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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 8, 2000

MEMORANDUM

SUBJECT: ID# ND000005. Cloquintocet-mexyl on wheat. 24(c) Request with Rotational Crop Data.

DP Barcode:	D268038	PRAT Case:	069400
Submission No.:	S581106	Caswell No.:	None
Chemical #:	999999	Class:	Safener
Trade Name:	Discover™ Herbicide	EPA Reg. No.:	100-907
MRID No.:	45149902	40 CFR:	180.560

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

THROUGH: Stephen Dapson, Branch Senior Scientist
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Health Effects Division (7509C)
Stephen C. Dapson 08/09/2000

TO: Treva Alston/Kerry Leifer, PM Team #5
Minor Use, Inerts, and Emergency Response Branch
Registration Division (7505C)

The state of North Dakota has requested a 24(c) registration for the safener cloquintocet-mexyl (Discover™ Herbicide) on spring wheat (including Durum). North Dakota requests rotational crop intervals of 0 days for spring wheat and 30 days for all other crops. A letter dated 5/25/00 from Novartis and a Novartis rotational crop study are included in the submission.

EPA registered Discover™ Herbicide on 6/6/00 for use on spring wheat. The registered label specifies rotational crop intervals of 0 days for spring wheat, 3 months for leafy vegetables, 5 months for other small grains, and 12 months for all other crops. HED indicated (PP#7E04920, D257181, N. Dodd, 4/7/00) that shorter rotational crop restrictions could be obtained provided that supporting confined rotational crop data were submitted.

CONCLUSION

Since residues of concern in rotational crops are not expected to be at quantifiable levels, a 30-day rotational crop restriction for crops without registered food uses and a 0-day rotational crop restriction for spring wheat (including Durham) are appropriate.

RECOMMENDATION

HED has no objection to the proposed 24(c).

DETAILED CONSIDERATIONS

Formulation

Discover™ Herbicide is an emulsifiable concentrate containing 22.3% clodinafop-propargyl active ingredient (ai) and 77.7% inerts. The formulation contains 2 lb ai/gal. [See the Confidential Appendix of D257181 (PP#7E04920, N. Dodd, 4/7/00) for the percentage and lb ai/gal of cloquintocet-mexyl.]

Proposed Use

Apply Discover™ Herbicide to spring wheat (including Durum) in ND at the rate of 3.2-4.0 fl oz Discover™ Herbicide/A [see the Confidential Appendix of D257181 (PP#7E04920, N. Dodd, 4/7/00) for lb ai/A of cloquintocet-mexyl]. Apply to spring wheat from the 2-leaf stage to emergence of the 4th tiller. Apply by ground or air. Do not apply through any type of irrigation system. Do not graze livestock or feed forage from treated areas for a minimum of 30 days following application. Do not feed hay for 30 days following application. Do not harvest for 60 days following application. Make only one application per crop season. Do not treat wheat under seeded to forages. Always apply with DSV Adjuvant.

The 24(c) requests the following rotational crop restrictions:

Crop	Rotational Interval
spring wheat (including Durum)	0 days
lettuce and other leafy vegetables	30 days
small grains other than spring wheat (including Durum)	30 days
all other crops	30 days

Nature of the Residue in Wheat

Wheat metabolism studies have been reviewed (D257181, N. Dodd, 4/7/00). HED's Metabolism Assessment Review Committee (MARC) met on 2/15/00 (D263289, N. Dodd, 2/25/00). The nature of the residue in wheat is adequately understood for the purposes of a time-limited registration and the proposed 24(c). The residues of concern in wheat are cloquintocet-mexyl (CGA-185072) and its acid metabolite CGA-153433.

Nature of the Residue in Animals

Ruminant and poultry metabolism studies have been reviewed (D257181, N. Dodd, 4/7/00). HED's Metabolism Assessment Review Committee (MARC) met on 2/15/00 (D263289, N. Dodd, 2/25/00). The nature of the residue in ruminants and poultry is adequately understood for the purposes of a time-limited registration and the proposed 24(c). The residues of concern in ruminants and poultry are cloquintocet-mexyl and its acid metabolite CGA-153433.

Analytical Methods

Adequate enforcement methods are available for the parent (REM 138.01) and the metabolite CGA-153433 (REM 138.10). The petitioner indicated that the limits of quantitation (LOQ's) for parent in REM 138.01 are 0.02 ppm in wheat grain and 0.05 ppm in forage, hay, and straw, and that the LOQ's for CGA-153433 in REM 138.10 are 0.02 ppm for wheat grain and 0.05 ppm for forage, hay, and straw. A satisfactory EPA method validation has been conducted by BEAD (D262416, Elmer Hayes, 6/22/00); the conclusions regarding the LOQ's are under concurrent review in HED.

