, which identifies two impurities by name and number. On the CSF two other impurities have been renamed to clarify and use consistent nomenclature. These deficiencies are resolved. No further product chemistry data are required for this petition.

2. CB Conclusion on **Directions for Use/Labeling**

The petitioner has presented a revised label for use of Tough® 45 WP on cabbage and field corn, and for Tough® 3.75 EC on peanuts and field corn. These revisions have the suggested PHI's and feeding restrictions in a logical place on the label. The petitioner has now proposed adequate directions for use of pyridate on field corn, peanuts and cabbage. The deficiency is resolved. No further revisions for the Directions for Use are required.

3. CB Conclusion on **Harmonization of Tolerances**

An International Residue Limit (IRL) Status Sheet is attached to this review that shows there are no Codex or Mexican tolerances for pyridate and metabolites on cabbage or peanuts. There is a Canadian tolerance for total pyridate on corn at 0.1 ppm. This is a negligible residue type limit. The Canadian total pyridate tolerance on corn can not be harmonized with the proposed pyridate corn tolerance of 0.03 ppm.

RECOMMENDATION

TOX considerations permitting and considering that there are no chemistry deficiencies remaining with this petition CBTS makes the following recommendation:

- Since total residues of pyridate, per se, its CL 9673 metabolite, and conjugates of the metabolite are not expected to exceed the proposed tolerances under the proposed Tough® conditions of use, CB recommends for the 0.03 ppm total pyridate tolerance on cabbage, for the 0.03 ppm tolerance on corn grain, forage, silage and fodder and for the 0.03 ppm on peanut and peanut hulls tolerance. The tolerance expression should be as specified in our review of April 5,1990 by F.D. Griffith, Jr.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY/PRODUCT IDENTITY

Deficiency (From our February 6, 1991, review)

61-1. Product Identity and Disclosure of Ingredients

The Agency Review dated 6/28/90 requires additional information pertaining to the product composition of the Agrolinz 90.96% T (EPA File Symbol No. 42545-LO) including nominal concentrations for each impurity structurally related to the active ingredient or present at a level equal to or greater than 0.1% by weight of the TGAI.

In response, Agrolinz has submitted data (1990; MRID 41694801) that include an updated CSF listing the required nominal concentrations. These data are presented in Confidential Appendix A and satisfy the requirements of the 40 CFR 158.155 (Guideline Reference No. 61-1) regarding the identity of the Agrolinz 90.96% T (EPA File Symbol No. 42545-LO). No additional data are required; however, we note that one impurity appears to have been incorrectly named on the current CSF. In addition, the previously reviewed CSF (CBRS Nos. 6611 and 6612, dated 6/38/90) and the corrected CSF bear the same date, 3/27/90; new and revised information must be submitted on a new EPA Form 8570-4 (Rev. 2-85)

and

62-3. Enforcement Analytical Methods

The Agency Review dated 6/28/90 requires additional information pertaining to enforcement analytical method for the Agrolinz 90.96% T (EPA File Symbol No. 42545-LO) including validation studies depicting the accuracy of the analytical methods submitted for enforcement purposes.

In response, Agrolinz has submitted the additional validation studies (1990; MRID 41694801) for the enforcement analytical methods. These data are presented in Confidential Appendix E and satisfy the requirements of 40 CFR 158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 90.96% T (EPA File Symbol No. 42545-LO). No additional data are required; however, we note that the registrant should identify two impurities presently designated only by numbers.

Petitioner's Response

The petitioner has submitted a revised Confidential Statement of Formula (CSF) for the Agrolinz 90.96% T (EPA File Symbol No. 42545-LO).

CB Comments

The revised CSF is dated 4/1/91. This corrects the discrepancy in dates on previous CSF's. This part of the deficiency is resolved.

For the enforcement analysis methods the petitioner has now identified compounds "274" and "277". These compounds are listed on the 4/1/91 CSF both by numbers and chemical names. This part of the deficiency is resolved.

The revised CSF corrects the name of the impurity. In addition the petitioner has also renamed impurity number 2 in order to clarify and utilize the same nomenclature used to rename the impurity in question. This is acceptable to CB. The deficiency is resolved.

