EFFICACY STUDY REVIEW

by Kevin J. Sweeney, Entomologist - IB Kevin J Sweeney 04/30/01

To: Leonard Cole

Date: April 30, 2001

EPA File Symbol:100-~~RERL~~ RREL d100- EUP-111

Product Name: IMPASSE barrier

Registrant: Syngenta Crop Protection, Inc.

PM: George LaRocca

Action: 175

Submission No(s). S587442 & D271186

Chemical: lambda-cyhalothrin(I) applied at 0.77% a.i.

OPPTS Guideline: 810.36

Instructions: Review efficacy results of IMPASSE against termites. Review label directions.

Studies Submitted: Three volumes of efficacy data were submitted by the registrant in support of the pending EUP and section 3 registration.

MRID 452295-01 IMPASSE Barrier Biology Update by P. Wege, Entomology Department at the University of Florida at Gainesville and Zeneca, UK and Japan.

MRID 452417-01 IMPASSE Barrier: A Review of Biological Data by P. Wege, Entomology Department at the University of Florida at Gainesville and Zeneca, UK and Japan, and USDA Forest Service, Gulfport, MS

MRID 45 2417-02 Modeling of the Performance of the Impasse Barrier by R.Murray-Smith and E. Beling, ASTRAZENECA Limited, UK and Zeneca Agrochemicals, UK

The evaluation of data is presented below along with conclusions and recommendations.

These volumes contain the results of laboratory and field termiticide bioassays in which IMPASSE was compared to untreated product and no barrier product at all. In addition, IMPASSE was also compared to other barrier products used as positive control replicates in these experiments. Heat joined product films were tested in the laboratory only. Tests were conducted against termites from the genera *Reticulitermes*, *Coptotermes*, and *Globitermes* in trials conducted in the U.S., Malaysia, United Kingdom, and Japan.

LABORATORY DATA

Laboratory data were collected with the subject product against termites using the following methods: topical application; soil penetration; tube assays; pipe assay; and arena assays.

TOPICAL APPLICATION - TOXICITY The data reported for use of this method were summarized from the 1990 article published by Su & Scheffrahn in the Journal of Economic Entomology. In their study, a micropipette was used to topically apply insecticide to worker termites in microliter quantities. Termites were transferred to petri dishes, and the LD_{50} determined. The topical toxicity (ug insecticide/gram of worker body weight) of the termiticides lambda-cyhalothrin, permethrin, cypermethrin, bifenthrin, deltamethrin, chlorpyrifos, and chlordane was determined for applications to the Eastern subterranean termite, *Reticulitermes flavipes*, and the Formosan termite, *Coptotermes formosanus*. A linear regression was used to analyze the data and estimate the EC_{95} values for each insecticide.

Lambda-cyhalothrin was the second most toxic insecticide against the Formosan termite and the third most toxic against the Eastern subterranean termite. These results show that *Eastern subterranean* worker termites are 7x more susceptible to lambda-cyhalothrin when compared to Formosan worker termites (0.04 ug/g vs. 0.29 ug/g). Formosan termites are also less susceptible than *Ixodes* ticks to lambda-cyhalothrin when published sources of data are compared..

Syngenta estimated (from **extrapolation**) that the amount of lambda-cyhalothrin necessary to kill (via the "dermal" route) an Eastern subterranean termite worker is 0.0001ug/worker termite while 0.0024ug/worker is required for Formosan termites (Confidence intervals were not provided for these LC_{99} values.) From this extrapolation, the registrant expects that the 2.75mg of lambda-cyhalothrin/mm^2 in the IMPASSE barrier is sufficient to kill termites. In fact, the dose/mm^2 is estimated to be enough to kill 10,000 or more worker termites.

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SOIL PENETRATION - REPELLENCY Termite penetration into insecticide treated soil was measured in open ended glass tubes (1.4cm wide x15cm high) containing 5cm segments of moistened soil sandwiched between two sections of agar (one measuring 1 cm, the other 3 cm). Two wooden applicators and a piece of paper were placed into a 5cm void adjacent (above) to the 3cm agar layer. Eighty worker and one soldier termite were introduced into the 5cm void and the tube was sealed with a metal cap. On the opposite end, paper (termite food source and attractant) was placed adjacent (below) the 1 cm agar layer and the tube sealed with a metal cap. Four insecticides (permethrin, cypermethrin, lambdacyhalothrin, and tefluthrin) were tested at a range of concentrations (0, 0.01, 0.1, 1, 10, and 100 ppm) to determine the concentration range for partial soil penetrations (defined as > 0 cm but < 5 cm). Two samples from three colonies (6 replicates - one per dose? or six per dose?) each of both the Formosan and Eastern subterranean termite were tested against each insecticide. The experiment was conducted at approximately 25°C for up to seven days or until termites penetrated the treated soil barrier. These data were subjected to a linear regression analysis to estimate the insecticide concentration capable of repelling 95% of the foraging worker termites.

