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PP#6F1799 Chlorothalonil in/on Soybeans.
Amendment of 2/19/80 (revised Sections B, D, and F).

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Diamond Shamrock has requested a decrease in the requested tolerance for Chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloro-isopthalonitrile from 0.2 ppm to 0.05 ppm. A request was also made for the added use of the Bravo 500 formulation on soybeans. The original petition requested the proposed use for the Bravo 6F formulation. Residue data is submitted to support the revised Section F.

Both formulations of the proposed use contain the same inerts with minor changes in proportions of each inert. The Bravo 6F formulation has already been discussed (J.S. Cox, PP#6F1799, 11-17-76). No change in the proposed use has been made. If and when a tolerance is established on soybeans, we have no objection to the use of the new formulation.

The petitioner has submitted residue data for Chlorothalonil and its 4-hydroxy metabolite on soybean trash taken from fields after harvesting of the mature soybeans. Six geographical locations are represented from fields treated with the accumulative total equivalent of 5 pints of Bravo 6F (2.5 lbs a.i./A) per season. One location involved the single treatment of 10 pts of Bravo 6F per acre (5 lbs a.i./per season; almost twice the recommended maximum application rate).

Additional studies submitted included a processing study in which residues were determined in trash, soybean meal and soybean oil. A study was also submitted reporting the residues of Chlorothalonil, hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) in treated soybeans.

All studies were submitted to support the petitioner's argument that Chlorothalonil residue, and residues of its 4-hydroxy metabolite on soybeans reported previously (PP#6F1799), are the result of contamination of seeds with trash during harvesting. The petitioner contends that in commercial harvesting of soybean seeds, soybeans trash is routinely separated from the beans. Therefore, because soybean trash contains most of the residues, soybean samples analyzed previously showed residues due to this contamination with trash, and because commercial harvesting separates the beans from the trash, a tolerance of 0.05 ppm for Chlorothalonil and its 4-hydroxy metabolite in/on soybeans is adequate.

The submitted data reflecting application at the 1.1 lbs a.i./A application rate show residues of chlorothalonil and its 4-hydroxy metabolite in trash as 0.05-1.13 ppm and 0.05-0.20 ppm, respectively. At the 1.9 lbs a.i./A application rate, residues were reported as 0.03-1.35 ppm and 0.02-0.20 ppm for chlorothalonil and its 4-hydroxy metabolite, respectively. One study at 3.75 lbs a.i./A (5X) showed 3 ppm and 0.26 ppm residues of chlorothalonil and its 4-hydroxy metabolite, respectively. For the above studies, the PHI's varied from 42-76 days.

Soybean Processing Study

Soybeans were treated twice with five pints of Bravo 6F per acre. This rate is 2X the maximum recommended application. Trash was removed from the soybean samples before processing to meal and oil. The analytical methods used for the determination of Chlorothalonil and its polar 4-hydroxy metabolite are similar to the PAM II enforcement method and minor modifications thereof. These minor modifications to the enforcement method are not expected to affect the analytical results (W. Cox, PP#6F1799, 11/17/76). Validation data indicates 66-105% recovery for Chlorothalonil and 43-100% recovery for the 6-hydroxy metabolite (all values corrected for recovery from second clean up and non-treated controls). Residues of Chlorothalonil in soybean oil, meal and trash are reported as 0.05, 0.01 and 1.28 ppm. No detectible 6-hydroxy metabolite residue was reported for soybean oil and meal. Soybean trash contained 0.11 ppm metabolite residue. When the micrograms of Chlorothalonil and 6-hydroxy metabolite are added up for each processed product plus trash and divided by the total weight of sample (including trash) the residue is reported as 0.06 ppm Chlorothalonil plus 6-hydroxy metabolite. Prior to processing, assay values for triplicate analyses of soybeans were 0.06 ppm, 0.06 ppm and 0.09 ppm Chlorothalonil.

Assuming the trash collected from the fields after harvesting approximates the trash found in harvested soybeans (e.g., dirt, broken piece of beans, stems, leaves, etc.), we conclude that most of the residues of Chlorothalonil and its 4-hydroxy metabolites reported in soybeans (see W.S. Cox, PP#6F1799, 11/17/76) are probably due to the contamination of the beans with trash. However, information from U.S.D.A. indicates that soybeans are sold in commerce with allowable amounts of trash up to 5%. For international trade, the trash content can be as high as 3%. Taking those values of allowable trash as soybeans travel in commerce and multiplying by the above values of residues reported in farm trash, we conclude the residue profile is similar to that reported in the original petition for harvested soybeans. In addition, more recent information (Fawbush, J.G., Soybean Preparation, J. Am. Oil Chemists' Soc., June 1977 (Vol. 54) and personal communication with J.G. Fawbush, Central Soya Company, Inc., Fort Wayne, In.) available to us indicates soybeans, prior to processing, are cleaned to remove large trash, dirt, sand and loose hulls. No particular minimum trash level is attempted. Therefore, because the mill cleaning process is not as efficient as cleaning by hand (where every bit of trash is removed), we must assume there is 1-3% trash in soybeans processed for oil. We therefore find that the requested tolerance of 0.05 ppm for Chlorothalonil plus its 4-hydroxy metabolite is not supportive from the data, and we must reiterate our earlier conclusions that the residue data will support a 0.2 ppm tolerance.

IMPURITY INFO IS NOT INCLUDED

A final study (Residues of Chlorothalonil, hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) on Soybeans, Report DS-2787) was submitted to augment the petitioner's argument that residues of Chlorothalonil and its 4-hydroxy metabolite are due to contaminating farm trash. Bravo 500 and Bravo W-75 formulations containing a maximum of [redacted] HCB and [redacted] PCBN were applied to soybeans in MO, FL, OH and TX. Soybean samples, manually cleaned of trash, were analyzed for Chlorothalonil, HCB and PCBN.

Results for two applications at 1, 1.8 and 2 lbs. a.i./A/application gave reported residues of <0.010 ppm -0.019 ppm, <0.003 ppm -0.006 ppm and <0.005 ppm -0.024 ppm for Chlorothalonil, HCB and PCBN, respectively. PHI's ranged from 40 to 57 days from the last application. The analytical method for Chlorothalonil is similar to the enforcement method. Validation for Chlorothalonil, HCB and PCBN was submitted for the above analytical method. Soybean samples were fortified with HCB and PCBN at 0.020,0.030 and 0.050 ppm each (from the submitted data it is assumed that samples were fortified separately with Chlorothalonil, HCB or PCBN). Chlorothalonil was added at 0.02, 0.03 and 0.10 ppm. Recoveries for HCB and PCBN fortified samples ranged from 73-145%. Chlorothalonil validated samples ranged from 50-95%.

The above samples were manually cleaned of farm trash and do not necessarily represent this commodity as it travels in commerce. However, because of the low levels of contamination of HCB and PCBN, we foresee no residue problems for these contaminates in/on soybeans under the proposed use.

Recommendation:

We recommend against the decrease in the requested tolerance to 0.05 ppm. However, we do reiterate that the submitted data will support and we do recommend for the earlier requested tolerance of 0.2 ppm Chlorothalonil and its 4-hydroxy metabolite.

TS-769:RCB:P. Errico:gs:X77324:CM#2:RM810:8/9/80
cc: RF, Circ., P. Errico, Watts, FDA, TOX, EEB, EFB, PP#6F1799
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