There are no further product chemistry deficiencies remaining to be resolved.

DIRECTIONS FOR USE/LABELING

Deficiency (From our April 25, 1990, review)

The petitioner needs to further revise the directions for use for Tough 45 WP and Tough 3.75 EC. The Livestock Safety paragraphs should be deleted. Under the Use directions section a separate paragraph titled Restrictions should clearly define the livestock feeding restrictions suggested. These include no feeding of treated peanuts vines and hay, 45 days before feeding cabbage, and no grazing or feeding of treated corn grain, forage, or fodder within 68 days application of pyridate.

Petitioner's Response

The petitioner has submitted revised labels for use of Tough® 3.75 EC and Tough 45 WP on cabbage, field corn, and peanuts.

CB Comments

On the revised Tough® 45 WP label the petitioner has deleted the entire Livestock Safety paragraph as CB had suggested. Under the Section Use Direction the petitioner has in the Use on Cabbage a 45 day PHI. Also under Use on Cabbage the petitioner

now has a Restrictions paragraph prohibiting use of treated cabbage as livestock feed for 45 days after application. In the Use on Field Corn section the petitioner has a 68 day PHI for corn and a new Restrictions paragraph that prohibits grazing or otherwise feeding of treated corn grain, forage or fodder within 68 days of application. This part of the deficiency is resolved.

On the revised Tough® 3.75 EC label the petitioner has deleted the entire Livestock Safety paragraph as CB had suggested. Under the section Use Directions the petitioner has in the Use on Peanuts a Restrictions paragraph prohibiting grazing or otherwise feeding of treated peanut hay and vines to livestock. In the Use on Field Corn the petitioner has a Restrictions paragraph prohibiting the grazing or other wise feeding of treated corn grain, forage, or fodder within 68 days of application. This part of the deficiency is resolved.

The petitioner now has proposed an adequate set of directions for use of Tough® 3.75 EC (pyridate a.i.) on peanut and field corn. The petitioner has proposed an adequate set of directions for use of Tough® WP (pyridate a.i.) on cabbage and field corn.

OTHER CONSIDERATIONS - HARMONIZATION OF TOLERANCES

A revised International Residue Limit Status Sheet (IRLS) is attached to this review. There are no Mexican or Codex tolerances established for total pyridate residues on cabbage or peanut, thus compatibility of tolerance is not a problem in this instance. There is a Canadian tolerance for total pyridate residues on corn at 0.1 ppm. This is a negligible residue type limit. The Canadian pyridate tolerance on corn at 0.1 ppm can not be harmonized with the proposed U.S. pyridate on corn tolerance at 0.03 ppm.

Attachment: International Residue Limit Status Sheet

cc: R.F.,Circ(7),Reviewer(FDG),PP#8F3603,PIB/FOD(Furlow), FDA(P.Corneliussen),DRES/SACB(Kariya).

H-H7509C:CBTS:Reviewer(FDG):vg:6/13/91:CM#2:Rm814B:557-0826: edit:fdg:6/14/91.

RDI:SecHd:RSQuick:6/14/91:BrSrSci:RALoranger:6/14/91.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Pyridate (Tough®)

CODEX NO. ____

CODEX STATUS:

☑ No Codex Proposal Step 6 or above

Residue(if Step 8): ____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 8F3603

RCB Reviewer F.D. Griffin Jr 5/11/91

Residue: For 40 CFR 180.xxx, Pyridate*, its metabolite and metabolite conjugates

Crop(s)	Limit (mg/kg)
Cabbage, with and without wrapper leaves	0.03
Corn; grain, forage, silage, fodder	0.03
Peanuts; nutmeat and hulls	0.03

CANADIAN LIMITS:

☑ No Canadian limit (on ~~above~~ cabbage)

Residue: ____

Crop(s)	Limit (mg/kg)
Corn	0.1**

MEXICAN LIMITS:

☑ No Mexican limit

Residue: ____

Crop(s)	Limit (mg/kg)

NOTES:

* O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl carbonothioate

** Negligible residue ~~type~~ limit

Form revised 1986