S.F.

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

DEC 21 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Reregistration of Imazalil (List B, Case 2325, Chemical 111901). Magnitude of the Residue in Wheat and Barley (171-4(k)) and in Processed Commodities of Wheat and Barley (171-4(l)). DP Barcode D194151. MRID Nos. 42868101, 42852001, and 42852002. CBRS No. 12386.

From: Stephen Funk, Ph.D., Chemist
Special Review, Section I
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Through: Andrew Rathman, Section Head
Special Review Section I
Health Effects Division (7509C)

To: Kathryn Davis, CRM 52\Kathleen Depukat
Reregistration Section 2
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

Attached is the review of the Janssen Pharmaceutica response to the *Phase 4 Review* request for field trial studies for wheat and barley grown from imazalil-treated seed . This information was reviewed by Dynamac Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies.

The wheat and barley field trial studies are fully acceptable, and no additional wheat or barley data (171-4(k)) are required for

purposes of reregistration. The data indicate that the combined residues of imazalil and R14821, the current residue of concern, are not likely to exceed the established 2 ppm tolerances for wheat and barley straw, the proposed revised tolerance of 0.5 ppm for wheat and barley straw, and the proposed new tolerance of 0.05 ppm for barley and wheat forage. The data do NOT support the established tolerances of 0.05 ppm for barley grain and wheat grain. The method combined limit of quantitation is 0.08 ppm, and apparent residues in control grain samples were as high as 0.17 ppm. The registrant should propose a new tolerance of 0.2 ppm for barley grain and a new tolerance of 0.2 ppm for wheat grain. The tolerances will be reevaluated at the time of the RED. These conclusions are predicated on the acceptability of a method validation study currently under review.

The previous tentative conclusion (S. Funk, CBRS No. 11586, 04/06/93) that processing studies are not required for barley and wheat is affirmed by the results presented in this submission. The tolerances for the raw agricultural commodities will encompass the processed commodities. The requirements of GLN 171-4(l) are fulfilled for barley and wheat for purposes of reregistration of imazalil.

Please advise if additional information is needed.

Attachment 1: Task 4: Registrant's Response to Residue Chemistry Data Requirements (11/10/93).
Attachment 2: Residue Chemistry Status Sheet

cc with attachments 1 and 2: Imazalil List B File
cc with attachment 1: RF, S. Funk, Subject File, Dynamac Corp.
cc without attachments: Circ.

RDI:A. Rathman:12/16/93:M. Metzger:12/17/93:E. Zager:12/17/93:
H7509C:CBRS:S.Funk:305-5430:CM#2:RM803-A:SF(1293.12):12/14/93.

DYNAMAC
CORPORATION
Environmental Services

Final Report

IMAZALIL
Shaughnessy No. 111901; Case No. 2325 (CBRS No. 12386; DP Barcode D194151)

TASK 4
Registrant's Response to Residue Chemistry Data Requirements

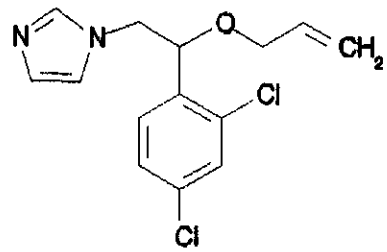
November 10, 1993

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

IMAZALIL



Shaughnessy No. 111901; Case 2325

(CBRS No. 12386; DP Barcode D194151)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Imazalil Phase 4 Reviews (S. Funk, 10/19/90) required data depicting residues of imazalil [1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1H-imidazole] and its metabolite R14821 [1-(2,4-dichlorophenyl)-2-(1*H*-imidazole-1-yl)-1-ethanol]] in/on wheat and barley grain, forage, and straw grown from imazalil-treated seeds. Residue data from wheat and barley processing studies were also required. A protocol for a wheat field trial was subsequently reviewed and approved by CBRS (S. Funk, CBRS No. 8108, 7/16/91). Based on preliminary residue data from wheat and barley grain grown from seeds treated at 10x the maximum label rate, the registrant requested a waiver from grain processing studies. Pending review of the entire field study, CBRS (S. Funk, CBRS No. 11586, 4/6/93) concluded that wheat and barley grain processing studies would not be required. Janssen Pharmaceutica has submitted magnitude of residue data (1993; MRIDs 42868101, 42852001, and 42852002) from wheat and barley commodities harvested from imazalil-treated seeds. These data are reviewed here to determine their adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to the magnitude of the residue in wheat and barley RACs and processed commodities. Other data requirements specified in the Phase 4 Reviews are not addressed herein.

