November 10, 1972

PP #1F1171 and FAP #1H2661. Chlordimeform (formerly Chlorphenamidine) on various commodities. Comments on the amendment of 10/4/72 (revised Sections B and F).

Petition Control Branch
and Toxicology Branch

In the PCB reject letter of 9/11/72 the petitioner was informed of the following deficiencies (see also our memo of 9/1/72):

1. The proposed label restriction prohibiting the use of chlordimeform on prunes grown for drying is not practical.

2. An appropriate tolerance for residues on dried prunes is required.

In response to Deficiency #1, the petitioner has submitted a revised label which does not include the restriction prohibiting the use on prunes grown for drying. We, therefore, can consider Deficiency #1 to be resolved.

In response to Deficiency #2 the petitioner proposes a 15 ppm food additive tolerance for residues of chlordimeform on dried prunes. In our memo of 9/1/72, we concluded that a tolerance of 15 ppm would be appropriate for residues on dried prunes, and therefore, we can now consider Deficiency #2 resolved.

Conclusions and Recommendations

1. Deficiencies #1 and 2 have been resolved.

2. Pharmacological considerations permitting, we recommend for the establishment of the proposed tolerances for residues of chlordimeform and its metabolites containing the 4-chloro-o-toluidine moiety calculated as chlordimeform, in or on peaches, nectarines and cherries at 5 ppm; plums (fresh prunes) at 4 ppm; walnuts at 0.1 ppm; and in dried prunes at 15 ppm (food additive tolerance).

John M. Worthington
Chemistry Branch
Pesticides Tolerances Division

cc: Tox.Br., RO-130(FDA),Mr.C.Smith(PRD),Chem.Br.,PP #1F1004

JMWorthington:sgd 11/10/72 RD/I - GBeusch 11/10/72 RSQuick 11/10/72

September 1, 1972

PP #1F1171 and FAP #1H2661, Chlorphenamidine on various commodities. Comment on the amendment of 6/19/72 (Revised Sections B, D, and F).

Petitions Control Branch
and Toxicology Branch, PTD

In PCB's reject letter of 4/5/72, the petitioner was informed of the following deficiencies (see also memo of 3/16/72 by J. Worthington):

1. The residue data submitted for plums and prunes are inadequate to determine if the residues in these commodities will exceed the proposed tolerances.

2. No tolerance proposal is required for walnut shells because nutmeat is considered the raw agricultural commodity of walnuts.

3. Additional residue data (number of applications, preharvest interval, and time of applications) are required for plums and dried prunes. These data should include the determination of residues that would result from the application of Chlorphenamidine before the fruit is present on the tree as well as information regarding the stage of development of the trees and the date at the time of spraying.

This amendment is in response to PCB's reject letter. It revises Sections B, D, and F.

The revised Section F proposes a 5 ppm tolerance on peaches, nectarines, and cherries, a 4.0 ppm tolerance on plums and a 0.1 ppm tolerance on walnuts for residues of N'(4-chloro-o-tolyl)N,N dimethylformamidine (trade name Chlorphenamidine, proposed common name chlordimeform) and its metabolites containing the 4-chloro-o-toluidine moiety calculated as N'(4-chloro-o-tolyl) N,N dimethylformamidine. It deletes the tolerances for residues of Chlorphenamidine on walnut shells and dried prunes. The other proposals remain the same.

The revised Section B imposes an additional label restriction prohibiting the use on prunes grown for drying. In the conference of 4/13/72, we stated that a "fresh fruit market only" restriction may be acceptable if it could be shown that such a restriction would be practical. We would consider the restriction practical if it could be demonstrated that the varieties of plums or prunes produced for fresh market were

distinct from those produced for drying. The petitioner has failed to demonstrate this. Four letters have been submitted by prune producers that state they would not consider a use for "fresh prunes only" discriminatory. The letters do not comment on the question of practicality. We are not inclined to consider the label restriction adequate. However, this point is no longer pertinent since we are recommending for a food additive tolerance of 15 ppm (see below).

The revised Section D includes additional ifnormation on the residue data submitted in the original petition. The information indicates that the single high value was high because the fruit was harvested before it was mature (and was considerably smaller in size than mature fruit) in order to obtain data for a residue decline study at the 21-day preharvest interval. This was the only value that indicated residues may exceed the proposed tolerance. Data were also requested to determine residues that would result from applications before bloom. However, because these applicatimns are to be made before fruit is present on the tree, and because of the length of time between petal fall and harvest (about 140 days), we now conclude that residues from these applications will not be significant when compared to the 4.0 ppm tolerance. We therefore conclude that the residue data for plums are adequate to demonstrate that residues resulting from the proposed use will not exceed the proposed tolerance.

Data for dried prunes are submitted. The data determining weight loss upon drying indicate that there is about a 66% weight reduction due to the loss of water. A 66% weight loss corresponds to a concentration of 3X. Residue data are also submitted for these prunes. Residues are reported to be 5X greater after drying. However, it is our judgment that the discrepancy here is probably due to method varibility. We therefore conclude that residues in prunes would concentrate upon drying at about the maximum theoretical rate of 3.5X. It has been determined that residues in plums from the proposed use will not exceed 4.0 ppm. Thus a 15 ppm tolerance for residues on dried prunes would be appropriate.

Conclusions

1. We can now consider the residue data adequate to demonstrate that residues from the proposed use will not exceed the proposed 4.0 ppm tolerance for plums.

2. We cannot consider the proposed label restriction prohibiting the use on prunes grown for drying adequate. A food additive tolerance proposal is required for a favorable recommendation. It is our judgment that a 15 ppm tolerance level would be appropriate.

3. A tolerance is no longer proposed for walnut shells. We reiterate our previous conclusion that the proposed 0.1 ppm tolerance for walnuts is adequate.

Recommendations

1. We find that we cannot recommend for the proposed tolerance for plums for the reason stated in Conclusion #2.

2. We reiterate our previous recommendation for the establishment of the proposed tolerances on peaches, nectarines, and walnuts.

John M. Worthington
Chemistry Branch
Pesticides Tolerances Division

cc: Tox.Br.
RO-130(FDA)
C.Smith(PRD)
Chem.Br.
PP #1F1171

JMWorthington:jrf
9/1/72
RD/I - RSQuick-8/30/72
JGCummings-9/1/72

David L. Ritter, Pharmacologist
Toxicology Branch
Pesticides Tolerances Division

cc: JGCummings
PRD/EPA
Atlanta Branch
Perrine Branch
Division Reading File
Branch Reading File
PP# 1F1171
FAP# 1H2661

AUG 4

R/D Init: Whitmore 8/1/72
DLRitter:dtb 8/2/72