PP# 5F1537 & FAP# 5H5061. Thiabendazole on potatoes and in potato waste. Evaluation of analytical methods and residue data.

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Merck & Company, Incorporated, proposes a tolerance of 3 ppm for residues of the systemic fungicide thiabendazole on tubers and a food additive tolerance of 30 ppm for residues of thiabendazole in or on waste from commercial processing of tubers. It is clear from the data in the petition, as well as the petitioner's discussion of the data, that the intent of this petition is to propose tolerances for potatoes and potato processing waste to cover postharvest applications of thiabendazole. We suggest use of "potato(es)" in lieu of "tuber(s)" in the Regulations if and when the tolerance is established.

There is an existing tolerance of 0.1 ppm for residues of thiabendazole in or on potatoes grown from seed potatoes treated with the fungicide (see PP# 4E1473). When the currently proposed tolerance is established, the existing Regulation making reference to seed potatoes should be deleted from the Regulations.

Tolerances for residues of thiabendazole are established under Section 180.242. The tolerances range from 10 ppm in or on apples, citrus and pears (from postharvest applications) and sugar beet tops to 0.02 ppm in or on sweet potatoes (from postharvest applications). Food additive tolerances ranging from 3.5 to 35 ppm have also been established (Section 561.380). A tolerance for milk, set at 0.1 ppm for combined residues of thiabendazole and its 5-hydroxy metabolite, is established under 180.242 to cover the feed uses of treated commodities. In addition, residues in the meat and milk of livestock of 0.1 ppm for meat and of 0.05 ppm for milk, both expressed in terms of the parent compound only and regulated by CFR 21, Section 556.730.*

*Note: The discrepancies, involving meat and milk, in CFR 40, 180.242 and CFR 21, 556.730, should be worked out by joint agreement between the respective offices of Enforcement (FDA) and the EPA Office of General Council (see below under Meat and Milk).

Conclusions:

1. The nature of the residue from the proposed use is adequately understood. Thiabendazole per se is the only residue of concern in or on potatoes and in potato waste.

2. Adequate analytical methods are available for enforcement.

3. The proposed tolerance is adequate to cover the residues expected to result from the proposed use.

4a. The use falls into category 2 of Section 180.6(a) with respect to residues in milk and the meat, fat and meat byproducts of livestock.

4b. The existing tolerances under CFR 40, Section 180.242 for milk and under CFR 21, Section 556.730 for the tissues and organs of livestock are adequate to cover secondary residues from the proposed use.

4c. The use falls into category 3 of Section 180.6(a) with respect to residues in poultry and eggs.

Recommendation

Contingent upon the appropriate revision of Section F, and if TB and EEEB considerations permit, we recommend that a tolerance of 3 ppm for potatoes be established to replace the existing tolerance of 0.1 ppm for residues of thiabendazole on potatoes grown from treated seed potatoes. We also recommend, with the same caveats, that the proposed food additive tolerance be established.

Note: As explained under "Residues in Meat and Milk," we are also recommending that a tolerance of 0.1 ppm be established for residues of thiabendazole and its 5-hydroxy metabolite in the fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep. This is for the administrative convenience of EPA and should not involve a request for an amended Section F from the petitioner.

Detailed Considerations

Formulations

The two formulations intended for the proposed use on potatoes are the same as those discussed in PP# 4E1478 (see memo of June 13, 1964): these are a 42% flowable liquid and a 60% wettable powder. All inerts in these formulations are now cleared under 180.1001(c) and (d) (personal communication, D. L. Ritter, TB).

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Thiabendazole is approximately 98% pure. The impurities in technical thiabendazole were discussed in PP# 3F1332; due to the low levels and nature of the technical impurities, we anticipate no residue problem from such impurities.

The synthesis of thiabendazole is summarized in Merck Index.

Proposed Use

The proposed use for potatoes involves application rates which are the same as those for seed potatoes as discussed in PP# 4E1470, cited immediately above. Potatoes for storage are treated by spraying with a 1500 ppm aqueous suspension over the unwashed potatoes as they move on a conveyor belt into storage. An additional treatment is permitted before shipment for food or processing purposes, as well as before cutting for seed purposes. Alternatively, the second application may be made as a dip using the same concentration of thiabendazole in the aqueous dip.