Multiresidue Methods

Multiresidue method testing data for parent and CGA-153433 were submitted (D257181, N. Dodd, 4/7/00). The data were forwarded to FDA for determination of sufficiency (D255566, N. Dodd, 5/12/99).

Storage Stability Data

Storage stability data for parent and CGA-153433 in wheat grain and straw have been reviewed (D257181, N. Dodd, 4/7/00). The data gaps did not preclude establishment of a time-limited registration.

Residue Data

Residue data on wheat have been reviewed (D257181, N. Dodd, 4/7/00). Tolerances for the combined residues of cloquintocet-mexyl and its acid metabolite CGA-153433 have been established under a time-limited registration at 0.1 ppm for wheat grain, forage, hay, and straw.

Processed Commodities

A wheat grain processing study was reviewed (D257181, N. Dodd, 4/7/00). Data gaps did not preclude establishment of a time-limited registration.

Confined Accumulation in Rotational Crops

The following confined rotational crop study has been submitted with the 24(c) request (see citation below). The performing laboratories were Novartis Crop Protection, Inc., at Greensboro, NC, Dewey, IL, and Vero Beach, FL.

MRID 45149902 Peffer, R.C. (2000) Study on Confined Rotational Crops after Soil Application of [Quinoline-3-^{14}C]-CGA-185072, Novartis Study Number 407-98, unpublished study sponsored by Novartis Crop Protection, Inc., 46 pp.

In-life phase

[Quinoline-3-^{14}C]-CGA-185072 was applied to bareground plots in Dewey, IL in 1998 at the rate of 20 g CGA-185072/ha (0.02 lb safener/A). The radiochemical purity was ≥99.0% and the specific activity was 54.2 μCi/mg (2.01 Mbq/mg). Mustard (a leafy vegetable), turnips (a root crop), and wheat (a small grain) were planted in the treated soil at 30 and 92 days after application. Wheat was also planted 271 days after application. Mustard and turnips were harvested at maturity. Wheat was harvested at 25% maturity, 50% maturity, and full maturity. Mature wheat was separated into grain and fodder (straw plus husks). Turnips were separated into leaves (above ground portion) and tubers.

Total radioactive residues (TRR)

Total radioactive residues were determined by combustion and liquid scintillation counting. The total radioactive residues in rotational crops after application of [quinoline-3-^{14}C]-CGA-185072 to bareground plots were below the limit of quantitation (<0.002 ppm) as shown in Table 1 below.

Table 1. Total Radioactive Residues in Rotational Crops after Application of [Quinoline-3-^{14}C]-CGA-185072 to Bareground Plots			
Crop/Plant Part	Days between Application of the Herbicide and Planting of the Rotational Crops	Days between Planting of the Rotational Crops and Harvest	CGA-185072 Equivalents (ppm)
mustard leaves	30	55	<0.002*
	92	55	<0.002
turnip leaves	30	55	<0.002
	92	55	<0.002
turnip roots	30	55	<0.002
	92	55	0.000
wheat forage -25% mature	30	55	<0.002
	92	55	<0.002
	271	31	<0.002
wheat forage - 50% mature	30	247	<0.002
	92	247	<0.002
	271	58	0.000
wheat fodder-100% mature	30	300	0.000
	92	300	<0.002
	271	98	0.001
wheat grain- 100% mature	30	300	0.000
	92	300	0.000
	271	98	0.001

*LOQ = 0.002 ppm

Extraction and Hydrolysis of Residues, and Characterization/Identification of Residues

Since residues in rotational crops grown in soil treated with [quinoline-3-^{14}C]-CGA-185072 were <LOQ, no extractions or characterizations were conducted on those crops.

Storage Stability

Samples were shipped frozen from Dewey, IL to Vero Beach, FL and then to Greensboro, NC, where they were stored at -20°C. Samples were combusted within 3 months of harvest.

Summary

Total radioactive residues in rotational crops (mustard, turnips, and wheat) planted 30 days after soil was treated with [quinoline-3-^{14}C]-CGA-185072 were less than the LOQ of 0.002 ppm.

Since residues of concern in rotational crops are not expected to be at quantifiable levels, a 30-day rotational crop restriction is appropriate for crops without registered food uses.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

As discussed in D257181 (N. Dodd, 4/7/00), this use falls under 40 CFR §180.6(a)(3) since no secondary residues are expected to occur in commodities from cattle, goats, hogs, horses, poultry, and sheep.

cc: RF, SF, N. Dodd (810C), PM#23, PM#5, PP#7E04920, M. Rust
RDI: S. Dapson:8/8/00
7509C:RAB3:CM#2:Rm810C:305-5681:N.Dodd:nd:8/8/00

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