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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F04177. Dimethenamid (129051 SAN 582H) in Soybeans. Amendment of October 27, 1993.
DP Barcode: D196509. CBTS No. 12784
Case: 284369: Submission: S452575. MRID:429904-01, -02.

FROM: Martha J. Bradley, Chemist
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TO: Cynthia Giles-Parker/James Stone, PM 22
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AND

Albin Kocialski, CCB/HED

THRU: Debra Edwards, Chief
Chemistry Branch 1 - Tolerance Support
Health Effects Division (H7509C)

Sandoz Crop Protection Corporation has responded to the deficiencies listed in our review of September 29, 1993 for the use of dimethenamid on soybeans. The deficiencies, response and our comments/conclusions are listed below.

Permanent tolerances have been established for dimethenamid on corn grain, fodder and forage at 0.01 ppm in 40 CFR 180.464. Temporary tolerances on soybeans, forage and hay at 0.01 ppm expire 3/1/94.

Summary of Deficiencies Remaining to be Resolved

None

Conclusions:

1. Adequate recovery data are submitted for dimethenamid at the limit of quantitation (0.01 ppm) in soybean grain, forage, hay and straw. This deficiency is resolved.

2. CBTS concurs with the Petitioner's arguments that storage stability data for dimethenamid in soybeans and its products are adequate and additional storage stability data are not needed at this time.

3 and 4. CBTS concludes that possible residues of dimethenamid at the 0.01 ppm level may occur in soybean forage. Residues of dimethenamid are not likely to exceed the proposed tolerance of 0.01 ppm in soybean grain from the proposed use. The feed use of the forage, hay and straw is restricted.

Recommendation:

CBTS recommends for the proposed tolerance of 0.01 ppm dimethenamid on soybean grain.

NOTE TO DIETARY EXPOSURE SECTION: The dietary risk assessment should be based on a residue of 0.2 ppm in soybeans instead of the 0.01 ppm tolerance. The Metabolism Committee concluded at a meeting held 12/1/93 that it would be more appropriate to use the total racioactive residue (0.2 ppm) observed in the soybean metabolism study for calculating dietary risk.

Detailed Considerations

Deficiency 1. An analytical method, TDS No. BS2304, is available for enforcement of 0.01 ppm dimethenamid in corn. Additional recovery data are needed for fortifications at 0.01 ppm in soybeans, since these data are only available for a soybean processing study.

Response 1. Additional recovery data were submitted for dimethenamid in soybean grain, forage, hay and straw at fortification levels of 0.01 ppm (26 samples), 0.02 ppm (1 sample) and 0.05 ppm (1 sample). Recoveries ranged from 70 to 113% with an average of 96%.

Comments/Conclusions 1. Adequate recovery data are submitted for dimethenamid at the limit of quantitation in soybean grain, forage, hay and straw. This deficiency is resolved.

Deficiency 2. Storage stability data are needed for soybean processed commodities and for soybeans stored up to 26 months before analyses.

Response 2. The Petitioner argues that the demonstrated stability of dimethenamid residues in frozen storage for soybeans for 16 months and for corn for 21 months is sufficient to be

extrapolated to the maximum of 23 or 26 months that some soybean samples were stored before analysis. Additional storage stability data are submitted for soybean grain, forage and hay from seven new residue trials, with data available for 10 to 12 months of storage.

The Petitioner also states that soybean processed products, stored for 8 to 9 months before analysis are similar enough to the soybean grain, that the storage stability would be the same as in the grain. In oil and soapstock fractions, the demonstrated stability of dimethenamid subjected to hydrolysis shows that it would be stable in these matrices. In addition, no detectable residues were found in soybean grain from a 5X application rate. Neither were detectable residues found in the soybean fractions processed from beans treated at the 5X rate. The theoretical maximum concentration in soybean fractions is 12. From this, it can be calculated that detectable residues would not be expected in soybean fractions. The petitioner states that a stability study in soybean processed products will not add value to the regulatory decision on the proposed tolerance.

Comments/Conclusions 2. CBTS concurs with the Petitioner's arguments that storage stability data for dimethenamid in soybeans and its products is adequate and additional storage stability data are not needed at this time.

Deficiencies 3 and 4. Provided additional recovery data at 0.01 ppm and storage stability data are adequate, CBTS concludes that residues of dimethenamid in soybeans are not likely to exceed the proposed 0.01 ppm tolerance.

Provided storage stability data are adequate, CBTS concludes that residues of dimethenamid in soybean processed products are not likely to exceed the rac tolerance.

Response 3 and 4. Additional field residue studies are submitted, two from Illinois, two from Iowa and one each in Indiana, Mississippi and Missouri from 1992. At each site, a single broadcast application of dimethenamid at 1.5 lbs ai/A (the maximum label rate) was made by three means, preplant incorporated, preemergence and early postemergence. Samples of soybean forage, grain, hay and straw were collected from each plot at the physiologically appropriate time. The samples were frozen and analyzed within 12 months of harvest. No detectable residues (<0.01 ppm) were found in all the grain, hay and straw treated samples. Nineteen forage samples had no detectable residues while two forage samples from one location had apparent residues of 0.011 ppm. A corresponding control sample showed a residue of 0.006 ppm, thus creating uncertainty of real dimethenamid residues in the forage samples.

Comments/Conclusions 3 and 4. CBTS concludes that possible residues of dimethenamid at 0.01 ppm may occur in soybean forage, and that residues of dimethenamid are not likely to be detected in soybean grain, hay or straw from the proposed use.

cc: Circu, RF, PP#3F04177, Bradley
H7509C:CBTS:M Bradley:CM#2:Rm804:305-7324:02/16/94
RDI:RSQuick:02/17/94:RALoranger:02/18/94
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