

Sub File



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUMOFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Imazalil. Case No. 2325. Magnitude of Residue in Winter Wheat Forage, Straw and Grain Grown From Treated Seed. MRID No. 43285001. CBRS No. 14026. DP Barcode: D205092.

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Janssen Pharmaceutica has submitted a magnitude of residue study entitled "Imazalil and Metabolite (R14821) in Winter wheat Forage, Straw and Grain Grown From Imazalil Treated Seed", D. B. Helmer, 5/31/94, Report No. AGR30. The seeds were treated with imazalil at ca 100 ppm (1x) and 1000 ppm at the Gustafson Research and Development Center, McKinney, TX and then planted and grown near Charleston, KS (supervised through Diamond Ag Research, Garden City, KS). Samples of treated seeds, grain, forage and straw were analyzed at Janssen Research Foundation, Beerse, Belgium.

CBRS has previously reviewed field trial studies for wheat and barley grown from imazalil-treated seed (S. Funk, 12/21/93, CBRS No. 12386). Seeds were treated with imazalil (1x, 3x, 6x, or 11x) at Gustafson Research and Development Center, McKinney, TX. Field studies were conducted in ID and WA for spring barley, MN, MT, and ND for spring wheat, and KS, OK, and TX for winter wheat. The review concluded that these studies were fully acceptable and no additional wheat or barley data (171-4(k)) were required for reregistration. It was further concluded that combined residues of imazalil and its metabolite R14821 would not exceed the established tolerance (2 ppm) or proposed revised tolerance (0.5 ppm) for wheat and barley straw, and the proposed tolerance of 0.5 ppm for barley and wheat forage. However, the residue data did NOT support the established tolerances of 0.05 ppm for barley and wheat grain.

Because of the combined limit of quantitation of 0.08 ppm and the apparent residues in control grain samples of 0.17 ppm, the review recommended the registrant propose a new tolerance of 0.2 ppm for barley grain and 0.2 ppm for wheat grain.

The 12/21/93 review also concluded that processing studies were not needed based on the residues found in grains of barley and wheat grown from seeds that had been treated at exaggerated rates.

Results of the current submission show that residues were <0.02 ppm imazalil and <0.03 ppm R14821 in grain whether the seeds had been treated at 110 ppm or 1000 ppm. Residues were <0.06 ppm imazalil and 0.08 ppm R14821 in forage, and <0.08 ppm imazalil and 0.05 ppm R14821 in straw following seed treatment at 110 ppm. Control samples of forage, straw, and grain contained 0.06 ppm or less imazalil and 0.08 ppm or less R14821 (see Table 1 below). Days from sampling to analysis were 230 days or 460 days. Imazalil and R14821 are stable in wheat grain and forage for up to 24 weeks at -20 C but decline significantly in wheat straw (D. Miller, 11/18/93, CBRS No. 11898). Results of sample reanalysis discussed in the 12/21/93 review indicate imazalil and R14821 are stable in wheat grain and straw while frozen for at least 300 days.

Table 1. PPM residues of imazalil and R14821 in wheat forage, straw and grain

	Imazalil	R14821	Total
Treated seed, 0 ppm	<0.02	Not analyzed	
Treated seed, 110 ppm	105.7		
Treated seed, 1000 ppm	937.9		
Wheat forage, control	0.06	0.07	0.13
Wheat forage, 110 ppm	<0.06*	0.08	0.11
Wheat straw, control	<0.08#	0.05	0.09
Wheat straw, 110 ppm	<0.08	0.05	0.09
Wheat grain, control	<0.02‡	<0.03†	0.03
wheat grain, 110 ppm	<0.02	<0.03	0.03
Wheat grain, 1000 ppm	<0.02 (3)	<0.03 (3)	0.03 (3)

* limit of quantitation for wheat forage

limit of quantitation for wheat straw

‡ limit of detection of imazalil for wheat grain

† limit of quantitation of R14821 for wheat grain

CONCLUSIONS AND RECOMMENDATION

1. The current study submitted under MRID No. 43285001 corroborates the residue data discussed in CBRS 12386 (S. Funk, 12/21/93). Finite residues of imazalil and R14821 were found in

the wheat forage and straw harvested from seeds treated at 1x rate and are within the 0.5 ppm proposed tolerance. Residues in wheat grain were less than 0.03 ppm resulting from 1x or 10x use rate (in the current study) and ranged 0.04-0.07 ppm from the previous database (1x, 3x, 6x, and 10x). Control samples of wheat grain contained 0.03-0.07 ppm combined imazalil residues; the control grain sample (0.17 ppm) previously noted was suspect. The established tolerance of 0.05 ppm for wheat and barley grain is not adequate and needs to be revised to 0.1 ppm. The 0.5 ppm tolerances proposed for forage and straw of wheat and barley are adequate.

2. We repeat our conclusion made in the 12/21/93 review that processing studies for wheat and barley are not required. The tolerances for the raw agricultural commodities will also be adequate for the processed commodities.

3. The GC/ECD method, using either an internal or external standard, is adequate for collecting data on residues of imazalil and R14821 in the grain, forage and straw of wheat and barley (L. Cheng, 1/10/94, CBRS No. 11295).

GLN 171-4(k) and 171-4(l) for wheat and barley are satisfied.

cc:Circ, SF, RF, List B File, Cheng

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7509C:CBRS:LCheng:CM#2:RM810D:1/10/95:04:IMAZALIL\WHEATRES