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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

PC Code No. 118205
DP Barcode D289061
April 18, 2003

SUBJECT: New Chemical Screen for Lufenuron for Use as a Termite Bait

TO: Arnold Layne, Product Manager
Joseph Tavano, PM Team Reviewer
Registration Division

FROM: Lucy Shanaman, Chemist, ERBIII, EFED
John Jordan, Biologist, ERBIII, EFED

Through: Kevin Costello, Geologist, RAPL, ERBIII, EFED
Ben Smith, Chief, ERBIII, EFED

The Environmental Fate and Effects Division (EFED) has completed a preliminary chemical screen for Lufenuron for use as a termiticide with 0.15% a.i. incorporated in a cardboard matrix in and around buildings. The proposed label is not explicit about the application rate.

A multitude of studies was provided. Their screening evaluation is detailed in the attachments. Many of the studies would not be required for this particular application. The studies are all at least eight years old and suggest low toxicity with the possible exception of invertebrate and avian reproductive effects. There were no plant studies provided, which is a potential concern.

For this particular application, the received studies appear adequate for further evaluation by the contractor with the exception of the Mysid shrimp study. That study suggests very high toxicity, but did not demonstrate an NOAEC. Of course, it is not clear that study is relevant to this particular application.

DP BARCODE: D289066

CASE: 065347
SUBMISSION: S631675

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/21/03

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 010 NEW CHEMICAL SCREENING
RANKING : 0 POINTS ()
CHEMICALS: 118205 Lufenuron 0.1500%

ID#: 000100-RRTU LUFENURON TERMITE BAIT
COMPANY: 000100 SYNGENTA CROP PROTECTION, INC.
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: JOSEPH TAVANO 703-305-6411 ROOM: CM2 214
RECEIVED DATE: 02/04/03 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 289066 EXPEDITE: Y DATE SENT: 03/21/03 DATE RET.: / /
CHEMICAL: 118205 Lufenuron
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	3/21/03	/ /
BRAN: IO ERB3	3/24/03	/ /
SECT: IO	3/24/03	/ /
REVR : Kevin Costello	3/24/03	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 05/20/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

NEW CHEMICAL SCREEN Attention: Doug Urban Please perform a New Chemical screen for Lufenuron a New CHemical to be used as a termite bait. A label and CSF is attached for the End Use Product. The data is attached with data package D289061 for the Technical.Reduced Risk Status has been requested by registrant.

* * * DATA PACKAGE EVALUATION * * *

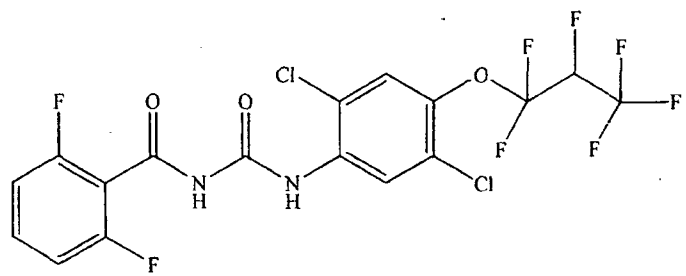
No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
289065	SAB/IO	03/21/03	05/20/03	Y	Y	Y

2

The results of an initial screen of the environmental fate study reports submitted to support Lufenuron (PC 1182025; CASRN 103055-07-8) for use as a termiticide bate when mixed with paper pulp, and housed in a ridged plastic casing. Submitted study reports, tabulated below, appear to be sufficient to conduct an environmental fate assessment for the stated use. However, should Lusenuron be considered for other uses, additional environmental fate data (aqueous and soil photolysis, biotic aquatic metabolism, bioconcentration in fish, and field dissipation) would be required.



Screen of Lufenuron (PC# 1182025).