The qualitative nature of the residue in plants and animals is not adequately understood. The Phase 4 Reviews required the registrant to prove the stability of the tritium-labeled imazalil used in the banana, orange, and barley metabolism studies. Use of the tritium label was tentatively accepted (L. Cheng, CBRS No. 10342, 09/25/92), and the subject studies will be reviewed. Janssen Pharmaceutica has submitted a wheat metabolism study (1993, MRID 42626901; DP Barcode D187506) that is currently under review by CBRS. The nature of the residue in ruminants is understood; however, the requirement for a poultry metabolism study remains outstanding. An interim poultry metabolism study has been reviewed (S. Funk, CBRS Nos. 12661 and 12704, DP Barcode D195726, 11/16/93).

Two GC/ECD methods are available for enforcing imazalil tolerances in plants and animals and are listed in PAM, Vol. II as Methods I and II. These methods have undergone successful EPA method tryouts; however, both methods require fortification of control samples for use as external standards in

calibrating the GC/ECD response.

Tolerances have been established for the combined residues of imazalil and its metabolite R14821 in/on raw agricultural commodities (40 CFR §180.413(a)). Food/feed additive tolerances have also been established for the combined residues of imazalil and R14821 in processed plant commodities (40 CFR §185.3650 and §186.3650).

Codex MRLs for residues of imazalil in/on various plant commodities are currently defined in terms of parent imazalil, whereas, the U.S. tolerance definition includes the metabolite R14821 in addition to parent. Codex MRLs (CXL) have been established for residues of imazalil in/on wheat grain (0.01 ppm) and wheat straw and fodder, dry (0.1 ppm), and are lower than U.S. tolerances for imazalil in/on wheat grain (0.05 ppm) and straw (2 ppm). There are currently no Codex MRLs for imazalil residues in/on barley commodities.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted data adequately depict residues of imazalil and its metabolite (R14821) in/on forage, straw, and grain of barley and wheat grown from seeds treated with imazalil at 1x the maximum label rate. The available barley and spring wheat data indicate that the combined residues of imazalil and R14821 resulting from seed treatments are not likely to exceed the established 2 ppm tolerances for wheat and barley straw, or the proposed tolerances of 0.5 ppm for wheat and barley forage and straw. However, the data do not support the established tolerance of 0.05 ppm for wheat grain. Based on a combined limit of quantitation (LOQ) of 0.08 ppm for imazalil and R14821 in/on grain and on apparent residues of 0.04-0.17 ppm in control grain samples, the registrant should propose a revised tolerances for barley and wheat grain of 0.2 ppm to reflect the sensitivity of the data collection analytical method. No additional residue data are required for barley or wheat.

2. CBRS concludes that barley and wheat grain processing studies are not required based on the theoretical concentration factors for barley and wheat grain processed commodities (1.2-9x), on apparent residues <LOQ from the use of exaggerated application rates (6.3x and 10x), and on the use pattern (seed treatment), which is unlikely to result in surface residues on the grain. The combined residues of imazalil and R14821 in barley and wheat processed commodities are not likely to exceed the residues in/on grain.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Residues of imazalil and R14821 in/on forage, straw, and grain samples from the submitted wheat and barley field residue studies (1993; MRIDs 42868101, 42852001, and 42852002) were determined using a GC/electron capture detector (ECD) method with an internal standard, R35162 (1-[2-(2,4-dichlorophenyl)-cyclopentyl-methyl]-1H-imidazole). The imazalil-treated seeds were analyzed using the same GC/ECD method, but R35162 was used as an external standard due to the higher levels of imazalil in/on the treated seeds. This GC/ECD method is a modification of Method I in PAM, Vol. II, and is essentially the same as a GC/ECD method for determining imazalil residues in/on bananas that has been reviewed and deemed adequate by the Agency (S. Funk, CBRS No. 10602; 6/24/93). The method description and validation data for the method were reported separately by the registrant and are currently under review (DP Barcode D187506; 1993, MRID 42626902). The reported limits of detection for imazalil and R14821 are 0.02 and 0.01 ppm, respectively. The reported LOQs for imazalil in grain, forage, and straw are 0.05, 0.06, and 0.08 ppm, respectively; and the LOQs for R14821 in grain, forage,

