



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: 87-VA-01.
87-VA-02.
Section 18 Request for the Use of Harmony (DPX-M6316) on Wheat and Barley.
No Accession Number
RCB Nos. 1808, 1809

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To: Emergency Response and Minor Use Section
Registration Division (TS-767C)

The Virginia Department of Agriculture and Consumer Services and the Virginia Cooperative Extension Service request a Section 18 Specific Exemption authorizing application of Harmony (DPX-M6316) to control wild garlic in wheat and barley. Harmony is a 75% a.i. dry flowable formulation of methyl 3-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate produced by DuPont. Applications will be made on a maximum of approximately 85,000 acres throughout Virginia.

No tolerances are presently established for residues of Harmony. Temporary tolerances were established in conjunction with PP#4G3138 for residues of DPX-M6316 in or on wheat and barley grain at 0.05 ppm and in or on wheat and barley straw at 0.1 ppm (FR 50(99), p.21117). Preparation of a Registration Standard is currently being undertaken.

The proposed use involves applications of Harmony at 1/3 to 2/3 ozs. product (0.25-0.5 ozs.a.i.)/A/application between the 2-leaf and boot stages. No PHI is stated, but the minimum interval between the boot stage and harvest is approximately 36 days implying an effective PHI of 36 days. Applications could be made using ground (minimum 5 gallons water/A) or aerial (minimum 3 gallons water/A) equipment. Harmony would

be-applied as a foliar spray together with a non-ionic surfactant of at least 80% strength. The maximum number of applications per season is not stated. A grazing/feeding restriction for treated hay and forage is not imposed.

Metabolism studies for wheat and barley were submitted in conjunction with PP#4G3138 (Acc. No. 072845) and reviewed by J.M. Worthington (11/1/84). An additional metabolism study was submitted with PP#6F3431 and is currently being reviewed. It was concluded in the 11/1/84 memo that parent DPX-M6316 is the primary residue of concern in wheat and barley, and for the purposes of this Section 18, we reiterate this conclusion.

Two analytical methods have been used to generate residue data for Harmony residues in or on barley and wheat grain and straw. The primary difference between these methods is the extraction step. In the first method, all commodities are extracted with ethyl acetate and acetic acid followed by partitioning against sodium bicarbonate. In the second method, wheat grain is extracted with ethyl acetate followed by partitioning against sodium bicarbonate; and barley grain, and wheat and barley straw are extracted with 0.1 M sodium bicarbonate. The remainder of the analytical procedure is similar for both methods. The sodium bicarbonate solution is acidified, partitioned against methylene chloride, and the methylene chloride solution is evaporated to dryness. The residue is redissolved in cyclohexane/isopropanol (3:1) and filtered through a millipore filter. Analysis is accomplished (parent only) by HPLC using a photoconductivity detector. The reported limits of detection are 0.02 ppm for grains and 0.05 ppm for straws. Recoveries for wheat and barley grain fortified at 0.02 ppm ranged from 71-98% and from 87-105% respectively; and recoveries from wheat and barley straw at fortification levels of 0.05 ppm ranged from 68-112% and 67-95% respectively.

The latter analytical method was submitted to the EPA Analytical Section for Method Try-Out, and some difficulties were encountered (see W.R. Bontoyan, 10/31/86). However, for the purposes of this Section 18 only, we consider this method adequate for enforcement purposes.

Residue data were submitted with PP#4G3138 (Acc. No. 072845) and PP#6F3431 (Acc. No. 263751). Wheat from OH, CO, DE, ND, MN, ID, OK, KS, FL, WA and CA and barley from CO, ID, OR, ND, WA, SD, CA and MT were treated with ground or aerial applications of Harmony at rates of 0.25-4.0 lbs.a.i./A for a single treatment. At PHIs of 45-118 days, no detectable residues were found in wheat or barley grain (<0.02 ppm) or straw (<0.05 ppm). None of these data reflect the minimum PHI, however, many of the trials utilized applications at rates up to 3 times the maximum proposed rate (some studies utilized applications up to 8X, but samples were stored at room temperature for extended periods after they were obtained).

Based on these data, and for the purposes of this Section 18 only, we conclude that residues are not likely to exceed 0.05 ppm in or on wheat and barley grain and 0.1 ppm in or on wheat and barley straw as a result of the proposed use.

A small grain processing has not been done for Harmony. However, since no detectable residues were found in wheat or barley grain at exaggerated rates up to 2.5X for barley and up to 3X for wheat, for the purposes of this Section 18 only, we estimate that residues will not exceed 0.05 ppm in the processed fractions of wheat and barley.

Meat, Milk, Poultry and Eggs

Animal feeding studies are not available for Harmony. However, no detectable residues of Harmony were found in barley at application rates up to 2.5X or in wheat at application rates up to 3X. Based on this, and for the purposes of this Section 18 only, we conclude that residues are not likely to be found in eggs, milk or in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep as a result of the proposed uses.

Conclusions

- (1) For the purposes of this Section 18 only, we conclude that the residue of concern for applications of Harmony to wheat and barley consists of the parent compound only.
- (2) For the purposes of this Section 18 only, we conclude that residues of Harmony are not likely to exceed the following values as a result of the proposed uses:

<u>Commodity</u>	<u>Maximum Likely Residue (ppm)</u>
Wheat grain	0.05
Barley grain	0.05
Wheat hay, straw, forage	0.1
Barley hay, straw, forage	0.1
Wheat milled products (including bran, flour, middlings and shorts)	0.05
Wheat germ	0.05
Barley milled products (including hulls, bran, flour and pearl barley)	0.05
Barley germ	0.05

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- (3) No detectable residues were found in barley at application rates up to 2.5X, or in wheat at application rates up to 3X. Based on this, and for the purposes of this Section 18 only, we conclude that residues are not likely to be found in eggs, milk or in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep as a result of the proposed uses.
- (4) For the purposes of this Section 18 only, we conclude that the HPLC analytical method discussed in PP#6F3431 (Acc. No. 263751) is adequate for enforcement purposes.
- (5) Residue data are available for 1 application per season of Harmony only. No residue data are available reflecting residues found in wheat or barley at the shortest possible PHI of 36 days (a 45-day PHI is the shortest PHI used in these trials). In the absence of data reflecting multiple applications of Harmony to small grains, applications of Harmony made under the authority of this Section 18 should be restricted to one application per season.
- (6) Analytical reference standards are available from the Pesticides and Industrial Chemicals Repository.

Recommendations

Provided applications are restricted to 1 per season for applications to wheat and barley, we have no objections to this Section 18. An agreement should be made with the FDA regarding the legal status of the treated commodities in commerce.

cc: Harmony (DPX-M6316), S.F., R.F., Section 18 S.F., Circu,
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