UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

Date: 12/19/2007

MEMORANDUM

SUBJECT: PP#7E7194. Cloquintocet-mexyl: Proposed Use as Safener with the Active Ingredient Pyroxsulam on Wheat.

PC Code: 999999
DP Barcode: D344556
CAS#99607-70-2

FROM: Douglas Dotson, Ph.D., Chemist D. Dotson
Registration Action Branch 2
Health Effects Division (7509P)

THROUGH Dennis McNeilly, Chemist
Richard Loranger, Ph.D., Branch Senior Scientist R. Loranger
Registration Action Branch 2, HED

TO: Tracy H. Ward/Karen Angulo, RM Team 08
Inert Ingredient Assessment Branch
Registration Division (7505P)

Dow AgroSciences, LLC, has requested the use of the safener cloquintocet-mexyl with the new active ingredient pyroxsulam. Pyroxsulam is an herbicide proposed for the postemergent control of grass and broadleaf weeds in spring and winter wheat. The end use products are GF-1274 and GF-1674. In support of the proposed use of cloquintocet-mexyl on wheat, Dow AgroSciences submitted four residue chemistry studies: a magnitude of the residue study depicting the residues of cloquintocet-mexyl in wheat grain, forage, hay, and straw, a storage stability study, an analytical method study, and an independent laboratory validation (ILV) of the analytical method. Draft data evaluation records (DERs) were prepared for these studies. The DERs that were prepared were done so as part of a joint review by Australia, Canada, and the United States.

Received in
RRC 01/29/2008
CW

RECOMMENDATIONS

HED recommends in favor of revising 40CFR §180.560 to include pyroxsulam along with pinoxaden and clodinafop-propargyl as herbicides with which cloquintocet-mexyl may be used. As cloquintocet-mexyl is already approved for use on wheat, and the residues in the field trials did not exceed the currently established tolerances for wheat commodities, the current tolerances are adequate. The tolerances do not need to be modified as a result of the proposed use. The ratio of safener to active ingredient in the pyroxsulam formulations is not 1:4 as it is for the pinoxaden and clodinafop-propargyl formulations. As a result, HED recommends that the words "in a 1:4 ratio of safener to active ingredient" be deleted from 40CFR §180.560(a).

Summary of Registered/Proposed Uses

In 40CFR §180.560, tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid, [(5-chloro-8-quniolinyl)oxy]-, 1-methylhexyl ester) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley) or clodinafop-propargyl (wheat only) in a 1:4 ratio of safener to active ingredient. The tolerances are established on the following food commodities: wheat grain, wheat forage, wheat hay, wheat straw, barley grain, barley hay, and barley straw. A tolerance of 0.1 ppm is currently established for each of these commodities. The Registration Division increased the wheat forage tolerance to 0.2 ppm and the wheat hay tolerance to 0.5 ppm. These revised tolerances have not as yet been published in the Federal Register as a Final Rule, however. The regulatory decisions regarding the uses on wheat and barley are discussed in the previous risk assessment (Memo, D313217, W. Cutchin, 11/29/2005) and residue chemistry summary document (Memo, D257181, N. Dodd, 4/7/2000) prepared for cloquintocet-mexyl.

DowAgroSciences submitted copies of the proposed labels for GF-1274 and GF-1674. GF-1274 contains approximately 7.5% by weight of both pyroxsulam and cloquintocet-mexyl. GF-1674 contains approximately 3% by weight pyroxsulam and 9% cloquintocet-mexyl. The following use restrictions are stipulated on the labels. For GF-1274, do not apply more than 3.5 oz. per acre per growing season (0.016 lb cloquintocet-mexyl/Acre per season). For GF-1674, do not apply more than 6.75 fluid oz. per acre per growing season (0.040 lb cloquintocet-mexyl/Acre per season). A 60-day PHI is stipulated on both labels. In addition, both labels state that the treated crop is not to be cut for hay or grazed within 7 days after application.

Analytical Methodology

Adequate enforcement methods are available for enforcement of the existing tolerances on wheat and barley (Memo, D313217, W. Cutchin, 11/29/2005). The two methods are the HPLC/UV method REM 138.01 for determination of cloquintocet-mexyl and the HPLC/UV method REM 138.10 for determination of cloquintocet acid. In support of the current tolerance petition for use of cloquintocet-mexyl with pyroxsulam, the registrant submitted Analytical Method M313 for the determination of cloquintocet-mexyl and cloquintocet acid in plant commodities. The registrant also submitted an ILV for the method. Residues are separated and detected by LC/MS/MS. Samples of wheat grain, forage, and hay were fortified at 0.01 ppm and 0.10 ppm. Recoveries of both compounds fell within the range of 70-120% for all analyses. The ILV

confirmed that Analytical Method M313 is suitable for determination of the analytes. See the study DER for more details concerning this analytical method and its ILV (46908309.DER, D336045, B. Finch, *et al.*, in review). Residues are not expected in animal commodities and no tolerances for animal commodities are being established. As a result, an analytical method for residues in animal commodities is not required.