Subdivision N Guideline #	Description	MRID	Title	Submitting Laboratory ID	Does this study have a "fatal flaw"?
161-1	Hydrolysis	45853201	Hydrolysis of CBA-184699 Under Laboratory Conditions	Ciba-Geigy Ltd.	No
161-2	Photodegradation in Water				
161-3	Photodegradation on Soil				
162-1	Aerobic Soil Metabolism	45853202	Degradation of CGA-184699 in Soil Under Aerobic, Aerobic/Anaerobic and Sterile/Aerobic Conditions	Ciba-Geigy Ltd.	No
162-2	Anaerobic Soil Metabolism	45823202	Degradation of CGA-184699 in Soil Under Aerobic, Aerobic/Anaerobic and Sterile/Aerobic Conditions	Ciba-Geigy Ltd.	No
162-3	Anaerobic Aquatic Metabolism				
162-4	Aerobic Aquatic Metabolism				

Subdivision N Guideline #	Description	MRID	Title	Submitting Laboratory ID	Does this study have a "fatal flaw"?
163-1	Mobility (Adsorption/Desorption)	45853203	Adsorption / Desorption CGA-184699 in Various Soil Types	Ciba-Geigy Ltd.	No[1]
163-1	Mobility (Column Leaching)	45853204	Leaching Characteristics of Aged Soil Residues of CGA-184699 in Two Soils After Percolation of 508 mm Artificial Rain	Ciba-Geigy Ltd.	No
163-1	Mobility (Column Leaching)	45823205	Leaching Characteristics of Aged Soil Residues of CGA-184699 in Two Soils After Percolation of 200 mm Artificial Rain	Ciba-Geigy Ltd.	No
163-2	Laboratory Volatility				
164-1	Terrestrial Field Dissipation				
165-4	Accumulation in Laboratory Fish				

[1] Position of raiolabel not given, eventually needs clarification, but collective results from three 163-1 studies indicate that this omission does not fatally flaw the study

Ecological Effects - New Chemical Screen for Lufenuron

What studies are required ?

The proposed use is only as a termiticide with 0.15% a.i. in a cardboard matrix which is in a bait station. In this situation it is not clear, in the guidelines, which studies would be required. The registrant provided the following studies:

Acute Toxicity of CGA-184699 to Daphnia magna
Test for acute toxicity of CGA-184699 Technical to Rainbow Trout and Bluegill
Acute Toxicity of CGA 184699 to Mysid Shrimp (Mysidopsis bahia)
The Dietary Toxicity (LC 50) of CGA-184699 to the Bobwhite Quail CGA-184699
Mallard Duck Dietary Reproduction and Tolerance Studies
The Acute Oral Toxicity (LD 50) of CGA-184699 to the Mallard Duck
The Dietary Toxicity of CGA-184699 to the Mallard Duck
Acute Oral Toxicity (LD-50) of CGA-184699 to the Bobwhite Quail
Bobwhite Quail Dietary Reproduction and Tolerance Studies

All of the studies received had various deficiencies, but most of the acute studies established the termiticide's low toxicity. The studies were all accomplished in accord with OECD guidelines, and should be sent to the contractor for further evaluation. No plant studies were submitted by the registrant.

Acute Toxicity to Freshwater Fish

The registrant provided flow-through testing for two species, bluegill and rainbow trout. The technical grade was used for testing. The treatment groups were randomly assigned and appear to be essentially balanced, but separate weights of the groups were not provided at the start of the study. There were no trout deaths at 75 mg/L Lufenuron. The solvent used exceeded the recommended 135 mg/L in both species. For bluegill, 365 mg/L of solvent was used. Analytical methods and detection limits appeared adequate. There was one death in the bluegill control. In the bluegill study, pesticide concentration increased over time to the end of the study. There were no deaths in the bluegill study up to > 29 mg/L.

Conclusion: Fish studies are probably useable for demonstrating a NOAEC, but there are study deficiencies which are significant.

Acute Toxicity to Daphnia magna

The recommended acclimation period of 7 days was not observed, but 5 or more concentrations were used. The recommended stirring of the sample material did not appear to have been

5

followed , but the oxygen concentrations were more than adequate, i.e., 9.2 to 10.1 ppm. Some of the supporting data were not readable. The 20 ppb aluminum and the 20 ppb lead were noted in the water used in the experiment, but there was no control group mortality.