The soil penetration study showed the repellency of the tested insecticides to Formosan and Eastern subterranean termites. As expected, the amount of insecticide residue in the soil required to repel Formosan termites was much greater than for Eastern subterranean termites. Comparing the topical toxicity to repellency for each pyrethroid insecticide shows that permethrin, the least toxic by the topical route, was the most repellent in soil. Soil applied lambda-cyhalothrin was as repellent as permethrin to the Eastern subterranean termite but eight times less repellent to the Formosan termite. The data suggest that (if Howell 1990 is correct) sub-repellent doses (doses that termites cannot detect) of lambda-cyhalothrin and other pyrethroid insecticides present in soil could result in termite kill upon termite passage thru the treatment areas since a series of sublethal insecticide doses from contact with treated soil would occur. Of course, such lower doses could only be achieved by a lower application rate and this would decrease the longevity of the active ingredient in the soil, hence, the length of protection time.

The registrant **suggests** that the lambdacyhalothrin layer in this product enables it to resist termite penetration and ultimately protect the structure. If holes or other perforations are made in IMPASSE, the repellent and termiticidal properties of lambdacyhalothrin might prevent termite passage thru the barrier because lambda-cyhalothrin would move from the insecticidal layer into the soil. However, the degree of protection is dependent on the size of the hole in the barrier. **Small holes bring worker termites into contact with a toxic or repellent dose of lambda-cyhalothrin., while large holes afford termites easy passage through the barrier and into the structure.**

TUBE ASSAYS - IMPASSE AND OTHER PRODUCTS - BARRIER EVALUATION

Three different lab assays were used to assess the effectiveness of the IMPASSE and other barrier products against Formosan termites and multiple species from the genus *Reticulitermes*.

Tube Assay 1 - Basic method Barrier product material was placed between two open-ended plastic cylinders, each containing soil, placed one on top of another and held in position by a rubber band. A layer of agar was hardened on top of the soil and a disc of filter paper placed on top of the agar. Twenty to fifty worker termites were placed in the upper cylinder and the unit was stored for four weeks at 28^0 C. At the end of four weeks, the experimental unit was observed for evidence of barrier penetration and damage.

UK Test (I) Results with Tube Assay 1. The method above was modified to include the following treated replicates: product with 5mm punch hole, product with 5mm cocktail stick hole, 15 mm hole, and 20 mm scalpel cut. The barriers evaluated were IMPASSE blank, IMPASSE 1% lambda-cyhalothrin, Kordon, Termifilm, WF 2811 and WF 2813. Intact product (no holes) was tested for the blank IMPASSE barrier only. There was one replicate for each treatment against *Reticulitermes speratus.*

Termites penetrated the 5mm holes in the IMPASSE blank and the 15 mm hole in IMPASSE 1%. There were no termite penetrations in any other treatments. Tunneling activity was less near the treated IMPASSE product when compared to the untreated (blank) product. In the perforated IMPASSE product, termite mortality was evident in all replicates except the 15 mm hole replicate. Mortality was probably the result of termite contact with lambdacyhalothrin treated surfaces. **These data also show that termites are not repelled by the IMPASSE barrier when the hole size exceed 5 mm, suggesting that not enough insecticide moves out of the lambda-cyhalothrin layer to deposit a residue in adjacent soil.**

UK Test (II) Results with Modification of Tube Assay 1. The above test was repeated after six months of storage with two replicates each of IMPASSE 1%, WF 2813, Kordon and Termifilm. The test species was Eastern subterranean termite, *Reticulitermes flavipes*. The 5 mm hole in one of the 1% IMPASSE replicates was penetrated and dead termites were found adjacent to penetration location. No other penetrations occurred in any other treatments. Tests were evaluated again at 12 months and termites died 4 weeks (13 months) after exposure.

Japan Research Station and Malacca, Malaysia Test Results with Modification of Tube Assay 1. The test was the same as previously described but the treatment replicates were as follows for blank IMPASSE and 1% IMPASSE: 5mm hole (with hole punch), 5 mm puncture with sharp object, 20 mm cut, unsealed overlap of two pieces of product, scratched product, intact (no damage) product, and negative control with no barrier. The Japan Station test was conducted with *Reticulitermes speratus*, while the Malaysian evaluation was performed with *Globitermes sulphureus*.

