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SHAUGHNESSY NO

REVIEW NO.

EEB REVIEW

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MRID #(S) _____

DP TYPE 001 Submission Related Data Package

PRODUCT MANAGER, NO. Cynthia Giles-Parker 22

PRODUCT NAME(S) Bravo 500

TYPE PRODUCT Fungicide

COMPANY NAME ISK Biotech Corp.

SUBMISSION PURPOSE Review Proposed Amendment to Add

Additional Applications to Existing

Use Site, Sweet and Sour Cherries

COMMON CHEMICAL NAME Chlorothalonil



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

AUG 16 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Proposed Amendment to Existing Use of Chlorothalonil
on Cherries
DPBarcode: D166714

FROM: Douglas J. Urban, Acting Chief *for H. J. Cronin* 8/16/91
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: Cynthia Giles-Parker PM 22
Herbicide/Fungicide Branch
Registration Division H7505C

INTRODUCTION

The registrant of chlorothalonil, ISK Biotech Corp., has requested to amend their label for use of Chlorothalonil on cherries.

PROPOSED AMENDMENT

Currently, the label permits applications of chlorothalonil to cherries at various times; post-harvest and winter or early season application. The proposed change is to permit application up to within 30 days of harvest except that if cherries are harvested by machine into water, it may be applied up to 7 days pre-harvest. The proposed use rates (see attached supplemental label) are essentially the same as those previously evaluated by R. Stevens in a 1-28-82 review. The maximum use rate is 4.17 lbs ai/acre.

Calculation: Bravo 500 contains 4.17 lbs ai per gallon (8 pints)
The maximum use rate is 8 pints (one gallon) per acre, or 4.17 lbs ai/acre.

In the 1-28-82 review, the EEB concluded that additional information were needed before a hazard assessment could be completed. These data included:

1. A Daphnia magna full life cycle study, and
2. Aquatic field testing.

The Daphnid life cycle study requirement has been fulfilled. The field study was submitted, but does not adequately address the concerns of using chlorothalonil according to this label. The use for which the study was conducted was soybeans and corn. The use rate was 1.4 lbs ai/acre. Therefore, that study is inadequate to negate EEB's presumption of hazard.

Note that the concern for chronic effects to birds was unknown then because the existing avian reproduction testing was not performed at high enough levels (max concentration = 50 ppm).

TERRESTRIAL ASSESSMENT

Using the maximum application rate of 4.17 lbs ai/acre, the maximum residues in ppm on short grass would be 1000 ppm (chlorothalonil) and 75 ppb (DS-3701, a primary degradate of chlorothalonil). The degradate estimates are based on data suggesting that an average of 7.5% of the parent becomes the degradate.

This expected residue level does not exceed the mammalian acute concern levels nor the reproductive NOEL of 15,000 ppm. Impact to mammals is not expected.

This residues do not exceed the avian LC50's nor the avian reproductive NOEL for mallards of 10,000 ppm. They do exceed the NOEL of 50 ppm for bobwhite. At 1000 ppm, an unexplained yellowing of the adult birds occurred. Until the biological and ecological significance of this yellowing is explained, as was requested in the EEB 8-31-89 memorandum, EEB cannot conclude that chronic exposure concentrations above 50 ppm are safe to birds. The maximum residues of DS3701 exceed the NOEL (50 ppm) for the mallard but not the NOEL (100 ppm) for the bobwhite. Because chlorothalonil is moderately persistent and may be applied repeatedly on cherries, chronic exposure is likely.

AQUATIC ASSESSMENT

During a typical runoff year, the following maximum concentrations are estimated in water adjacent to a grove of trees (orchard) treated with chlorothalonil. The concentrations are extrapolations from the results of a SWRRB model that was used to estimate runoff and an EXAMS II that was used to simulate its fate in the aquatic habitat. Originally, the model was run using 3.15 lbs ai/acre. The values below are for 4.17 lbs ai/acre.

¹ NOEL from previous avian reproduction test; Fink, 1976, MRID# 41441.

Rate lbs. ai/A	Water Body Concentration (ppb)		
	Pond ² water/sediment	Stream 1 ³ water	Stream 2 ⁴ water
4.17 (cherries)	39 / 616	18	6

The concentrations in pond water adjacent to a cherry grove exceed the lowest fish LC50 (fathead minnow, 23 ppb). This EEC also exceeds the fish life cycle NOEL of 3 ppb and the LOEL of 6.5 ppb.* Acute effects to fish are likely and, since multiple applications are permitted, chronic effects are expected. The concentrations in the water column do not exceed the Daphnia magna LC50 of 70 ppb they do approach the life cycle NOEL of 39 ppb. The EEC does exceed the oyster EC50 of 3.6 ppb. Therefore, certain more sensitive aquatic organisms are likely to experience acute and chronic effects from this use. Granted, the oyster is an estuarine species, but it is expected that freshwater mollusks would exhibit a similar sensitivity. The concentrations in sediment do exceed concern levels for invertebrates, some of which may dwell in benthic habitat. The significance of this exposure would be determined in field testing.

RISK SUMMARY

It is expected that the use of chlorothalonil on cherries will have a chronic effect on birds, and both an acute and chronic effect on fish and some invertebrates (mussels and benthic dwellers).

DATA REQUIRED

The registrant must submit additional information on the biological and ecological significance of the discoloration observed in the avian reproduction study. This may be in the form of research to further explain the phenomenon or field testing to show that the discoloration either does not occur in the field or that it does not impact survival and/or reproduction of avian species.

Aquatic field testing is required to negate the concern for impact to aquatic organisms. It is recommended that this be a multiple pond test system in which replicate ponds are loaded with chlorothalonil at levels determined by aquatic exposure models. These treated ponds must be matched with untreated

² A Georgia farm pond 2 meters deep, with 1 hectare surface area.

³ A short (100 meter) connecting stream (3 meters wide X 0.5 meters deep) from the pond to stream 2.

⁴ Long section of stream (300 meters) that is 3 meters wide X 0.5 meters deep.

control ponds to measure potential effects of chlorothalonil. It is acceptable that more than one treatment level be used if the registrant wants to cover a range of exposure levels representing different use rates or conditions.

A protocol must be submitted for this field testing for review by EEB.

CONCLUSION

The EEB recognizes that this is an amendment, adding additional uses to an existing label use site. However, since it involves adding treatments during times of the year when chlorothalonil was not used, it represents additional exposure, and possibly exposure to species previously not exposed. Furthermore, the EEB has previously expressed concern for similar use sites and use rates that are lower than proposed for cherries. The EEB cannot concur with this label amendment. The required data may provide information that could change this conclusion.

If you have questions, please contact Dan Rieder.

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Pages 6 through 8 are not included.

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- ☐ Identity of product inert ingredients.
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 - ☐ Sales or other commercial/financial information.
 - ☒ A draft product label.
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