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MEMORANDUM

Subject: PP#1F4029. Metsulfuron methyl in/on Wheat and Barley. Evaluation of Analytical Method and Residue Data. MRID #'s 420165-01, -02, -03, -04, -05, -08, and 420806-01. CBTS#'s 8958 and 8959. DP Barcode 171707 and 171709.

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5/4/93

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E. I. du Pont de Nemours and Company proposes revised tolerances be established on the r.a.c.'s of wheat grain (0.1 ppm), wheat straw (0.3 ppm), barley grain (0.1 ppm), and barley straw (0.3 ppm) for the combined residues of the herbicide metsulfuron methyl (methyl-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate) and both the free and bound forms of its metabolite [methyl-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate].

Tolerances have been established (40 CFR 180.428) for the combined residues of metsulfuron methyl and its 4-hydroxy-metabolite (free and bound) in/on barley (grain, 0.05 ppm, green forage, 5.0 ppm, hay, 20.0 ppm, straw 0.1 ppm), wheat (grain, 0.05 ppm, green forage, 5.0 ppm, hay, 20.0 ppm, straw 0.1 ppm), and grass (fodder, 15.0 ppm, forage, 15.0 ppm, hay, 15.0 ppm).

Tolerances for the residues of metsulfuron methyl only are established at 0.1 ppm for meat, fat, and meat by-products (except kidney) of cattle, goats, hogs, horses, and sheep and at 0.5 ppm for kidney of cattle, goats, hogs, horses, and sheep. A 0.05 ppm tolerance is established for milk.

The proposed tolerances are intended to cover the higher expected residues on wheat and barley grain and straw from a requested shorter preharvest interval for these commodities. No other tolerances are pending at this time.

Comments/Conclusions

1. The manufacturing process has been adequately discussed in previous tolerance requests. CBTS concludes that impurities are not likely to be a residue problem.

2. The nature of the residue in wheat and barley is adequately understood based upon data from other crops. The combined residues of metsulfuron methyl and its metabolite IN-G7460 (free and bound) are the residues of concern.

3. The nature of the residue in animals is adequately understood. The residue of concern in meat and milk is the parent metsulfuron methyl only.

4. The analytical methods for determining the residues of metsulfuron methyl and its metabolite (free and bound) in wheat and barley r.a.c.'s are adequate for enforcement of the proposed use.

5. Adequate storage stability studies have been submitted to validate the wheat and barley residue data.

6. The proposed tolerances are adequate on the r.a.c.'s of wheat grain and straw, and barley grain and straw.

7. The proposed tolerance for the r.a.c.'s will adequately cover residues that could be in wheat or barley processed products.

8. The established tolerances for residues in meat and milk are adequate to cover secondary residues from the proposed use on wheat and barley.

10. There are no Codex, Canadian, or Mexican limits established for metsulfuron methyl or its metabolite in/on wheat or barley. Therefore, no compatibility problems exist.

Recommendations

We recommend for the proposed revised tolerances of 0.1 ppm for the r.a.c.'s wheat grain and barley grain, and 0.3 ppm for wheat straw

and barley straw for the combined residues of the herbicide metsulfuron methyl (methyl-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate) and both the free and bound forms of its metabolite [methyl-2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate, IN-G7460].

Detailed Considerations

Manufacturing Process and Formulation

The synthesis and impurities of technical metsulfuron methyl have been reviewed previously (See memos of 6/21/85, P. Errico and of 11/4/85, K. Arne). No residue problems are expected from the impurities at the reported levels. The proposed formulation contains 60% a.i. metsulfuron methyl and 40% inerts.

Proposed Use

E. I. du Pont de Nemours and Company proposes to use Ally®herbicide for selective weeding to aid in grain harvesting. Ally®is to be sprayed by ground or air equipment at rates of 0.1 oz./A (0.06 oz.a.i./acre) with or without 2,4-D as a tank mix using a minimum of 3 gallon of water/A by ground and 1 gallon of water/A by air. Applications of this herbicide are not to exceed 0.1 oz. (0.06 oz.a.i.) per acre in some US locations in a 10 month period and others a 22 month period is required. Applications are made once the crop is in the dough stage but no later than 10 days before harvest.

Note: The current label allows a 20-day PHI for wheat and barley grain and straw harvest. It also allows up to 0.12 oz. a.i./A/season, twice the proposed maximum label of 0.06 oz. a.i./A/season. No changes are proposed for the 0-day PHI for wheat and barley green forage and hay.