Termites penetrated the blank IMPASSE thru the 5mm hole and 20mm cut but not thru the 5mm puncture. The 1% IMPASSE was penetrated thru the 5mm hole also. In both the treated and blank product, the intact product was not penetrated by termites. **This indicates that the barrier itself affords some protection against termite penetration.** The surface of the product does not have enough lambda-cyhalothrin to kill termites unlike other barrier films tested in these experiments.

University of Florida Test a Modification of Tube Assay 1. These assays were conducted in smaller assay units with a diameter of 20mm. Three colonies each of the Eastern subterranean and Formosan termite were used. The ten treatments in this experiment consisted of intact and nail-hole punctured blank IMPASSE, 0.5% and 1% IMPASSE, delaminated 1% IMPASSE, and heat seamed 1% IMPASSE. The experiment was conducted for only five weeks.

The results showed that **punctured blank IMPASSE** was **penetrated** by both species. Formosan termites were able to enlarge the hole in the blank barrier. **1% IMPASSE** treatments **were not penetrated** and the holes sealed with soil by termites, presumably in response to the presence of the lambda-cyhalothrin emitted from the punctured barrier.

However, the experiment was flawed because the experimental unit allowed termites to tunnel around the treatment, the path of least resistance.

TUBE ASSAY METHOD 2 Worker termites were funneled to the puncture in the product barrier to insure they would locate it. Five replicates of each of the following treatments were made for the 1% and blank product: 0.5 mm hole made with a needle, 1 mm hole made with a needle, 2 mm hole made with a nail, 3 mm hole made with a blunt steel rod, a fork tine penetration, two clean 10mm cuts in a cross shape, a heavily scratched surface made with coarse sandpaper, and undamaged intact barrier IMPASSE product. The holes were measured with a camera and Optimas software. The termite species tested was the Eastern subterranean termite, *Reticulitermes flavipes*. A destructive assessment was made after three weeks.

Only one of the treated IMPASSE replicates, the 2 mm hole sample, was penetrated by termites. The termites that penetrated the barrier died after passage. Nine of the 29 (31%) remaining IMPASSE 1% samples had the punctures blocked off by termites in response to the presence of lambda-cyhalothirn. 90% of IMPASSE blank replicates were penetrated by termites. Termites enlarged the hole in many of the blank IMPASSE samples (# not provided but the holes were nearly doubled in some replicates). The scratched IMPASSE replicates, treated and untreated, showed termite damage from chewing which shows that the amount of lambda-cyhalothrin in the surface layers of 1% IMPASSE is insufficient to repel or kill termites.

The registrant believes that for termites to attack the barrier, there needs to be a rough surface or some queue to begin feeding at a location. This study did not test this hypothesis.

PIPE ASSAY METHOD - UK Each arena was constructed from a 110 mm diameter PVC pipe cut into two sections, 15cm and 5cm in length. Section A contained the termites, section B contained wood. The IMPASSE barrier was placed between the sections and the two sections held together against the barrier by rubber bands. There were four treatments: IMPASSE blank - intact and perforated (2 mm hole), and 1% IMPASSE - intact and perforated (2 mm hole). Each treatment was replicated ten times. Once a week, the unit was rotated 90 degrees to account for environmental bias. The trial is ongoing but results through 16 weeks indicate that all blank IMPASSE samples have been penetrated while no penetrations occurred in 1% treatment.

ARENA ASSAY This laboratory assay tested what effect prolonged contact with barrier products had on termites. IMPASSE, Cecil, and Kordon barrier were tested. The registrant concluded that prolonged contact with the IMPASSE treated and blank barrier did not seem to have a significant impact on termite behavior. The other barriers caused termite activity to rapidly decline, then cease, indicating mortality. Termites were not repelled or killed by the 1% lambda-cyhalothrin IMPASSE product since surface deposits were less than 2.7×10^{-6} ug/cm^3. The other barrier products had 10,000x to 100,000x more insecticide deposited on the surface of the barrier.

Termite Penetration of the IMPASSE barrier (I). Slits were cut through a 10cm square petri dish using a heated scalpel. Slits were cut in Blank IMPASSE (2.26 mm wide) and IMPASSE 1% (1.89 mm wide) barrier and aligned with the slits in the petri dishes so termites could gain access to the barrier.

Termites passed thru the blank IMPASSE but did not penetrate the IMPASSE 1%. Termites making contact with the slit material in the 1% product were killed. The narrow slit caused contact with the insecticide layer and subsequent mortality. However, termites (*R. flavipes*) were not repelled.

