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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 1/24/07

Subject: Cloquintocet-mexyl on Wheat and Barley. Comments Concerning Potential Petition for Amended Registration.

DP Number: 335806	Decision Number: 353510
PC Code: 700099	MRIDs: None
40 CFR: 180.560	Chemical Class: Herbicide safener

From: Nancy Dodd, Chemist *Nancy Dodd*
Registration Action Branch 3
Health Effects Division (7509C)

Through: Leung Cheng, Chemist *Leung Cheng*
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and

Paula Deschamp, Branch Chief *Paula Deschamp*
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To: Tracy H. Ward/Daniel Rosenblatt, RM Team #5
Inert Ingredient Assessment Branch
Registration Division (7505C)

Background

Cloquintocet-mexyl (Axial™ Herbicide, EPA Reg. No. 100-1199) is registered for use on spring wheat (excluding durum), winter wheat, and barley. The current label contains the following "Crop Use Directions:"

- Make one application per crop season.
- Do not graze livestock or harvest forage for hay from treated areas for a minimum of 50 days following application.

- Do not harvest grain for 60 days following application.
- Do not use on barley which will be grazed by livestock or made into silage for feed.
- Do not apply both Discover and Axial products to the same crop in the same season.

Based on a letter from Syngenta to RD (Jim Tompkins) dated 31-AUG-2006, the petitioner is requesting the following amendments:

1. The petitioner wants to increase the tolerance on wheat forage from 0.1 ppm to 0.20 ppm.
 - 2a. The petitioner wants to revise the 50-day restriction to a 30-day restriction: "Do not graze livestock or harvest forage for hay from treated wheat and barley for a minimum of 30 days following application."
 - 2b. The petitioner thinks that the feeding/grazing restriction for barley, "Do not use on barley which will be grazed by livestock or made into silage for feed," is not needed.
3. The petitioner thinks detectable residues will not occur in livestock based on the goat and poultry metabolism studies and, therefore, livestock analytical methods, livestock feeding studies, and livestock tolerances are not needed.

Discussion

More than the required 20 wheat field trials were previously reviewed (DP Number 308470, N. Dodd, 11/16/05). These trials included application to both spring wheat and winter wheat. Eight trials in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 (KS; 1 trial), 6 (OK; 1 trial), and 8 (KS, OK, and TX; 4 trials) were conducted on winter wheat reflecting application in the fall. Including all field trial data (i.e., including winter wheat treated in the fall which had detectable residues in forage and hay at PHI's of 27-33 days), maximum residues were 0.12 ppm in wheat forage, 0.19 ppm in wheat hay, 0.1 ppm in wheat straw, and 0.07 ppm in wheat grain. Also from DP Number 308470, maximum residues were 0.048 in barley hay, 0.050 ppm in barley straw, and <0.01 ppm in barley grain. The petitioner is now (August 31, 2006 letter) proposing a tolerance of 0.20 ppm on wheat forage. The petitioner originally proposed tolerances of 0.20 ppm on wheat forage and 0.50 ppm on wheat hay. (EPA validated LOQs are 0.05 ppm for parent in wheat forage, hay, and straw and 0.02 ppm for parent in wheat grain; and 0.05 ppm for the metabolite CGA-153433 on all wheat commodities.)

PHI's of submitted data (MRIDs 46012905, 46012918, and 46203206) are mostly approximately 30 days for forage and hay.

The livestock diets have been revised using "Table 1 Feedstuffs" (October 2006) and comments from Jerry Stokes and Bernard Schneider (e-mail 12/22/06). Possible livestock feedstuffs from uses on wheat and barley are listed in Table 1 below. Reasonably balanced diets for livestock are

calculated in Table 2 below. Note that the tolerances used in the tables are 0.20 ppm for wheat forage, 0.50 ppm for wheat hay, and 0.10 ppm for other commodities.

Feedstuff	Type	Tolerance, ppm	% Dry Matter	% Diet			
				Beef	Dairy	Poultry	Swine
Barley hay	R	0.10	88	25	40	NU	NU
Barley straw	R	0.10	89	10	10	NU	NU
Wheat forage	R	0.20	25	25	40	NU	NU
Wheat hay	R	0.50	88	25	40	NU	NU
Wheat straw	R	0.10	88	10	10	NU	NU
Barley grain	CC	0.10	88	50	45	70	20
Wheat grain	CC	0.10	89	20	20	70	NU
Wheat milled bypds	CC	0.10	88	40	40	50	50
Asp grain fractions	CC	0.10	85	5	NU	NU	NU

Feedstuff	Type	Tolerance, ppm	% Dry Matter	% Diet				Residue (ppm)			
				Beef	Dairy	Poultry	Swine	Beef	Dairy	Poultry	Swine
Wheat hay	R	0.50	88	15	15	NU	NU	.085	.085	0	0
Corn forage/silage	R	0	40	30	30	NU	NU	0	0	0	0
Wheat milled bypds	CC	0.10	88	40	40	50	20	.045	.045	0.05	0.02
Corn, field, grain/ other grains/grain milled byproducts	CC	0	88	5	5	30	65	0	0	0	0
Soybean, meal/other oilseed meals or seeds	PC	0	92	10	10	20	15	0	0	0	0
Totals				100	100	100	100	0.13	0.13	0.05	0.02

* "Table 1 Feedstuffs" (October 2006) with comments from Jerry Stokes and Bernard Schneider (e-mail, 12/22/06).

