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G.R. - *[initials]*

COMMISSIONER OF FOOD AND DRUGS

May 1, 1967

William Stokes
Petitions Control Branch, SCI-R

BRIEFING MEMORANDUM
Rohm and Haas Company
Independence Mall West
Philadelphia, Pa. (AF 24-037)

file - Tolerances for residues of Dithane M-45 --
Pesticide Petition No. 6F0476
Food Additive Petition No. 7H2118

Dithane M-45 is the trade name for a fungicide consisting of a coordination product of zinc ion and maneb (manganous ethylenebisdithiocarbamate) containing 20 percent manganese, 2.5 percent zinc, and 77.5 percent ethylenebisdithiocarbamate.

Tolerances have been established for Dithane M-45 on bananas at 15 ppm (2 ppm in pulp), papayas at 10 ppm (no residue in the edible pulp), melons at 7 ppm (no residue in the edible portion), and tomatoes at 7 ppm established June 1, 1966 (31 F. R. 7741).

Pesticide Petition No. 6F0476 as amended requests tolerances for the coordination product calculated as zinc ethylenebisdithiocarbamate as follows:

- 65 ppm in or on peanut vine hay and sugar beet tops.
- 25 ppm in or on the straws of barley, oats, rye, and wheat.
- 15 ppm in or on fodder or forage of field corn, sweet corn, and popcorn.
- 10 ppm in or on apples, celery, crabapples, fennel, pears, and quinces.
- 7 ppm in or on cranberries, cucumbers, grapes, and summer squash.
- 5 ppm in or on the grains of barley, oats, rye, and wheat.
- 2 ppm in or on carrots and sugar beets.
- 0.5 ppm in or on cottonseed; field corn, sweet corn, and popcorn (kernels plus cob with husks removed); peanuts, kidney, liver.

Food Additive Petition No. 7H2118 as amended requested tolerances of 28 ppm in raisins and 20 ppm in milled fractions, other than flour, of barley, oats, rye, and wheat when present therein as a result of the application of Dithane M-45 to the growing crops.

The Pesticide Regulation Division, U. S. Department of Agriculture, has certified the usefulness of Dithane M-45 for the purposes for which pesticide tolerances are sought. They find the proposed tolerances reasonably reflect the amount of residues likely to result from the proposed usage. The Livestock Slaughter Inspection Division has no objection to these tolerances and advises they consider the methods proposed in the petition adequate for animal tissue and enforcement of their laws.

Received
FSA/Pest. Br.

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The Division of Food Standards and Additives finds that the analytical method proposed in the petition does not distinguish between residues of the various dithiocarbamates for which tolerances have been established. They find the analytical method does distinguish between dithiocarbamates and other pesticide chemicals. The class limitation in the introductory paragraph and subparagraph (3) of Section 120.3(a) additionally limits residues of Dithane M-45 in the presence of other dithiocarbamates. They find that residues from use of Dithane M-45 as proposed in the petition will not exceed the proposed tolerances and that the level in flours produced from grains will not exceed 1 part per million. They find that the tolerance levels for most of crops for which tolerances are proposed in these petitions could be exceeded by residues from the application of other dithiocarbamates for which higher tolerances have previously been established. Because the residue method does not distinguish between the various dithiocarbamates and to provide for adequate regulatory control, we are suggesting amendment of § 120.3 by adding to subsection (d) a new provision that where tolerances are established for more than one dithiocarbamate on the same raw agricultural commodity, the total residue of such pesticides shall not exceed that permitted by the highest of the tolerances calculated as sineb. On this basis, they find the analytical methods adequate for enforcement of the proposed tolerances. They also find that residues of Dithane M-45 in the feed items at the proposed tolerance levels do not transfer to milk (<0.01 ppm) or meat other than kidney and liver (<0.1 ppm).

The Division of Toxicological Evaluation finds that these tolerances are safe.

The Bureau of Veterinary Medicine has no objection to the establishment of these tolerances. The Fish & Wildlife Service, USDI, has no objection.

We recommend that the attached order be signed and published.

APPROVED:

W. S. McFarland, Chief
Pesticide Control Branch
Bureau of Science

L. L. Ramsey, Assistant Director
for Regulatory Programs
Bureau of Science

cc: ICE (FSA) DTE FRW GC(Hearing Clerk) BVM
VBE: mjo:5/1/67; WS:mak:3/27/67; WS:mcs:3/21/67
JF: JFt: GJBeusch:3/20/67;4/12/67; GGFitzhugh:3/24/67; DMBaker:3/27/67
LLRamsey:4/17/67; CEGundlach:4/17/67