

2-7-85

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121301

SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 11.28.84 OUT 2.7.85

FILE OR REG. NO. 100-ALJ

PETITION OR EXP. PERMIT NO. 5F3180

DATE OF SUBMISSION 9.20.84 [redacted] 11.15.84 (celery, lettuce)

DATE RECEIVED BY HED 11.20.84

RD REQUESTED COMPLETION DATE 2.15.84

EEB ESTIMATED COMPLETION DATE 2-8-84

RD ACTION CODE/TYPE OF REVIEW 100, 101/ new chemical

TYPE PRODUCT(S): I, D, H, F, N, R, S Insect growth regulator

DATA ACCESSION NO(S). 073085

PRODUCT MANAGER NO. A. Heyward (17)

PRODUCT NAME(S) Trigard 75W

COMPANY NAME Ciba-Geigy

SUBMISSION PURPOSE Proposed registration [redacted]

celery and lettuce

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
121301	cyromazine	75

Pesticide Name: Trigard 75 W

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

Ciba-Geigy Corp. has applied for section 3 registrations of Trigard 75 W for [REDACTED] celery and lettuce, as an insect growth regulator. Some additional fish and wildlife safety data were also submitted with this review.

100.2 Formulation Information

Active:

(cyromazine)

N-cyclopropyl-1,3,5-triazine-2,4,6-triamine75%

Inerts25%

100.3 Application Methods, Directions, Rates

Celery and Lettuce

For leafminer control, apply 1/6 th lb/A as a foliar spray in a minimum of 50 gallons of water by ground or 5 gallons by air as leafminers first appear. Repeat applications at 7-day intervals as necessary to maintain control.

Notes : to avoid illegal residues, 1) Do not make more than

12 applications to one crop of celery or 8 applications to one crop of lettuce; 2) Do not make the last applications within 7 days of harvest.

100.4 Target Organisms

leafminers

100.5 Precautionary Labeling

"Environmental Hazards"

Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply directly to lakes, streams or ponds. Do not apply when weather conditions favor drift from target areas."

101 Hazard Assessment

101.1 Discussion

This review is performed as a full risk assessment since no registrations for cyromazine have been issued.

The fish and wildlife safety data submitted with this review (chronic fish, chronic aquatic invertebrate, and avian reproduction studies) were not solicited by previous reviews since Tier I data did not indicate the need for such studies at that time. Since the Registration Division and Hazard Evaluation Division offices requested that this review be "expedited", EEB is delaying the formal validation of the the chronic and reproductive studies submitted. Since we did not request these studies in our previous reviews it was agreed that these applications could be reviewed without formal validation of these studies at this time. However, we will comment generally about these studies (see Adequacy of Toxicity Data section 101.4) and caution that these studies may be found inadequate. Future reviews of these or other uses may require that valid chronic and reproductive studies be submitted. We caution that if the studies submitted with this review (Acc. No. 073085) are later found "invalid" or "supplemental", that additional or repeat studies may be required to support further registrations, special reviews or registration standards.

Pending Registration Action

Special considerations - generally one crop per growing season would be treated and that irrigation is extensively used. Fields are generally rectangular and irrigation ditches are supplied by main canals. Water is pumped from these canals to control water levels in the ditches. Aerial applications to these fields will result in direct contamination of the irrigation canals thus resulting in a "worst case" exposure for aquatic resources. [REDACTED] production was not considered to represent as hazardous an exposure from the aquatic point of view.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

EEB reviewed the active ingredient cyromazine in previous reviews of a chicken feed premix (Larvadex) and EUP's for lettuce and celery. We found that cyromazine is relatively non-toxic in acute tests with aquatic organisms and in acute and dietary tests with birds. The residues expected to result from the proposals further indicated that no unreasonable hazard would be expected to result.

The current applications are for 0.125 lb. a.i. per acre, with a maximum of up to 12 applications per crop. EEB's assumes that 12 aerial applications are extremely unlikely due to usual cropping practices, expense and infrequent occurrence of infestations of such magnitude that such extensive applications would be required.

Since cyromazine can be quite persistent in certain soil conditions we can assume no degradation of parent compound as a worst case. With all 12 applications applied (equivalent to 1.5 lb ai/A) theoretical maximum residues on short range grass and leafy crops are 400 and 200 ppm respectively. No unreasonable acute or dietary hazards, in terms of bird kills, would be expected in these cases.

