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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: Diflubenzuron, Section 409 Tolerance for Soybean Hulls. Reregistration
Case No. 0144 Chemical No. 081501 No MRID # DP Barcode D217679
CBRS #15904

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THRU: Edward Zager, Chief *Edward Zager*
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TO: Susan Jennings, PM Team 72
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Recommendation

Because the concentration of diflubenzuron (DFB) in a "ready to eat" animal feed concentrate formulated using soybean hulls at 25% of the feed mix is not appreciably higher than the tolerance level for the rac, under current policy, there is no need for a Section 409 tolerance for soybean hulls. The soybean soapstock tolerance (40 CFR 186.2000) should be revoked because soybean soapstock has been deleted from Table II (June, 1994).

Background

CBRS had previously determined that a Section 409 food additive tolerance for diflubenzuron (DFB) on soybean hulls was necessary (S.Knizner, 6/29/95, D216808). Based on recently issued policy guidance (M.Metzger and E.Zager, "Revised Procedures for Review of Processing Studies and Determination of Need for Section 409 Tolerances", 7/17/95) CBRS has re-examined this issue.

Soybean hulls would not require a Section 409 tolerance if the concentration of DFB residue in animal feed when "ready-to-eat (RTE)" (i.e., in a mixed or formulated concentrate ration) is less than or not appreciably higher than the 0.05 ppm tolerance established for the soybean rac.



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Based on consultations with animal husbandry experts (associated with the University of Missouri), CBRS has ascertained that soybean hulls would not comprise more than 25% of any "ready-to-eat" feed concentrate. CBRS assumes that the remaining 75% of the feed concentrate would be comprised of feedstuffs not bearing residues of DFB.

Magnitude of the Residue in Soybeans and Soybean Hulls

Soybeans - The current tolerance for the raw agricultural commodity soybeans is 0.05 ppm (40 CFR 180.377). The Residue Chemistry Chapter of the DFB RED (3/16/95) noted that acceptable data on soybeans are available for purposes of reregistration and these data adequately support the established tolerance for residues of diflufenzuron in/on soybeans.

The Residue Chemistry Chapter of the Diflufenzuron Registration Standard (11/84) cited 61 tests on soybeans representing the major soybean producing regions. Residues of diflufenzuron in/on soybean seeds were nondetectable (<0.05 ppm) in/on 46 samples harvested 18-107 days after one or two foliar applications of diflufenzuron (WP) each at 0.03-0.0625 lb ai/A (0.5-1x); and residues were <0.05-0.17 ppm in/on 38 samples harvested 18-109 days after one or two foliar application each at 0.125-0.25 lb ai/A (2-4x). A GC/ECD analytical method was used in these studies (Thompson Hayward Analytical Method No. 10) and the limit of quantitation was 0.05 ppm. This method has been validated by the Agency and is used for enforcement purposes (PAM Vol.II, Method I).

Additional field residue data are also available from 16 side-by-side tests using a 25% WP and the 2 lb/gal FIC formulation (8 tests per formulation). Residues of diflufenzuron *per se* were <0.01-0.03 ppm in/on 32 samples of soybean seeds harvested 20-23 days after the second of two foliar applications of diflufenzuron each at 0.0625 lb ai/A (1x) using either aerial or ground equipment. An HPLC/UV analytical method was used for data gathering in this study (Uniroyal Method L-3-86-4) with a 0.01 ppm limit of quantitation.

Conclusion: Because the highest average field trial (HAFT) result with detectable diflufenzuron residues is 0.03 ppm, CBRS will use this level for DFB residues in the rac for RTE calculations.

Soybean Hulls - CBRS previously determined that the residues of parent diflufenzuron concentrate by up to 8.2x in the hulls of treated soybeans after processing. The Residue Chemistry Chapter of the DFB RED (3/16/95) noted that an acceptable soybean processing study was cited in the Residue Chemistry Chapter of the Diflufenzuron Registration Standard (11/84). Residues of diflufenzuron in commodities processed from soybean seeds fortified with diflufenzuron at 0.112 ppm were 0.92 ppm in hulls, <0.05-0.08 ppm in meal and crude and refined oils, and 0.19 ppm in soapstock. Concentration of residues occurred only in hulls (8.2x) and soapstock (1.7x). As the commodity soybean soapstock has been deleted from Table II (June, 1994), the feed additive tolerance for soybean soapstock is no longer appropriate and should be revoked.

Conclusion: Residues of diflubenzuron may concentrate by up to 8.2x in the hulls of treated soybeans after processing.

Calculations

Based on an 8.2x concentration factor and residues of 0.03 ppm in the rac, the residue level of diflubenzuron in soybean hulls is calculated as 0.246 ppm.

$$0.03 \text{ ppm DFB in soybeans} \times 8.2 \text{ (concentration factor for hulls)} = 0.246 \text{ ppm DFB in soybean hulls}$$

Assuming 25% of a "ready to eat" feed concentrate can consist of soybean hulls, and the balance of the components in the feed concentrate do not bear DFB residues, the residue level of DFB in the "ready to eat" animal feed concentrate would be 0.06 ppm.

$$0.246 \text{ ppm DFB in soybean hulls} \times 25\% \text{ of feed concentrate} = 0.06 \text{ ppm in RTE feed}$$

Conclusions

Because the residue level of DFB in a "ready to eat" animal feed concentrate formulated using soybean hulls at 25% of the feed mix is not appreciably higher than the tolerance level for the rac, under current policy, there is no need for a Section 409 tolerance for soybean hulls.

NOTE to PM: A copy of this memo is being forwarded to J.Fleuchaus (OGC) and A.Lindsay (PSPS). The Residue Chemistry Chapter of the Diflubenzuron RED should reflect the conclusions of the this memo.