Note: Because of the use of potatoes for human or animal food and for processing, a tolerance higher than that established for potatoes grown for seed tubers is needed. The aqueous suspension is prepared by mixing 1.2 lbs. active in 100 gallons of water. One gallon of suspension is used per ton of potatoes.

Nature of the Residue

The fate of thiabendazole has been discussed in our reviews of PPs# 8F0674, 8F0724, 1F1031 and 3F1332. In all cases except that of PP# 3F1332 (thiabendazole on citrus) all tracer studies demonstrate that thiabendazole per se is the only component of concern in the residues.

In the case of treated citrus, thiabendazole is applied in a wax coating. The tracer study on citrus shows that, after a few weeks, as much as 20% of the thiabendazole residues stabilize as conjugates of thiabendazole and 5-hydroxy thiabendazole, small amounts of 5-hydroxy thiabendazole per se and related benzimidazoles. None of the individually identified or unidentified components exceeded 0.4 ppm on the treated citrus.. TB concluded in connection with PP# 3F1332 that the tolerance could be expressed in terms of thiabendazole only.

Based on all the available studies and considering the fact that this is a postharvest use, we conclude that the fate of thiabendazole on potatoes is the same as that for other commodities except citrus and that the nature of the residue from the proposed use has been adequately described.

Analytical Methods

PAM II contains methods for citrus fruits, bananas and sugar beets; these methods were developed by the petitioner and submitted in connection with previous petitions. All are based on isolation of the thiabendazole residues by ethyl acetate extraction, cleanup by partitioning and determining the residues in aqueous acid phase by spectrophetofluorometry.

The method for citrus was successfully tried out by AMS, CB on oranges at 2 and 4 ppm and on citrus pulp at 0.04 and 0.08 ppm.

The method for potatoes involves acid digestion on a steam bath followed by diastase digestion--these steps are not used in the PAM II methods. Since these steps are recognized techniques for chemically or enzymatically breaking down starch, we see no need for a tryout of the method for potatoes. However, the method for potatoes should be incorporated into PAM II as a separate method.

As stated in PP# 4E[illegible]78, the petitioner reports recoveries from potatoes ranging from 75 to 113% at levels between 0.04 and 1 ppm. Background values were reported as less than 0.05 ppm except for three samples which ranged up to 0.22 ppm--these were identified as "probably contaminated."

For potato processing waste, the petitioner points out that this byproduct is highly alkaline and must be "neutralized" with 1 N H_2SO_4 to a pH range of 4 to 9 prior to the initial acidification step in the method for potatoes. (As in the case for potatoes, the method for processing waste should be incorporated into PAM II.) Recoveries from potato waste are reported as averaging about 100% over the range 0.1 to 1.0 ppm.

No other tolerances for potatoes involve a pesticide containing the benzimidazole moiety have been established, we consider the method to be specific. Residue methods for meat and milk were conducted by the Food Additives Analytical Methods Section and were found to be adequate.

Residue Data

The data previously submitted in PP# 4E1470 are incorporated in this petition. The data reflect spray and/or dip treatments as permitted by the label.

The maximum residue from a 2X application was reported as 3.06 ppm (Idaho) and from 1X was 2.53 ppm (Minnesota). It should be noted that the latter value did not represent potatoes treated by normal commercial practice, in that nearly 3 gallons of suspension per ton were used in lieu of the 1 gallon per ton recommended.

The petitioner is requesting a tolerance of 3 ppm for the proposed use, although he indicates that this level may be higher than necessary. The data in PP# 4E1478 (potatoes grown from tubers treated for seed purposes) show that residues from the treatment of seed potatoes are negligible, i.e., less than 0.1 ppm. Also a study on the cooking and washing of potatoes demonstrated that rinsing in cold water (a procedure called for prior to analysis of potatoes by FDS enforcement methods) significantly reduced residues from postharvest treatment (approximately 50% of the residue was removed). Storage stability studies presented here show essentially no losses over a period of 30 weeks.