Although EEB has not yet formally validated a submitted study of domestic chicken reproduction with very high dietary levels of cyromazine fed over long periods we do note however that this study indicated possible adverse reproductive effects (reduced egg production and hatching success) at a dietary test level of 2000 ppm. A overall reproductive NOEL of 1000 ppm was suggested by that study and claimed by the registrant in this submission. However, we also note that numerical reductions in hatching success occurred at 1000 ppm although they claimed that it was not statistically significant. The suggestion of adverse effects in the chicken, which is not an acceptable test species for our purposes (mainly because it may not be as sensitive an indicator as bobwhite

Pending Registration Action

quail or mallard duck in reproduction tests) is enough to prompt EEB to suggest that further investigation of potential reproductive effects in appropriate wild birds be undertaken. However, considering the moderate acreage involved in these use patterns and the relatively low rates of application, which are expected to result in maximum theoretical residues on soil of <400 ppm, we do not expect reproductive impact to materialize in normal use according to label directions for celery lettuce. Insufficient residues would be present in birds diets for short periods of time. Thus, the conditions in the chicken reproduction test would not even be closely approximated in these use patterns.

Aquatic EEC's of 8ppb have been calculated for the irrigation canals which could receive direct application from aerial treatments.

Model

1. Main canal = 6 ft. deep
2. 0.125 lb. a.i./acre = 1.3 mg/ft²
3. 1.3 mg./ft² / 6 ft = 0.22mg./ft³
4. 1 ft³ water = 28.3 Kg.
5. 0.22 mg/ft.³ / 28 kg/ft.³ = 8ppb.

Since cyromazine is stable to hydrolysis we can assume that no breakdown of the parent compound will occur in a worst case (actually the parent will degrade by photolysis). Assuming the highly unlikely event of 12 aerial applications, this would result in maximum theoretical aquatic residues of 96 ppb. This does not exceed the most sensitive chronic MATC values (for daphnids >310 ppb < 640 ppb) and does not approach the acute aquatic values (LC50's > 80 ppm). Therefore EEB projects no unreasonable effects can be expected for aquatic organisms which may be exposed by these uses treated at the proposed rates.

101.3 Endnagered Species Considerations

None at this time.

101.4 Adequacy of Toxicity data

The submitted data is adequate to support the proposed registrations

Because the RD and HED divisional offices requested an expedited review of these use patterns and because of the known low toxicity moderate use patterns and modest residues expected (compared to acute and dietary toxicity values), it was agreed that formal validation of the chronic and avian reproduction studies could be postponed in order to expedite the review of these uses.

A cursory review of the submitted chicken study however, indicates the potential for avian reproductive impairment at very high dietary levels of cyromazine and should be further investigated in appropriate wild birds acceptable to EEB as test organisms. These do not include the domestic chicken, but do include Bobwhite quail (Colinus virginianus) and mallard duck, (Anas platyrhynchos). Two (2) avian reproduction studies, one on each species, are recommended as per Pesticide Assessment Guidelines. Because of the use patterns and application rates reviewed here however, such studies are not essential at this time but could be conducted under a conditional registration.

A cursory review of the fathead minnow chronic study submitted under this Acc. No. 073085 indicates that this is a "supplemental" study at best, since the fathead minnow was not as sensitive to this test substance as trout in flow-through LC₅₀ studies - fathead LC₅₀ = 700 ppm trout LC₅₀ = 51 ppm (data given in the fathead minnow chronic study of this submission).

We have no comment on the Daphnia chronic study at this time.

The above studies are not required to support these use patterns at the proposed rate of 0.125 lb ~~ai~~ /A.

101.5 Adequacy of Labeling

The proposed label statement for "Environmental Hazards" is inadequate. It must be changed to read:

" Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favor drift from target area."

102 Classification

N/A at this time

103 Conclusion

Pending registration
Action
EEB has completed a full risk assessment (3(c)(5) finding of the proposed registration of cyromazine for use on [REDACTED] celery and lettuce. Based upon the available data and use information EEB concludes that the proposed uses provide for minimal hazards to nontarget organisms.

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