and straw are 0.03, 0.02, and 0.04 ppm, respectively. The analyses were conducted by Janssen Research Foundation (Beerse, Belgium).

Storage Stability Data

Janssen Pharmaceutica has submitted frozen storage stability data (D. J. Miller, CBRS No. 11898, 11/18/93, MRID 42755301, DP Barcode D191318) for residues of imazalil and R14821 in wheat commodities stored at ≤ -20 °C. Imazalil and R14821 are stable in wheat grain and forage for up to 24 weeks at ≤ -20 °C. However, the parent and the reagulated metabolite decline significantly in wheat straw, i.e., a 40% decrease in 12 - 24 weeks, or about 2% per week. For purposes of tolerance evaluation, the field trial residue data for wheat straw and barley straw will be increased by 2X to correct for the loss of parent and metabolite over the 15 weeks (maximum) of sample storage.

Magnitude of the Residue in Plants

The Phase 4 Reviews (S. Funk, 10/19/90) required data depicting residues of imazalil and R14821 in/on wheat and barley grain grown from seeds treated with imazalil at 0.0101 lb ai/100 lb seed. Residue data were required representing winter wheat grown in KS, TX, and OK, spring wheat grown in ND, MT, and MN, and barley grown in WA and ID. Wheat data from ND and MT would be translated to barley for these two states.

Wheat and Barley

Tolerances of 0.05 and 2 ppm have been established for the combined residues of imazalil and its metabolite R14821 in/on grain and straw, respectively, of wheat and barley, 40 CFR §180.413(a). The registrant has proposed reducing imazalil tolerances for wheat and barley straw to 0.5 ppm and establishing new tolerances for residue in/on wheat and barley forage of 0.5 ppm (R. Cook, PP#5F3250, 1/7/93).

The registrant, Janssen Pharmaceutica, currently has one end-use product, a 0.86 lb/gal EC (EPA Reg. No. 43813-3), registered for use on wheat and barley seeds. The representative formulation used in the submitted field residue studies is a 2.56 lb/gal FIC (EPA Reg. No. 7501-127) formulated by Gustafson, Inc. Both labels list a maximum use rate of 0.01 lb ai/100 lb seeds, equivalent to 100 ppm (mg ai/kg seed).

Spring Barley. Janssen Pharmaceutica submitted data (1993; MRIDs 42852001) from three tests conducted in ID(2) and WA(1) depicting residues of imazalil and R14821 in/on forage, grain, and straw of spring barley grown from imazalil-treated seeds. Barley seeds were treated with imazalil (2.56 lb/gal FIC) at target application rates of 110 and 1000 ppm by Gustafson Research and Development Center (McKinney, TX) using simulated commercial practices. Subsequent analysis of the treated seeds indicated that the actual application rates were 76.5-108.6 ppm (~1x the maximum label rate) and 630.6 ppm (6.3x), respectively. Control and 1x-treated seeds were planted in ID and WA, and 6.3x-treated seeds were planted in ID. A single composited forage sample was harvested from control and 1x-treated plots at 40-42 days after planting (DAP), and single composited samples of grain and straw were harvested from control and 1x-treated plots at maturity (104-142 DAP). Only grain samples were harvested (142 DAP) from the 6.3x test in ID. All RAC samples were stored frozen (-37 to -10 C) until analysis by the analytical laboratory (Janssen Research Foundation). Sample storage intervals are reported in Table 1. Samples of treated seed, forage, straw, and grain were analyzed for residues of imazalil using the GC/ECD method discussed above. Two subsamples of control and 1x-treated matrices and three subsamples of 6.3x-treated grain were extracted and analyzed in duplicate.