The reported EC 50 was 0.0038 ppm and the Acute Toxicity 48 hour 0.010 ppm nominal concentration carried a 75% mortality rate. The NOAEC for CGA-184699 was 0.00033 mg/L. The recommended lighting period was 16 hours light and 8 hours darkness, but this study used 16 hours light and 30 minute simulated dawn and dusk periods.

Conclusion: The study demonstrates both a NOAEC and an LC 50, but there were many irregularities.

Acute Toxicity of CGA-184699 to Mysid Shrimp

This study is not being sent to the contractor T he purpose of the study was to estimate the acute toxicity (LC 50) of 14C-CGA-184699 to Mysid shrimp under static conditions. Twenty-four hour Mysid Shrimp were used.. The test material was classified as Very Highly Toxic to Mysid Shrimp. The NOAEC was <0.021 ug/L. The 96-hr LC 50 was 0.042 ug/L. Natural filtered sea water was used; the water was aerated prior to use.

Conclusion: It appears that this study has irregularities that would prevent it from satisfying guideline requirements. Nevertheless, the reported LOAEC of 0.021 ug/L is sufficiently low that, should a use other than the current bait station application be considered, another study would be required.

Bobwhite Quail Dietary Reproduction

Recommendations for Bobwhite Quail are for one male and 2 females per pen, but this study used 1 male and 1 female per pen. All of the environmental factors were according to recommendations and free access to feed was allowed. The domestic potable water analysis showed many pesticides at or below the ppm level.

Conclusion: Although the registrant states that 400 ppm is the NOAEC, it appears that the NOAEC could be lower than 200 ppm. This is a critical issue for more thorough investigation by the contractor.

Bobwhite Quail Acute Oral Toxicity

Preliminary range-finding determined that the test material was of low toxicity. After dosing, the observation period was 14 days. Five treatment levels are recommended, but only three levels were used, because there were no signs of toxicity at the highest level we require.

Conclusion: There were no mortalities, and therefore, it was not possible to determine LD50's. The highest dose level was 2000 mg/kg, and the LD 50 must be greater than 2000 mg/kg. These levels would probably be well in excess of levels of concern for this pesticide use.

Mallard Duck Dietary Reproduction

Treatments and controls were homogenous. A disproportionate number of eggs were discarded in the lowest treatment category. There were indications that too much solvent may have been used. All birds chosen were in apparent good health and were approaching their first breeding season. Body weights were all very similar and birds were from the same source.

Conclusion: It was concluded that dietary administration of up to 400 ppm CGA-184699 over a period of 4 weeks had no effect on health, body weights, or food consumption of Mallard Ducks. Also, the conclusion indicated that 200 ppm was the no adverse effect level. However, some effects were still evident at the 200 ppm level.

Mallard Duck - Acute Oral Toxicity

It was not possible to determine the acute oral toxicity (LD-50) of CGA-184699 Lufenuron, because there were no treatment effects from the highest dose (2000 mg/kg) or from any treatment. This study did not have the required 5 treatment levels. Also, 1 male was paired with one female, but two females and one male are recommended.

There were no signs of toxicity and no mortalities. Ten hours light and 14 hours darkness are recommended, but this study used 7 hours light and 17 hours darkness. Water from domestic water supply was used, but non-chlorinated water is recommended.

Conclusion: Although the study has deficiencies, it is probably adequate for establishing a NOAEC in the range likely to be found in the environment.

Mallard Duck- Dietary Toxicity

No range finding was accomplished, as the 5200 ppm did not produce a treatment response. There was no evidence of treatment responses (differences). No LC 50 could be calculated. Acclimation lasted for only 3 days; fifteen days are recommended. The feed used in the test was not analyzed for contaminants. A recommended solvent was .used.

Conclusion: The studies suggest there is no toxicity at 5200 ppm. This level would probably be well in excess of estimated exposure.

7