Termite Penetration of the IMPASSE barrier (II). A hole was made in the blank and treated barriers. The blank barrier had a 2.2 mm perforation, while the treated barrier had a 2.1 mm perforation. Termites (*R. flavipes*) passed through the perforations in both barriers and were not repelled. However, termites that came into contact with lambda-cyhalothrin when passing thru the hole in the 1% product died shortly after passage. The same termite species could not pass thru a 1.89 mm hole in the same barrier as discussed in (I). Therefore, the size of perforation affects the ability of termites to pass thru the barrier.

FIELD TRIAL DATA

Currently, concrete slab bioassays are in use to evaluate the IMPASSE product. Tests are on-going at the University of Florida at Fort Lauderdale under the direction of Nan-Yao Su (5/96 to present), USDA-FS sites in AZ, MS, FL, SC, and Midway Island (5/99 to present), and in Malacca, Malaysia at a Syngenta field station (2/99, 10/99, and 3/00 to present). The termite species challenging the barrier are *Reticulitermes flavipes* (Eastern subterranean termite) and *Coptotermes formosanus* (Formosan termite) in the United States, and *Globitermes sulphureus* in Malaysia.

The field trials are summarized in tables 15-19 on pages 38-41 of MRID 452417-01. They show that termite foraging and feeding pressure at the test sites is high but none of the IMPASSE replicates have been penetrated at any of the field sites. However, only 19 months of field data have been collected at some sites and only one year of USDA-FS trials are completed.

Conclusions and Recommendations

1. The submitted laboratory and field data are acceptable but do not fully satisfy the registration requirement for product performance. These data are sufficient to support an Experimental Use Permit (EUP).

2. None of test replicates have been penetrated to date in the concrete slab field bioassays. Termite species challenging the barrier are *Reticulitermes flavipes* (Eastern subterranean termite) and *Coptotermes formosanus* (Formosan termite) in the United States, and *Globitermes sulphureus* in Malaysia. However, 19 months of concrete slab data are not sufficient to evaluate a termiticide product application for effectiveness. Concrete slab data through five years are required. **In addition, concrete slab replicates should be established with repaired punctures and heat sealed seams to test their ability to resist termite attack. PVC concrete slab barriers replicates currently in use should have the IMPASSE barrier fastened to the PVC pipe as directed by the product label, not by experimental design.**

3. Lambda-cyhalothrin does not appear to migrate to the surface of the IMPASSE barrier product in quantities sufficient to kill or repel termites contacting the product's surface.

4. Based on the estimated LD_{99} values for topically applied lambda-cyhalothrin, 24x more lambda-cyhalothrin is required to kill a worker Formosan termite, *Coptotermes formosanus*, when compared to a worker Eastern subterranean termite, *Reticulitermes flavipes*. Eight times (8x) more lambda-cyhalothrin is required to repel Formosan termites when compared to the Eastern subterranean termite. However, the IMPASSE barrier product contains enough insecticide to kill up to 10,000 worker termites/mm^2 of either species.

5. Computer models examining the longevity of the lambda-cyhalothrin layer in the IMPASSE barrier product predict that the insecticide layer will be effective for 10 years. The model accounted for loss due to punctures or slits in the barrier. These predictions have not been validated in field testing with the subject product. They are estimates only.

6. The 2 mm S-layer of the IMPASSE barrier is essential to this product's performance because it has low lambda-cyhalothrin permeability. This characteristic prevents lambda-cyhalothrin contamination of the product surface, thus, limiting exposure during manufacture and application to human workers, while extending product life and presumably product performance.

7. In laboratory assays, cuts or penetrations in the IMPASSE barrier result in little loss of lambda-cyhalothrin. Lambda-cyhalothrin migrates less than a millimeter from the barrier penetration to the soil.

8. The ability of termites to penetrate the IMPASSE barrier appears to depend on the extent of barrier damage. Holes/slits in the barrier > 2 mm in diameter/width enable termites to breach the barrier. Termite survival upon barrier passage is dependent on the perforation size. If the hole in the barrier is large enough (> 5 mm or about 1/4") for termites to build mud tunnels and/or walk thru it without contacting the barrier edge or the small area of soil contaminated with insecticide leaving the barrier, termites can pass unscathed and the barrier will not afford protection at the point of damage. Therefore, **any damage to the barrier must be repaired.**