Representative chromatograms and sample calculations were provided. Residues of imazalil and R14821 in/on control and treated barley matrices are presented in Table 1. Based on a 2%/week linear decline of residues in straw during frozen storage, the registrant also presented data for total residues in straw corrected for decline of residues during storage. These values are reported in **bold** in Table 1. The application of a 2X factor to correct for the instability of imazalil and its regulated metabolite in/on stored straw gives a maximum straw residue of 0.12 ppm.

Geographic representation is adequate for barley. Along with data translated from spring wheat studies conducted in MN(12%), MT(14%), and ND(31%), the test states of ID(13%) and WA (5%) accounted for approximately 75% of the 1990 U.S. barley production (Agricultural Statistics, USDA, 1992).

The submitted spring barley data are adequate pending review of the wheat storage stability data (DP Barcode D191318) and the method validation data (DP Barcode D187506). The available barley data and the data translated from the spring wheat studies indicate that the combined residues of imazalil and R14821 resulting from imazalil seed treatments are not likely to exceed the established 2 ppm tolerance for barley straw or the proposed tolerances of 0.5 ppm for barley forage and straw. However, the data do not support the established tolerance of 0.05 ppm for barley grain. Based on a combined limit of quantitation of 0.08 ppm for imazalil and R14821 in/on grain and on apparent residues of 0.04-0.1 ppm in control grain samples, the registrant should propose a revised tolerance for barley grain of 0.1 ppm to reflect the sensitivity of the data collection analytical method. No additional residue data are required for barley.

Spring Wheat. *Janssen Pharmaceutica submitted data (1993; MRID 42852002) from four tests* conducted in MN(1), MT(1), and ND(2) depicting residues of imazalil and R14821 in/on forage, grain, and straw of spring wheat grown from imazalil-treated seeds. Wheat seeds were treated with imazalil (2.56 lb/gal FlC) at target application rates of 110 and 1000 ppm by Gustafson Research and Development Center (McKinney, TX) using simulated commercial practices. Subsequent analysis of the treated seeds indicated that the actual application rates were 82.5-97.2 ppm (1x) and 1162.4 ppm (11x), respectively. Control and 1x-treated seeds were planted in MN, MT, and ND, and 11x-treated seeds were planted in ND. A single composited forage sample was harvested from control and 1x-treated plots at 40 DAP, and single composited samples of grain and straw were harvested from control and 1x-treated plots at maturity (129-130 DAP). Only grain samples were harvested (130 DAP) from the 11x test in ND. All RAC samples were stored frozen (-26 to -7 C) until analysis by the analytical laboratory (Janssen Research Foundation). Sample storage intervals are reported in Table 1. Samples of treated seed, forage, straw, and grain were analyzed for residues of imazalil using the GC/ECD method discussed above. Two subsamples of each sample matrix were extracted and analyzed in duplicate. Representative chromatograms and sample calculations were provided. Residues of imazalil and R14821 are presented in Table 1. Based on a 2%/week linear decline of residues in straw during frozen storage, the registrant also presented data for total residues in straw corrected for decline of residues during storage. These values are reported in **bold** in Table 1. The application of a 2X factor to correct for the instability of imazalil and its regulated metabolite in/on stored straw gives a maximum straw residue of 0.12 ppm.

Geographic representation is adequate for spring wheat. The test states of MN(13%), MT(16%), and ND(42%) accounted for approximately 71% of the 1991 U.S. spring wheat production (Agricultural Statistics, USDA, 1992).

The submitted spring wheat data are adequate pending review of the wheat storage stability data (DP Barcode D191318) and the method validation data (DP Barcode D187506). The available spring wheat data indicate that the combined residues of imazalil and R14821 resulting from imazalil seed treatments are not likely to exceed the established 2 ppm tolerance for wheat straw, or the proposed tolerances of

0.5 ppm for wheat forage and straw. However, the data do not support the established tolerance of 0.05 ppm for wheat grain. Based on a combined limit of quantitation of 0.08 ppm for imazalil and R14821 in/on grain and on apparent residues of 0.04-0.1 ppm in control grain samples, the registrant should propose a revised tolerance for wheat grain of 0.1 ppm that reflects the sensitivity of the data collection analytical method. No additional residue data are required for spring wheat.

