



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: April 13, 2009

SUBJECT: Label Amendment for Fresh Cab (EPA Reg. #: 82016-1), Containing 2.0% Fir Needle Oil (Active Ingredient). Review of Product Performance Study

Decision Number: 403501
DP Number: 362871
EPA File Symbol Number: 82016-1
Chemical Class: Biochemical
PC Codes: 129035
Tolerance Exemption: 40 CFR 180.
MRID Numbers: 47611701

From: Manying Xue, Chemist
Clara Fuentes, Biologist
BPB/BPPD (7511P)

Handwritten signatures of Manying Xue and Clara Fuentes.

To: John Fournier, Regulatory Action Leader
BPB/BPPD (7511P)

Action Requested:

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a petition for label amendment to increase the interval of efficacy from 30days to 100 days for Fresh Cab (EPA Reg. #: 82016-1) containing 2% of fir needle oil (the active ingredient). Fresh Cab has been classified as a biochemical which is proposed to be used to repel rodents in enclosed areas such as tractor cabs, electrical boxes, cabin cruisers, RV homes, and in non-living areas such attics, cellars, storage areas, garages, etc.

In support of this label amendment, the registrant has submitted an amended label, CSF and product performance study (MRID 47611701).

BPPD has reviewed and evaluated the submissions for the EP, Fresh Cab. The decisions are made to reflect the current OPP policies.

Recommendations and Conclusions

1. The submitted product performance study is **UNACCEPTABLE**, due to the following deficiencies which need to be corrected.
 - a) The registrant need to specify whether the test substance described as **various herbal ingredients** is the same as the proposed end use product for this registration;
 - b) Food-caching is not the best way to measure repellency since the product does not prevent mice from entering the treated room;
 - c) For demonstrating repellency, it is appropriate to measure the average time spent per mouse in either control or treated rooms;
 - d) The standard error of means should be reported. The study design should be increased statistical power and be replicated that is repeated more than once; minimum three times (does not mean increasing sample size, which is number of mice tested). BPPD recommends observing the mice for a given period of times (in minutes) every hour or half hour to come up with an average of time spent in one place or another.
2. The submitted label is **UNACCEPTABLE**. The statement under EARTH-KIND, Inc should be removed from the label which is misleading. The website and e-mail information should not be on the label.

Product Performance (OPPTS 810.1000)

EARTH-KIND, Inc. DBA Crane Creek Gardens has submitted a product performance study for the end use product, fresh cab (MRID 467844-16) to determine the level of repellency for 10 days starting at day 90. Fresh Cab contains 2.0% of the active ingredient, fir needle oil, and they are aged 90-100 days for demonstrating extended efficacy of the product up to 100 days.

Test Substance

Fresh Cab[®] (a.i., 2.0% w/w balsam fir oil, EPA Reg. No 82016-1) formulated by Crane Creek Gardens with various herbal ingredients that emit a scent in biodegradable pouches.

Test Methods

The study was conducted to determine the repellency of Fresh Cab[®] to wild house mice (*Mus musculus*) after the product had been aged for 90 days. The test was conducted in two study rooms (control and treated), each measuring 13.6 x 18.6 ft, for a floor area of approximately 250 ft². The rooms were connected by a 1-in diameter PVC pipe that ran

through the wall at floor level. The pipe allowed the mice access to both rooms, but did not allow the control room to be contaminated with the scent of the test material.

Summary of Results

During the test, the room temperature ranged from 19 to 26°C, and the relative humidity ranged from 32 to 63%.

Test results are summarized in Tables 1 and 2. Mice were observed in the control room 88% of the time, compared to 12% of the time in the treated room. During each observation period, the mean number of mice seen in the control and treated room was 4.40 and 0.60, respectively, a statistically significant difference.

Table 1. Mouse observation counts

Room	Study day																				Total	Repellency (%)
	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10		
Control	3	4	2	4	4	5	4	4	5	3	5	5	5	5	5	5	5	5	5	5	88	88
Treated	2	1	3	1	1	0	1	1	0	2	0	0	0	0	0	0	0	0	0	0	12	12

Data from p. 18, MRID 47611701

A total of 53 food cubes were removed from the plate in the control room, compared to 16 cubes removed in the treated room. The activity index in the control room was significantly higher than in the treated room.

Table 2. Food consumption counts

Room	Study day																				Total	Activity (%)
	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9	10	10		
Control	16	16	5	5	1	1	0*	20	10	10	2	2	0*	20	13	13	11	11	7	7	53	76.8
Treated	13	13	10	10	10	10	9	9	7	7	6	6	4	4	4	4	4	4	4	4	16	23.2

Data from pp. 15, 18, MRID 47611701

cc: J.Fournier; BPPD Chron File; OHAD/ARS
 M. Xue, BPPD, 04/13/09