Nature of the Residue

No additional plant metabolism studies were submitted with this petition. Radiolabelled studies have been conducted using wheat (field and greenhouse grown plants) and barley (field grown only). These studies have been reviewed previously (See memos of 6/21/85, P. Errico and of 11/4/85, K. Arne). The nature of the residue in plants is adequately understood. Metsulfuron methyl is metabolized to a 4-hydroxy-metsulfuron methyl and a glucose conjugate of this metabolite by green barley and green wheat. The residues of concern are the combined residues of the parent metsulfuron methyl and its 4-hydroxy metabolite (free and conjugate).

No additional animal metabolism studies were submitted with this petition. Radiolabelled studies have been conducted in the rat and

the goat. These studies have been reviewed previously (See memos of 6/21/85, P. Errico and of 11/4/85, K. Arne). The nature of the residue in animals is adequately understood. The residue of concern is the parent metsulfuron methyl only.

Analytical Method

PAM II analytical enforcement methods to determine residues of metsulfuron methyl in wheat and barley grain and straw are available. Two independent HPLC methods are needed to determine the combined residues of the parent and its A1 metabolite [both free (IN-G7460) and its glucose conjugate (IN-B9700)]. One determines the parent only (AMR-104-82, Revision B, "Determination of Residues of Metsulfuron Methyl in Crops By Liquid Chromatography") and the other measures the combined residues of the 4-hydroxy metabolite (both free and the glucose conjugate, AMR-238-84, Revision B, Residues of Metsulfuron Methyl Metabolites A and A1 in Cereal Grain Crops By Liquid Chromatography").

Additional methodology has been submitted in this petition. For determination of the parent only, an analytical method using two HPLC's with UV detection at 254 nm, i.e., one chromatograph performs sample cleanup and the second performs sample analysis ["Analytical Method for the Quantitation of DPX-T6376 (Ally®) in Wheat Grain and Straw", MRID#420165-08]. This method can also be run using a single instrument by changing to the analysis column after a sample cleanup on the first column. Another method measures the combined residues of the 4-hydroxy metabolite [both free and the glucose conjugate ("Analytical Method for the Determination of Residues of Metsulfuron Methyl Metabolites A and A1 in Cereal Grain Crops Using Immobilized Enzymes", MRID#420806-01)]. These methods are used for both wheat and barley grain and straw.

In this petition, PP#1F4029, residue data for metsulfuron methyl in wheat and barley grain and straw were collected using the more recently developed methods. Validation data are submitted for both parent and its regulated A1 metabolite. Wheat and barley grain samples are fortified at 0.02 ppm metsulfuron methyl and recoveries ranged from 75 to 90%. Recoveries of wheat straw fortified at 0.05 and 0.1 ppm metsulfuron methyl ranged from 54 to 86% and 68 to 73%, respectively. Recoveries of barley straw fortified at 0.05 ppm metsulfuron methyl ranged from 40 to 92%. Wheat grain fortified levels of metabolite A1 ranged from 0.02 to 0.28 ppm with recoveries from 64 to 95%, and barley grain fortified levels of metabolite A1 ranged from 0.05 to 0.28 ppm with recoveries from 52 to 93%. Wheat straw fortified levels of metabolite A1 ranged from 0.1 to 0.28 ppm with recoveries from 58 to 105%, and barley grain fortified levels of metabolite A1 ranged from 0.1 to 0.56 ppm with recoveries from 64 to 110%.

Validation data for wheat grain and straw are also submitted from an independent laboratory. Fortified levels of metsulfuron methyl in grain ranged from 0.012 to 0.12 ppm with recoveries from 68 to 100%. Fortified levels of metsulfuron methyl in straw ranged from 0.023 to 0.23 ppm with recoveries from 78 to 90%. Fortified levels of IN-G7460 in grain ranged from 0.03 to 0.5 ppm with recoveries from 77 to 98%. Fortified levels of IN-B9700 in grain ranged from 0.03 to 0.5 ppm with recoveries from 73 to 97%. No data are presented for barley.

Therefore, adequate analytical methodology is available for the residues of metsulfuron methyl and its metabolite IN-G7460 (and its glucose conjugate, IN-B9700) for the proposed use on wheat and barley.