9. The use of the IMPASSE barrier as directed by the EUP label has not undergone extensive field testing. There are no data available from testing at structures. The installation of this product in a manner capable of ensuring structural protection against termites is a sophisticated procedure. Therefore, I recommend APPROVAL OF AN EXPERIMENTAL USE PERMIT to test the effectiveness of the product as a termiticide pre-treatment in new construction but DO NOT RECOMMEND a section 3 registration at this time. A section 3 registration should NOT be considered until at least one year of EUP data (preferably two) have been collected by Syngenta and its cooperators and evaluated by EPA. Field testing under an Experimental Use Permit is likely to result in future label changes. This product must be installed properly to protect the structure. In most cases, improper installation can not be corrected without extensive destruction and repair to the structure's foundation. Unlike all other termiticide pre-treatments, this product proposes a program that requires no external perimeter treatment and the efficacy of an internal barrier only pre-treatment must be carefully evaluated to insure that structural protection can be achieved.

10. On page 18 of the label, there are directions on how to repair the IMPASSE barrier after pouring the concrete. The procedure seems possible but not feasible.

11. Please explain how the connecting tab formed by pleating and stapling the IMPASSE barrier **will not** provide an entry point for termites. Identify what "a suitable physical anchor" is for securing IMPASSE to the slab.

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12. The registrant may want to consider a procedure for inserting rust-proof rings or some other attachment mechanism into the barrier for use with anchors attached to concrete.

13. Please supply the Agency with samples of the bath box, boot for pipe, and connecting tabs for concrete attachment

14. For hollow block construction and brick veneer - how does IMPASSE afford structural protection? Installations in figures 4, 6 & 8, 10 and 14 describe situations for this type of installation. The is that such an installation may affect the stability of first course of brick or block on top of the barrier since the mortar would have to applied on the IMPASSE barrier and not the footing itself. Is rebar recommend to reinforce the lower courses of brick or block to insure stability? Second, in figure 4, there is a space at grade just under the top of the footer. Given the fact that no exterior perimeter treatment is required, how do you insure there will be no space between the barrier and the footer that termites can go around to gain access to cracks or spaces in the mortar joints of the block or veneer?

15. The label should have a statement prohibiting the use of this product in crawl spaces and plenums.

Recommendations:

1. I recommend APPROVAL OF AN EXPERIMENTAL USE PERMIT to test the effectiveness of IMPASSE as a termiticide pre-treatment in new construction but DO NOT RECOMMEND a section 3 registration at this time. A section 3 registration should NOT be considered or granted until at least one year of EUP data (preferably two) have been collected by Syngenta and its cooperators and evaluated by EPA. Field testing under an Experimental Use Permit is likely to result in future label changes. This product must be installed properly to protect the structure. In most cases, extensive destruction and repair to the structure's foundation is required to repair an improper installation. Unlike all other termiticide pre-treatments, this product requires no external perimeter treatment. The efficacy of a sub-foundation barrier only pre-treatment must be carefully evaluated to insure that structural protection can be achieved. Many states require a sub-foundation treatment and exterior perimeter.

2. Concrete slab bioassay replicates should be established with repaired punctures and heat sealed seams to test their ability to resist termite attack. PVC concrete slab barriers replicates currently in use should have the IMPASSE barrier fastened to the PVC pipe as directed by the product label, not by experimental design.

3. Answers to the requests for more information are required as described in the conclusions section.

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2. Field Trials

Table 7. Location and timing of ongoing trials with IMPASSE.

Trial No.	Location	Cooperator	Species	Start date	Method / Objective	Formulation
	Florida	N-Y Su / Univ. Florida	RF, CF	05/96		2% polyethylen
	Florida	N-Y Su / Univ. Florida		13/03/00		WF 2813
	Arizona	B Kard / USFS	RF	24/02/99		
	Florida (Tallahassee)	B Kard / USFS	RF	23/02/99		
	Mississippi	B Kard / USFS	RF	05/99		
	South Carolina	B Kard / USFS	RF			
	Midway Island	B Kard / USFS	CF			
Y01-00-Z701(a)	Malacca	In house	GS	26/02/99	Concrete slab assay. Comparison with Kordon and Termifilm.	WF2813, WF 28
Y01-00-Z710(b)	Malacca	In house	GS	23/10/99	Concrete slab assay. Comparison with Kordon and Termifilm. Effect of penetrating pipe.	WF2813, WF 28
Y01-00-Z710	Malacca	In house	GS	03/03/00	Pipe assay. Effect of hole size and abrasion on integrity.	WF2813, WF 28

RF = *Reticulitermes flavipes*
CF = *Coptotemes formosanus*
GS = *Globitermes sulphureus*

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