Winter Wheat. Janssen Pharmaceutica submitted data (1993; MRID 42868101) from four tests conducted in KS(2), OK(1), and TX(1) depicting residues of imazalil and R14821 in/on forage, grain, and straw of winter wheat grown from imazalil-treated seeds. Wheat seeds were treated with imazalil (2.56 lb/gal FlC) at target application rates of 110 and 1000 ppm by Gustafson Research and Development Center (McKinney, TX) using simulated commercial practices. Subsequent analysis of the treated seeds indicated that the actual application rates were 299.6 ppm (3x) and 1003.1 ppm (10x), respectively. Control and 3x-treated seeds were planted in KS, OK, and TX, and 10x-treated seeds were planted in KS.

The registrant indicated that no samples were harvested from the 10x-treated test in KS because there was no survival of wheat plants in that test. A single composited forage sample was harvested from control and 3x-treated plots in KS at 41 DAP; however, samples of grain and straw could not be obtained from the KS test site due to the sale of the test site. At the OK and TX test sites, a single composited forage sample was harvested from control and 3x-treated plots at 39 DAP, and single composited samples of grain and straw were harvested at maturity (269-290 DAP). In addition, the registrant reported that approximately 15% of the wheat growing in the OK test plots was volunteer wheat from a previous wheat crop.

All RAC samples were stored frozen (-37 to -10 C) until analysis by the analytical laboratory (Janssen Research Foundation). Sample storage intervals are reported in Table 1. Samples of treated seed, forage, straw, and grain were analyzed for residues of imazalil using the GC/ECD method discussed above. Two subsamples of each sample matrix were extracted and analyzed in duplicate. Representative chromatograms and sample calculations were provided. Residues of imazalil and R14821 are presented in Table 1. Because relatively high levels of residues were detected in control samples of grain and straw from OK and TX, grain and straw samples from these tests were reanalyzed at a later date to verify the initial results.

Geographic representation is marginal for winter wheat. Test data were incomplete from KS (forage only), which accounted for 26% of the 1991 U.S. winter wheat production (Agricultural Statistics, USDA, 1992). The remaining two tests in OK(10%) and TX(6%) accounted for only 16% of the 1991 winter wheat production. Grain and straw samples were not obtained from KS, and potentially representative data from OK were comprised due to contamination of the treated plots with untreated (volunteer) seeds. In addition, concentrations of imazalil in excess of the current tolerance for wheat grain (0.05 ppm) were detected in control samples of grain from both OK and TX tests, 0.17 ppm in control grain versus ND in treated grain; and control samples of straw from these tests had higher levels of imazalil and R14821 residues than did the treated samples, 0.12 ppm for control straw versus 0.09 ppm for treated straw. Because the use is seed treatment, as opposed to application to the soil or to growing crops, the spring wheat data will be combined with the winter wheat data in assessing the adequacy of the wheat field trials.

For winter wheat grain, the maximum combined residue was 0.17 ppm. For winter wheat straw, the maximum combined residue was 0.12 ppm, and application of a 2X factor to correct for storage instability yields a maximum residue value of 0.24 ppm. For winter wheat forage, the maximum combined residue was 0.04 ppm.

Table 1. Residues of imazalil and R14821 in/on wheat and barley forage, straw, and grain grown from seeds treated with imazalil at 1x and 10x the maximum label rate.