Overall, we conclude that the proposed tolerance of 3 ppm is adequate and appropriate. However, as mentioned in the introduction, Section F must be revised to replace the "tuber(s)" with "potato(es)."

Residues in Potato Processing Waste

The petitioner defines "tuber" processing waste as being a 9:1 mixture of the table trim waste and the waste from the tuber peels which are removed by hot alkali dip and then dried, hence the high alkalinity of the final product.

The petitioner presents a processing study which clearly demonstrates that peeled potatoes are essentially free of residues which will enter the feed item. By calculation, the petitioner estimates that residues from treated potatoes to processing waste will concentrate, at most, by a factor of 10. Based on this factor, he is proposing a food additive tolerance of 30 ppm.

This level (30 ppm) is probably higher than necessary due to the low level found in table trim waste; however, since it will not affect any of our considerations with respect to secondary residues in meat and milk, we consider it acceptable and adequate. As indicated, the food additive tolerance should be expressed for potato processing waste rather than as listed in Section F.

Residues in Meat and Milk

The petitioner presents information from two sources which indicates that potato processing waste is fed at up to 15% (dry diet) of cattle. This is in fair agreement (for dairy cattle) with information furnished us for feed items; the figure we normally use is 25% for dairy cattle, but we use 50% for beef cattle. These figures would translate into 7.5 ppm in the diet for dairy cattle and 15 ppm for beef cattle. Even if other available feed items were fed simultaneously, the feeding levels would not exceed 20 ppm. In any case, the available feeding studies include that it is only at about 28 ppm in the diet that measurable residues begin to appear

in the milk. The contribution of potatoes to the diet of cattle would be essentially the same as that for citrus pulp. Thus, for milk the established tolerance is adequate and the use falls into category 2 of 180.6(a).

Note: As indicated in the introductory remarks of this memorandum, there are inconsistencies between the pesticides regulation CFR 40, 180.242 and the veterinary drug regulation CFR 21 Section 556.730 with respect to the tolerances for meat and milk.

We believe it is now appropriate to establish a tolerance for residues of thiabendazole and its metabolite, 5-hydroxy thiabendazole in the fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep at 0.1 ppm [category 2 of Section 180(a)] and recommend that such tolerance be established concurrently with the tolerances proposed in this petition.

Our rationale for this recommendation is as follows:

1. Although we have previously considered the feed uses of crops treated with thiabendazole as being in category 3 of 180.6(a), we believe that the combined feed uses and drug uses (which could occur simultaneously) could lead to small residues in the liver and kidney, at least with no preslaughter interval.

2. Secondly, we now consider it to be inconsistent to have a tolerance for residues in the meat from the drug uses with a 4-day PSI and no tolerance in meat for the feed uses with no PSI.

3. Administratively, it will be advantageous to establish a tolerance for meat in the anticipation that the petitioner will probably submit future petitions involving additional food items.

4. Finally, in a telecon of April 25, 1974, R. S. Grigham, Chief, Petitions and Regulations Branch, Division of Compliance, Bureau of Veterinary Medicine, FDA, state that it would be desirable that the tolerance expressed under the FDA regulation (CFR 21, Section 556.730) and those expressed under CFR 40, Section 180.242 should coincide. He further stated that, since any regulatory action under these regulations would be taken by EPA, it would be (in his opinion) preferable that EPA take the initiative to effect the reconciliation of the existing inconsistencies.

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Poultry and Eggs:

While cooked potatoes may be used as a feed item for poultry, at up to 20% of the diet (dry basis), the data submittted show that there would be at most, trace residues in the washed, cooked potatoes; thus, the dietary intake would be of the order of <0.35 ppm (dry basis). While we have no poultry feeding study to consider, we feel that, in this case, due to the low level of residues involved and the virtual absence of any propensity for thiabendazole to store in mammals, we place the feed uses of treated potatoes in category 3 of Section 180.6(a) with respect to poultry and eggs. Therefore, a poultry feeding study is not needed.

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