No ruminant or poultry feeding studies were submitted. In the goat metabolism study (MRID's 44387458 and 44387460), a lactating goat was dosed with (3-¹⁴C)quinoline-labeled cloquintocet-mexyl for ten consecutive days at a dose level of 5 ppm. In the poultry metabolism study (MRID's 44387459 and 44387461), three laying hens were dosed with (3-¹⁴C)quinoline-labeled cloquintocet-mexyl for fourteen consecutive days at a dose level of 5 ppm. Residue levels in livestock commodities in the metabolism studies conducted at 5 ppm are extrapolated to 1X levels (based on a reasonably balanced diet using "Table 1 Feedstuffs," October 2006) in Table 3 below:

Table 3. Total Radioactive Residues (TRR) in Goat and Poultry Metabolism Studies Conducted at a 5.0 ppm Dosing Level and Extrapolated to 1X (0.13 ppm for Beef Cattle, 0.13 ppm for Dairy Cattle, 0.02 ppm for Swine, and 0.05 ppm for Poultry)		
Substrates	TRR from 5 ppm Dosing Level (ppm)	TRR Extrapolated to 1X (ppm)
Beef Cattle		
muscle (tenderloin)	0.003	0.000078
fat (subcutaneous)	0.001	0.000026
kidney	0.024	0.00062
liver	0.010	0.00026
Dairy Cattle		
milk (maximum)	0.084	0.0022
muscle (tenderloin)	0.003	0.000078
fat (subcutaneous)	0.001	0.000026
kidney	0.024	0.00062
liver	0.010	0.00026
Swine		
muscle (tenderloin)	0.003	0.000012
fat (subcutaneous)	0.001	0.000004
kidney	0.024	0.000096
liver	0.010	0.00004
Poultry		
muscle	ND (<0.001)	0.00001
fat	ND (<0.002)	0.00002
liver	0.01	0.0001
Eggs (whole)	0.006	0.00006

Conclusions

1. HED has no objection to raising the tolerance for wheat forage from 0.1 ppm to 0.20 ppm. HED recommends that the tolerance for wheat hay be raised from 0.1 to 0.50 ppm. (These levels have been assumed in the current livestock secondary residue calculations.) The established tolerances for wheat grain and straw and for barley grain, hay, and straw should remain at 0.10 ppm.
- 2a. HED has no objection to the 30-day PHI for forage and hay: “Do not graze livestock or harvest forage for hay from treated wheat and barley for a minimum of 30 days following application.”
- 2b. The statement “Do not use on barley which will be grazed by livestock or made into silage for feed” should be deleted.
3. Using “Table 1 Feedstuffs (October 2006) and assuming levels of 0.20 ppm for wheat forage and 0.50 ppm for wheat hay, residues calculated for the 1X feeding levels are lower than those originally calculated in DP Number 308470 (N. Dodd, 11/16/05). Because of the low levels of total radioactive residues found in livestock commodities in the ruminant and poultry metabolism studies and the corresponding low radioactive residues calculated for the 1X feeding levels, ruminant and poultry feeding studies are not needed, tolerances on livestock commodities are not needed, and analytical methods for livestock commodities are not needed. The uses on wheat and barley fall under 40 CFR §180.6(a)(3) since no secondary residues are expected to occur in livestock commodities.

Recommendations

The petitioner should submit a Section F to propose tolerances for the combined residues of cloquintocet-mexyl (acetic acid, [(5-chloro-8-quinolinyl)oxy]-, 1-methylhexyl ester and its acid metabolite (5-chloro-8-quinolinylacetic 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 of 0.20 ppm for *wheat, forage* and 0.50 ppm for *wheat, hay*. The established tolerances for wheat grain and straw and for barley grain, hay, and straw should remain at 0.10 ppm.

The petitioner should revise the Section B/label as follows: 1) The statement “Do not graze livestock or harvest forage for hay from treated areas for a minimum of 50 days following application” should be replaced with the following statement: “Do not graze livestock or harvest forage for hay from treated wheat and barley for a minimum of 30 days following application”; and 2) The statement “Do not use on barley which will be grazed by livestock or made into silage for feed” should be deleted.

cc: N. Dodd, L. Cheng, RAB3 File
RDI: N. Dodd (1/24/07); L. Cheng (1/24/07)



13544



R139520

Chemical: Acetic acid, {(5-chloro-8-quinolinyl)oxy}-, 1-methylhexyl ester

PC Code:
700099

HED File Code: 11000 Chemistry Reviews

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HED Records Reference Center
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