Sample	Test States	Application rate (ppm; mg ai/kg seed)		Number of samples	Residues (ppm)[b]			Frozen Storage Interval (days)
		Target rate	Actual rate[a]		Imazalil	R14821	Total Residue	
Spring Barley (MRID 42852001)								
Forage	ID, WA	0	-	2	ND[c], 0.32	ND[c], 0.02	0.03, 0.33	152-186
	ID, WA	110	76.5-108.5 (1x)[d]	2	ND, <0.06[e]	ND, 0.02	0.03, 0.04	152-186
Straw	ID, WA	0	-	2	ND, <0.08	<0.04	0.03, 0.06 **(0.046, 0.077)**[f]	78-122
	ID, WA	110	76.5-108.5 (1x)	2	<0.08	<0.04	0.06 **(0.077, 0.092)**	78-122
Grain	ID, WA	0	-	2	<0.05, 0.06	<0.03	0.04, 0.08	83-127
	ID, WA	110	76.5-108.6 (1x)	2	<0.05	<0.03	0.04	83-127
	ID	1000	630.6 (6.3x)	3	<0.05-0.05	<0.03	0.04-0.07	83
Spring Wheat (MRID 42852002)								
Forage	MN, MT, ND	0	-	3	ND-<0.06	,0.02	0.03-0.05	110-154
	MN, MT, ND	110	82.5-97.2 (1x)	3	ND-0.07	0.02	0.03-0.08	110-154
Straw	MN, MT, ND	0	-	3	ND-<0.08	<0.04	0.03-0.06 **(0.035-0.069)**	46-47
	MN, MT, ND	110	82.5-97.2 (1x)	3	ND-<0.08	<0.04	0.03-0.06 **(0.035-0.07)**	46-47
Grain	MN, MT, ND	0	-	3	<0.05-0.07	≤0.03	0.04-0.1	59-60
	MN, MT, ND	110	82.5-97.2 (1x)	3	ND-0.05	≤0.03	0.025-0.065	59-60
	ND	1000	1162.4 (11x)	3	ND-<0.05	<0.03	0.025-0.04	60
Winter Wheat (MRID 42868101)								
Forage	KS, OK, TX	0	-	3	ND-<0.06	ND	0.015-0.035	223-235
	KS, OK, TX	110	299.6 (3x)	3	ND	ND	0.015	223-235
Straw	OK, TX	0	-	2	<0.08	0.069, 0.076	0.109, 0.116 **(0.148, 0.165)**	92-103 (296-307)[g]
	OK, TX	110	299.6 (3x)	2	<0.08	0.045, 0.054	0.085, 0.094 **(0.121, 0.128)**	92-103 (296-307)
Grain	OK, TX	0	-	2	0.056, 0.168	ND	0.061-0.173	93-104 (296-307)
	OK, TX	110	299.6 (3x)	2	<0.05	ND	0.03	93-104 (296-307)

[a] Actual application rates were determined by analysis of treated seeds. [b] Residues are expressed in terms of each analyte [c] ND = not detected; the limit of detection for imazalil and R14821 are 0.02 and 0.01 ppm, respectively [d] Actual rate relative to the maximum label rate. [e] Values report as < reflect the LOQ for the GC/ECD method. The LOQ for imazalil in grain, forage, and straw is 0.05, 0.06, and 0.08 ppm, respectively; and the LOQ for R14821 in grain, forage, and straw is 0.03, 0.02, and 0.04 ppm, respectively. [f] Bolded values are corrected the decline of residues in straw during frozen storage based on the following formula: $z = y/[1-(0.02 \times A)]$; where z = corrected residue level, y = residue level detected at time A, and A = number of weeks in storage [g] Samples were reanalyzed at a later date to verify the results.

Wheat and Barley Processed Commodities

The Phase 4 Reviews required residue data from wheat and barley commodities processed from grain bearing detectable residues of imazalil and R14821. Based on preliminary residue data from wheat and barley grain grown from seeds treated at 10x the maximum label rate, the registrant requested a waiver from grain processing studies. It was tentatively concluded that wheat and barley grain processing studies would not be required pending review of the entire field study (S. Funk, CBRS No. 11586; 4/6/93).

In conjunction with the above barley and spring wheat field residue studies (1993; MRIDs 42852001 and 42852002), Janssen Pharmaceutica submitted data depicting residues of imazalil and R14821 in/on barley and wheat grain grown from seed treated at 6.3x and 11x the maximum label rate, respectively. These data are presented in Table 1. The combined residues of imazalil and R14821 in/on barley grain (6.3x) and wheat grain (11x) were both <0.08 ppm, which is the reported combined LOQ for grain using the GC/ECD method.

