

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 9/24/2008

SUBJECT: Pyroxsulam: Response to Registrant's Request for Change in Soybean Rotational Crop Interval and Changes in Adjuvant Concentrations

PC Code: 108702	DP Barcode: D354072
Decision No.: 393977	Registration No.: 62719-569
Petition No.: None	Regulatory Action: Section 3 Label Modification
Risk Assess Type: None	Case No.: None
TXR No.: None	CAS No.: 422556-08-9
MRID No.: 46908318 and 46908319	40 CFR: 180.638

- FROM: Douglas Dotson, Ph.D., Chemist Registration Action Branch 2 Health Effects Division (7509P)
- THROUGH: Richard Loranger, Ph.D., Senior Scientist Registration Action Branch 2 Health Effects Division (7509P)
- TO: James Stone, RM Team 23 Herbicide Branch Registration Division (7505P)

The Health Effects Division (HED) recently completed a human health risk assessment for the new active ingredient pyroxsulam. The chemical is an herbicide that was registered for use on wheat. The Office of Pesticide Programs (OPP) approved two labels for the use of pyroxsulam, GF-1274 and GF-1674. GF-1274 is a 7.5% water dispersible granule (WDG) and GF-1674 is a 2.5 lb per gallon oil dispersion (OD). The registrant, Dow Agrosciences, submitted a revised label for GF-1274, the 7.5% WDG formulation. The name of the revised product is PowerFlex Herbicide.

Along with the revised label, Dow submitted a letter dated 5/19/2008 to the attention of Joanne Miller/PM-23. In this letter, Dow stated that several revisions were being made to the label. Four of these revisions relate to the residue chemistry aspects of the herbicide. The first is to decrease the crop rotation interval for soybeans from nine months to three months. The other three involve changes in the adjuvants. Dow would like to increase the recommended concentration of the crop oil concentrate (COC) from 0.8% (v/v) to between 1.0 and 1.25% (v/v). In addition, Dow would like to increase the recommended concentration of the methylated seed oil adjuvant from 0.8% (v/v) to 1.0% (v/v). Dow also stated that a statement was being added to the label regarding the use of a non-ionic surfactant (NIS) only when spray solutions contain nitrogen fertilizer.

With regard to the decrease in the crop rotation interval for soybeans, the 9-month interval that is currently in effect is the interval that was originally proposed by Dow. Dow never submitted the results of a field rotational crop study for pyroxsulam. It did, however, submit the results of a confined rotational crop study. The only plantback interval that was used was 30 days. Residues were measured in the following commodities: mature potato tops, mature potato tubers, mature lettuce, wheat forage, wheat hay, wheat grain, and wheat straw. At the 30-day plantback interval, no parent compound was detected in any of these commodities and all metabolites were detected at ≤ 0.007 ppm. As a result, HED does not object to Dow's request to revise the label and decrease the soybean crop rotational interval from 9 months to 3 months. This decrease does not apply to any other commodities. If Dow would like to decrease any other crop rotational intervals, it must submit a request, and the request will be evaluated by HED.

As stated above, Dow requested three changes related to the adjuvants. The first was to change the recommended concentration of the COC from 0.8% (v/v) to between 1.0 and 1.25% (v/v). HED recommends that this request be granted. Pyroxsulam application is an early season use and the application rate is low. As a result, residue levels in grain, hay, forage, and straw were all low as well. Canadian field trials were reviewed in support of the tolerance petition. European field trial data were not reviewed, but were used to set the tolerances for forage and straw. In the Canadian field trials, residues were below the limit of quantitation (LOQ) of 0.01 ppm in all samples of grain, hay and straw. Residues were also below the LOQ in most forage samples. A small number of samples had residues that were slightly above the LOQ (i.e., as high as 0.036 ppm). In the European trials, the highest residue value for forage was 0.059 ppm and the highest straw value was 0.022 ppm. The requested increase in the COC concentration is a small one. It's very unlikely that this small increase will result in an appreciable increase in pyroxsulam residues. Therefore, pyroxsulam residues are not expected to exceed established tolerances as a result of the changes in COC concentration.

The second requested change involving adjuvants was to increase the methylated seed oil adjuvant concentration from 0.8% v/v to 1.0% v/v. HED recommends that this request be granted also. HED makes this recommendation for the same reasons as those given above for the requested change in the concentration of the COC.

The final requested label change was the addition of a statement regarding use of a non-ionic surfactant (NIS) only when solution contains nitrogen fertilizer. The label for GF-1274 states the following: "Non-ionic surfactant with at least 80% active ingredient at 0.25% to 0.50% v/v (1 to 2 qt per 100 gal. spray solution)." The proposed label for PowerFlex contains the same

statement but adds the following recommendations: "...for best results under dry or low humidity environments a rate of 0.50% v/v is recommended. Addition of spray quality urea ammonium nitrogen fertilizer (28-0-0 to 32-0-0 at 1-2 qt/acre) or ammonium sulfate fertilizer (21-0-0-24 at 1.5-3 lbs/acre) may be added to non-ionic surfactant to enhance control." HED does not object to the requested label amendment. HED does not anticipate that the addition of fertilizer to the NIS will result in a significant increase in pyroxsulam residues given the use pattern and low residues of the active ingredient.

<u>HED's Conclusions and Recommendations</u>: HED concludes that the proposed label revisions are acceptable. HED does not object to the decrease in the rotational crop interval for soybeans from 9 months to 3 months. HED does not object to the increase in the concentration of COC from 0.8% (v/v) to between 1.0 and 1.25% (v/v) for the reasons stated above. For the same reasons, HED does not object to the increase in the concentration of methylated seed oil adjuvant from 0.8% (v/v) to 1.0% (v/v). Finally, HED does not object to the addition of a statement regarding use of a NIS when the spray solutions contain nitrogen fertilizer.