April 19, 1972

FAP #2H5011. Chlordimeform* (formerly called Chlorphenamidine) in dried apple pomace. Evaluation of petition.

Petitions Control Branch
and Toxicology Branch

NOR-AM Agricultural Products, Inc., and CIBA Agrochemical Company jointly propose a food additive tolerance of 25 ppm for residues of chlordimeform, N'-(4-chloro-o-tolyl)-N,N-dimethylformadine, and its metabolites containing the 4-chloro-o-toluidine moiety calculated as chlordimeform, in dried apple pomace.

A pesticide tolerance of 3 ppm was established for apples (PP #0F0885). At the time of that review, residues in apple pomace were not a consideration because of the USDA policy statement of March 22, 1960 regarding feed uses. Therefore, no data were submitted or requested for apple pomace. However, since that time, we have learned that apple pomace should be considered as an item of feed. Therefore, in our review of a subsequent Chlordimeform petition, PP #2F1185 which also involved an animal feed, we requested data for apple pomace in order to categorize the use in regard to Sec. 180.6(a). This petition is a response to that request.

Conclusions

The proposed 25 ppm food additive tolerance is appropriate. Data show that residues up to 22 ppm are present in dried apple pomace derived from treated apples containing residues at the established tolerance level of 3 ppm.

In PP #0F0885, chlordimeform on apples and pears, we concluded that:

1. The metabolic pathway of chlordimeform in plants is well defined.

2. Adequate analytical methods are available to enforce the tolerance for chlordimeform in apples.

*Chlordimeform has now been proposed as a common name for Chlorphenamidine.

3. Soil persistence and the formation of azobenzene, azoxybenzene and triazene compounds in soil will not be a problem.

We reaffirm the above conclusions, and add that the analytical method is also adequate to enforce the food additive tolerance.

Recommendation

Pharmacological considerations permitting, and contingent upon the establishment of the meat and milk tolerances proposed for chlordimeform in PP #2F1185, we recommend for the 25 ppm food additive tolerance for dried apple pomace. If the meat and milk tolerances are rejected because of toxicological concern, then the established apple tolerance should be withheld.

Comments

The results of an apple processing study are presented. The whole apples, analyzed prior to processing, contained 4.92 ppm chlordimeform residues. Cider contained 1.98 ppm, wet pomace 9.23 ppm, and dried pomace 35.7 ppm chlordimeform residues. Using these figures the following calculations can be made:

$$\frac{9.23 \text{ ppm in wet pomace}}{4.92 \text{ ppm in whole apples}} = 1.9 \text{ concentration factor.}$$

$$\frac{35.71 \text{ in dry pomace}}{4.92 \text{ ppm in whole apple}} = 7.3 \text{ concentration factor.}$$

A tolerance of 3.0 ppm chlordimeform residues has been established for [illegible] (40CFR180.085).

Using the concentration factors calculated above, wet and dry pomace derived from treated apple containing residues at the tolerance level of 3 ppm would contain the following residues:

3 ppm x 1.9 = 5.7 ppm in wet pomace
3 ppm x 7.3 = 21.9 ppm in dry pomace

[illegible] data, we conclude that the proposed 25 ppm food additive [illegible] for dried apple pomace is appropriate. A tolerance is needed [illegible] pomace because it is the item of concern.

The carry over of residues into meat and milk is discussed in PP #2F1185.

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4/19/72

[illegible]PHENAMIDINE

[illegible]thyl-N'-(2-methyl-4-[illegible]phenyl)formamidine]

~~0G0652~~ 0.5 ppm-apples, → 9G0768 (grapes + pome)

0F0885 3 ppm-apples;4 ppm-peaches,plums & prunes; 5 ppm-pears

0H2457 10 ppm-dried prunes.

0F0980 2 ppm-cabbage, broccoli,cauliflower,brussels sprouts.

Petition File missing →

1G1022 - 5 ppm - cottonseed.

1F1171 - 5 ppm-eaches, nectarines, cherries; 4 ppm-plums (fresh prunes; 0.25 ppm - walnuts;

Incomplete data ⇒ 1H2661 - 15 ppm - dried prunes.

2F1185 - 5 ppm cottonseed; 0.2 ppm meat, fat, meat by-products of poultry; 0.1 ppm meat, fat, meat byproducts of cattle, goats, hogs and sheep

2H5011 - 25 ppm-dry apple pomace.

4E1433 - 1 ppm - tomatoes

4G1456 - 3 ppm - citrus fruits and hybrids

4F1477 - 12 ppm - pears