The maximum theoretical concentration factor for wheat processed commodities is 9x (Table 1, Maximum Theoretical Concentration Factors, 1/93) and the concentration factors for barley and wheat grain based on separation into components are 1.2-8.3x (Table 3, Maximum Theoretical Concentration Factors, 1/93).

Based on the theoretical concentration factors for barley and wheat grain processed commodities, on residues <LOQ from the use of exaggerated application rates (6.3x and 10x), and on the use pattern (seed treatment), which is unlikely to result in surface residues on the grain, CBRS concludes that barley and wheat grain processing studies are not required. The combined residues of imazalil and R14821 in barley and wheat processed commodities are not likely to exceed the residues in/on grain.

AGENCY MEMORANDA CITED IN THIS REVIEW

CBRS No: 8108
Subject: Protocols for the Citrus Processing and Winter Wheat Field Trials for Imazalil.
From: S. Funk
To: K. Davis
Date: 7/16/91
MRID(s): None.

CBRS No.: 10602
Subject: Analytical Method for the Determination of Imazalil and R14821 in/on Bananas, Citrus, and Citrus Processed Commodities. Research and Enforcement Method Comparison.
From: S. Funk
To: K. Davis and K. Depukat
Date: 6/24/93
MRID(s): 42454803, 42454804, and 42454805.

CBRS No.: 11586
Subject: Imazalil: (1) Wheat Processing Waiver Request; (2) Poultry Metabolism Protocol Change.
From: S. Funk
To: K. Davis and K. Depukat
Date: 4/6/93
MRID(s): None.

CBTS No.: None
Subject: Non-concurrence on draft FR Notice. PP#5F3250. Imazalil on forage and hay of wheat and barley.
From: R. Cook
To: C. Giles-Parker
Date: 1/7/93
MRID(s): None.

CBRS No.: 12661; 12704
Subject: Nature of residue in poultry.
From: S. Funk
To: K. Davis
Date: 11/16/93
MRID(s): 42949401

CBRS No.: 10342
Subject: Stability of tritium label.
From: L. Cheng
To: K. Davis
Date: 09/25/92
MRID(s): 42403101

CBRS No.: 11898
Subject: Storage stability in/on wheat.
From: D. J. Miller
To: K. Depukat
Date: 11/18/93
MRID(s): 42755301

MASTER RECORD IDENTIFICATION NUMBERS

The citations for MRID documents referred to in this review are presented below.

42626902 Ligtvoet, T. (1992) A Validated Gas Chromatographic Method for the Determination of Imazalil-related Residues in Wheat and Barley (Grain, Forage, and Straw): Final Report: Lab Project Number: 58. Unpublished study prepared by Janssen Research Foundation. 78 p.

42755301 Garnier, A. (1993) Storage Stability of Imazalil-Derived Residues in Wheat: Final Report: Lab Project Number: AGR10. Unpublished study prepared by Plant Protection Division, Janssen Research Foundation. 285 p.

42852001 Helmer, D. (1993) Magnitude of Residue: Imazalil and metabolite (R14821) in Spring Barley Forage, Straw, and Grain Grown from Imazalil Treated Seed: Lab Project Number: AGR12: AGR13: 920226. Unpublished study prepared by Janssen Pharmaceutica and Gustafson Research and Development Center. 214 p.

42852002 Helmer, D. (1993) Magnitude of Residue: Imazalil and metabolite (R14821) in Spring Wheat Forage, Straw, and Grain Grown from Imazalil Treated Seed: Lab Project Number: AGR13: 922105: 922409. Unpublished study prepared by Janssen Pharmaceutica and Gustafson Research and Development Center. 248 p.

42868101 Helmer, D. (1993) Magnitude of Residue: Imazalil and Metabolite (R14821) in Winter Wheat

Forage, Straw, and Grain Grown from Imazalil Treated Seed: Lab Project Number: AGR9: 91846. Unpublished study prepared by Gustafson Research and Development Center 391 p.