Storage Stability

Freezer storage stability studies were submitted for wheat grain, straw, and green forage. Samples of wheat grain were spiked with 0.1 ppm metsulfuron methyl and analyzed from 1 month up to 64 months. Samples of wheat straw were spiked with 0.2 ppm metsulfuron methyl and analyzed from 1 month up to 49 months. Samples of wheat forage were spiked with 0.1 ppm metsulfuron methyl and analyzed from 1 month up to 46 months. No data are presented for metabolites IN-G7460 and IN-B9700. No data are presented for barley. The storage stability data are adequate for the proposed use.

Residue Data

Data are submitted for wheat from field trials conducted in the states of CO, KS, MT, OK, ND, and TX and for barley from those conducted in MT and SD to support a 10-day PHI. Single ground applications at either 0.06 oz a.i./A (1X rate) and 0.12 oz a.i./A (2X rate) were applied at each site. Additional aerial applications were run in CO and MT at the 1X rate. Residue data for metsulfuron methyl and its metabolite IN-G7460 are presented for wheat grain and straw. In all states except TX, the residues of parent and metabolite are <0.02 ppm individually, but <0.04 ppm combined. In TX, at a 1X rate, up to 0.045 ppm parent alone is present, and up to 0.07 ppm at a 2X rate; residues of IN-G7640 are <0.02 ppm at both 1X and 2X. In the aerial applications, one sample analyzed at 0.22 ppm for metabolite IN-G7640, but gave parent <0.02 ppm at a 1X rate.

Data are submitted for barley from field trials conducted in the states of MT and SD. Single ground applications at either 0.06 oz a.i./A (1X rate) and 0.12 oz a.i./A (2X rate) were applied at each site. Additional aerial applications were run at the 1X (MT and SD) and 2X (SD only) rates. Residue data for metsulfuron methyl and its metabolite IN-G7460 are presented for barley grain and

straw. In SD, the residues of parent and metabolite are <0.02 ppm individually, but <0.04 ppm combined, for both the ground and aerial applications at 1X and 2X rates. In MT, at a 1X rate, no residues (<0.02 ppm) for parent or metabolite IN-G7460 are found. In a ground application, at a 2x rate, up to 0.031 ppm parent alone is present; residues of IN-G7460 are <0.02 ppm.

Therefore, the residue data are adequate for the proposed use and will support the proposed tolerances of 0.1 ppm for wheat and barley grain and 0.3 ppm for wheat and barley straw.

Additional residue data are presented in this petition for wheat and barley grain and straw at the proposed 1X and 2X rates, but at PHI's of 18 to 21 days (MRID#'s 420165-04 an 420165-05). This data cannot adequately support the proposed 10-day PHI and therefore will not be included in the discussion of the residue data in this review.

Processing study

A wheat processing study is submitted in this petition (MRID#420165-03). Metsulfuron methyl is applied at a 6X rate (0.38 oz. a.i./A) in a field trial conducted in CA. The wheat grain is harvested 8 days after treatment and processed in a manner that closely resembles commercial practices. The r.a.c. and the processed products are analyzed using the newly developed methodology discussed above. There are no detectable or quantifiable residues in the r.a.c. or the processed products. Therefore, no concentration of residues were observed in the processed fractions. Recoveries from 8 fortified samples ranged from 85 to 113% for metsulfuron methyl, 6 fortified samples ranged from 73 to 104% for IN-B9700, and 3 fortified samples ranged from 104 to 135% for IN-G7460.

Meat, Milk, Poultry, and Eggs

No additional feeding studies are submitted in this petition. A cow feeding study was reviewed previously and determined adequate to support the established tolerances on wheat, barley, and grasses. The proposed use, i.e., the decrease of the current 20-day PHI to a 10-day PHI, and the increase of the wheat and barley grain tolerances from 0.05 ppm to 0.1 ppm, and the increase of the wheat and barley straw tolerances from 0.1 ppm to 0.3 ppm, will not result in an increase of metsulfuron methyl residues in livestock meat, milk, or meat by-products. CBTS had previously stated that a poultry metabolism study and a poultry feeding study may be needed if future tolerance requests showed significant residues in poultry feed items. Based upon the proposed use and increases in tolerances, CBTS still will not require the poultry studies.

Other Considerations

There are no Codex or Mexican limits established for metsulfuron methyl or its 4-hydroxy-metabolite in/on wheat or barley. A negligible Canadian limit of 0.1 ppm has been established for metsulfuron methyl. Therefore, no compatibility problems exist.

cc: J. Stokes (CBTS); PP#1F4029; R.F.; Circu
RDI: PErrico:4/27/93:RLoranger:4/27/93
H7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:4/28/93

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