Magnitude of the Residue In Plant Commodities

The registrant submitted the results of twenty field trials that were performed in Canada. The trials were performed in NAFTA Growing Zones 5 (2 trials in Ontario), 7 (5 trials in Saskatchewan), 7A (3 trials in Alberta), and 14 (2 trials in Alberta, 4 trials in Manitoba, and 4 trials in Saskatchewan) during the 2005 growing season. At each test location, pyroxsulam was applied once at the 31-33 BBCH stage of growth as the GF-1674 formulation at 15 g a.i./ha (0.013 lb a.i./A). Cloquintocet-mexyl (0.8 % v/v), was added to the spray mixture for all applications, and it was applied at a rate of 45 g cloquintocet-mexyl/ha (0.040 lb cloquintocet-mexyl/A). The GF-1274 label states that the maximum seasonal application rate is 0.016 lb cloquintocet-mexyl per Acre and the GF-1674 label states that the maximum seasonal application rate is 0.040 lb cloquintocet-mexyl per Acre. See the study DER for more details concerning the Canadian field trials (46908319.DER, D336045, T. Sheremata and D. Dotson, in review).

Samples were stored for a maximum of 6.3 months. Freezer storage stability of cloquintocet-mexyl and cloquintocet acid was demonstrated for 9 months. Analytical Method M313 (discussed above) was used to analyze residues of cloquintocet-mexyl and cloquintocet-acid. Briefly, residues of cloquintocet-mexyl and cloquintocet-acid were extracted from wheat forage, hay, grain, and straw by blending twice with an acetone/citrate buffer (80:20, v/v) solution. The extract was purified using SPE, and cloquintocet residues were eluted from the plate using 0.1% formic acid in MeOH. A C^{13}-labeled internal standard was added to the extracts that were subsequently analyzed for cloquintocet-mexyl and cloquintocet acid by liquid chromatography with positive ion atmospheric pressure ionization (APCI) tandem mass spectroscopy (LC/MS/MS). The reported values for the LOD and the LOQ are 0.005 and 0.01 ppm, respectively. Method M313 was shown to be an acceptable data gathering method as the concurrent recoveries of cloquintocet-mexyl and cloquintocet acid ranged from 67-119% for all wheat matrices for spiking levels of 0.01-2.0 ppm for each analyte.

The field trials were performed at a 1x application rate for the GF-1674 formulation and at a 2.5x rate for the GF-1274 formulation. Residues of cloquintocet-mexyl were below the LOQ of 0.01 ppm in all wheat matrices. The maximum cloquintocet-acid residue values were <0.01 ppm in forage for PHIs of 7-14 days, 0.027 ppm in hay for PHIs of 28-43 days, <0.01 ppm in grain for PHIs of 50-110 days, and 0.034 ppm in straw for PHIs of 50-110 days. In both forage and grain, the maximum combined residue value of the two compounds was <0.02 ppm. In hay, the maximum combined residue value was <0.037, and in straw the maximum combined residue value was <0.044 ppm. The current tolerance for all four commodities is 0.1 ppm. Although none of the field trials were conducted in the United States, half of the trials were conducted in zones that extend into the U.S. or are on the Canadian border. Therefore, considering that all the observed residues were less than half of the established tolerances and were not significantly higher than the method LOQ, the current tolerances are adequate to cover residues of

cloquintocet-mexyl and cloquintocet acid when used with pyroxsulam according to the label directions for GF-1274 and GF-1674. The field trials were performed at a 2.5x application rate for the GF-1274 formulation. As the trials were performed at a higher application rate than is allowed on the label, the tolerances are still adequate.

Storage Stability

In the wheat field trials, samples were stored for up to 6.3 months prior to analysis. The registrant submitted the results of a storage stability study that was performed to support the field trials. Samples of wheat grain, wheat straw, wheat forage, spinach, tomatoes, potatoes, and soybeans were fortified with cloquintocet-mexyl and cloquintocet acid to levels of 0.01 and 0.10 ppm. After 9 months of storage at temperatures of ≤-20°C, percent recoveries of cloquintocet-mexyl ranged from 74-107% and percent recoveries of cloquintocet acid ranged from 72-101%. The storage stability data are adequate to support the storage durations used in the field trials. See the study DER for more details concerning the storage stability study (46908316.DER, D336045, T. Sheremata, *et al.*, in review).

cc: D. Dotson

13544

R156804

Chemical: Inert ingredient undetermined

PC Code:
999999

HED File Code: 11500 Petition Files Chemistry
Memo Date: 12/19/2007
File ID: DPD313217
DPD257181
DPD336045
Accession #: 000-00-0124

HED Records Reference Center
3/11/2008