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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Metalaxyl. Label Amendments for Peanuts. CBRS # **10743** & 10744. DP Barcode: D183657 & D183659.

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Ciba-Geigy has responded to CBRS and CBTS reviews (L. Cheng, 6/1/92, CBRS # 8043; PP#1F3993, J. Morales, 6/19/92, CBTS # 9011 which reiterates conclusions made in the 6/1/92 review) concerning the residue chemistry data gaps cited for peanuts in the Metalaxyl Registration Standard Residue Chemistry chapter (6/22/87). Included in this submission are label amendments to granular formulation products Ridomil PC® 11G (EPA Reg # 100-664) and Ridomil PC® (EPA Reg # 100-713).

The conclusions (2a, 2b, 2c) in the 6/1/92 review on peanuts will be repeated, then followed by the registrant response, and finally CBRS comments.

2a. The peanut field trial data indicate that tolerance-exceeding residues can result in or on peanut nutmeats from at-pegging applications of a G formulation at 1 lb ai/A (the maximum rate for this registrant's 1% G MAI formulation). The registrant stated that these data were submitted in support of the 5% G label (EPA Reg # 100-628), on which a maximum rate of 0.5 lb ai/A is specified at-pegging.

2b. If the registrant does not intend to support the 1% G formulation (EPA Reg # 100-664), they should cancel this registration or amend this label to specify a maximum rate of 0.5

lb ai/13,000 linear feet at-pegging. Otherwise they must propose a revised tolerance that is supported by adequate residue data. In addition, an explanation of the high apparent residues in control samples of hay (up to 4.5 ppm), hulls (0.63 ppm), and vines (2.4 ppm) is required, in order for these data to be found acceptable.

2c. Residue data are adequate to support reregistration of metalaxyl use on peanuts, provided the maximum use rate (at-pegging) for both the 1% and 5% G formulations is 0.5 lb ai/A or 0.5 lb ai/13,000 linear feet with 40 inch row spacing. Since the residue data were generated at PHI's of 65-92 days, the current PHI (45 days) must also be amended.

Ciba-Geigy Response to 2a, 2b, 2c: Data submitted to support the 5% G formulation should be used to support the 1% G formulation as well. Therefore, to make these labels consistent, the 1% G formulations (EPA Reg # 100-664 and 100-713) will be amended to recommend the following for pod rot control: 0.5 lb ai/14,520 linear feet at early pegging with 36-inch row spacing. This application rate is actually less a.i. per acre on a broadcast basis (2.57 lbs) than the 0.5 lb ai/13,000 linear feet at pegging with 40-inch row spacing (2.87 lbs) as requested in the EPA review. Five copies of amended labeling for each of the 1% products are submitted with this response.

The Agency review also indicated that the PHI for peanuts needed to be revised from 45 to 65 days. Currently, none of the Ridomil formulations used on peanuts specifies a PHI because applications are made during early development of the crop and the time between the last recommended application of Ridomil and harvest is dependent on the variety of peanut planted. Some varieties have growing seasons lasting as long as 160 days; for others, the growing season is about 120 days. To specify a PHI would be impractical for the grower, because the application at early pegging is tied into a growth stage. The grower has to have some degree of flexibility when applying Ridomil for pod rot control. Therefore, we have elected to not specify a PHI on the revised Ridomil PC labels submitted simultaneously with this response. This decision is consistent with the manner in which the other Ridomil labels have been handled by the Agency.

The proposed labels also contain the following restrictions: 1) Do not allow the feeding or grazing of peanut foliage or harvest residues by livestock and 2) Do not apply more than 75 lbs of Ridomil PC 11G/14,520 linear feet or 75 lbs of Ridomil PC/14,520 linear feet of row/season.

With respect to the apparent metalaxyl residues found in peanut hulls (0.06 ppm max), vines (2.4 ppm max) and hay (4.5 ppm max) of control samples, the source of these residues is unknown. However according to the Pesticide Assessment Guidelines, Subdivision O, "untreated controls" should be "reasonably low in

relation to the proposed tolerance." The apparent control residues in these peanut commodities are considerably lower than the current tolerances of 2 ppm, 20 ppm, and 20 ppm for peanut hulls, vines, and hay, respectively. Therefore, the data from this study are in compliance with the Pesticide Assessment Guidelines. (The registrant referenced the response following Conclusion 1 about the apparent residues in control samples.)

CBRS comments: Residue data generated using the 5G formulation are translatable to 1G formulations (MRID # 41870306). CBRS agrees with the registrant that the revised proposed rate applied at-pegging of 0.5 lb ai/14,520 linear feet (36-inch row) is slightly less than the tested rate (0.5 lb ai/13,000 linear feet, 40-inch row). Thus, the peanut residue data (0.16 ppm max in nutmeat, PHI=76 days) reflecting a single application of 0.25 lb ai/13,000 linear feet made at planting followed by a single application of 0.5 lb ai/13,000 linear feet made at-pegging are adequate to support the 0.25 or 0.5 lb ai/14,520 linear feet use rate. With respect to PHI, CBRS disagrees with the registrant that a PHI is not necessary. The peanut studies were conducted in all the major peanut growing areas (TX, OK, GA, AL, and VA) encompassing several varieties. The difference in length of growing season due to peanut variety should have been incorporated in the design of the studies. CBRS realizes that there is a range of growing seasons for different peanut varieties. However, in order not to exceed the tolerance of 0.2 ppm for peanut nutmeat, a PHI of 75 days must be imposed (see cited data point above). At this PHI, metalaxyl residues in peanut hulls are also within tolerance.

The apparent metalaxyl residues in peanut nutmeats were all <0.05 ppm. Since peanut hulls, vines and hay are not consumed by humans, and the apparent metalaxyl residues in these commodities are relatively low when compared to the established tolerances, CBRS accepts the peanut residue data contained in MRID # 41870306.

CONCLUSIONS AND RECOMMENDATION

1. Peanut residue data contained in MRID # 41870306 are acceptable.

2. On the basis of the peanut residue data, a PHI of 75 days must be imposed on products Ridomil PC® 11G (EPA Reg # 100-664) and Ridomil PC® (EPA # 100-713).

cc:Circ, RF, Reg Std File, Cheng
RDI:FSuhre:11/19/92:MMetzger:11/23/92:EZager:11/23/92
H7509C:CBRS:LCheng:CM#2:RM800D:11/16/92:02:

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