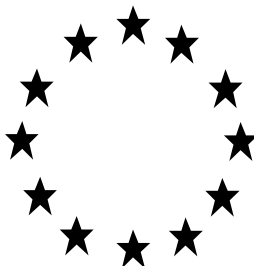


Competent Authority Report
Programme for Inclusion of Active Substances in
Annex I to Council Directive 98/8/EC



s-Methoprene (PT 18)

CAS-No. 65733-16-6

DOCUMENT IIIA (A5)

Evaluation Report

Rapporteur: Ireland

October 2010

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Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)		Official use only
5.1	Function (IIA5.1)	Insecticide
5.2	Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)	
5.2.1	Organism(s) to be controlled (IIA5.2)	Pharaoh ants (<i>Monomorium pharaonis</i>)
5.2.2	Products, organisms or objects to be protected (IIA5.2)	Indoor areas. For use throughout the EU community.
5.3	Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)	
5.3.1	Effects on target organisms (IIA5.3)	The eradication of the ant colonies exposed to S-Methoprene is a result of the morphogenetic effects of the insect growth regulator (IGR) on the brood stages coupled with the action of the compound on the ovaries of the queen which become atrophied and stop producing oocytes. The resulting sterility of the queens may be due entirely to the physiological effects of the hormone on the ovaries but may be compounded by the disruption of social interactions necessary for egg-laying as a result of the absence of brood stages killed by the morphogenetic action of the IGR.
5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)	
	PT18	2 × 3.5g baiting stations containing 0.5% (w/w) S-Methoprene are applied per 20 m ² .
5.4	Mode of action (including time delay) (IIA5.4)	
5.4.1	Mode of action	S-Methoprene is an insect growth regulator acting as a juvenile hormone mimic to disrupt the normal development of insects.

Section A5 **Effectiveness against target organisms and intended uses**

5.4.2	Time delay	Extermination of the colony should occur within 12 – 14 weeks.
5.5	Field of use envisaged (IIA5.5)	
	MG03: Pest control	PT 18 Insecticide
	Further specification	Ant bait
5.6	User (IIA5.6)	
	Professional	Product to be placed indoors next to the foraging routes of worker ants.
	General public	Product to be placed indoors next to the foraging routes of worker ants.
5.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)	
5.7.1	Development of resistance	S-Methoprene is not known to select resistance mechanisms in target organisms.
5.7.2	Management strategies	See point 5.7.1.
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	See Document III, Appendix 2 Business Confidential Information.

Section A5 **Effectiveness against target organisms and intended uses**

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11 th December 2007
Materials and methods	N/A
Conclusion	S-methoprene inhibits the egg-laying capacity of Pharaoh ant Queens leading to the eventual elimination of the colony at the end of the ant's life cycle. The IE CA considers the data to be acceptable for Annex I inclusion.
Reliability	The information provided is considered to be reliable.
Acceptability	The studies/information provided are considered to be acceptable. Robust study summaries where the effectiveness of s-methoprene has been satisfactorily demonstrated are provided in Document IIIB.
Remarks	At the authorisation stage a comprehensive data set will be required to demonstrate what resistance mitigation measures and testing regimes are in place.
	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 5.3: Summary table of experimental data on the effectiveness of S-Methoprene against target organisms

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>) Females, workers eggs, larvae, pre-pupae and pupae	Six colonies were exposed to PROTECT-B bait containing 0.5% S-Methoprene in Petri dishes which were 20 cm in diameter and covered in glue to prevent the escape of ants. Colonies contained 3 – 6 females, 80 – 120 workers and 50 – 70 eggs, larvae, pre-pupae and pupae. Petri dishes contained egg yolk, flies and water which were replenished twice daily.	Experimental colonies were treated over a 10 – 18 week period (13.7 weeks on average) with one bait box per Petri dish.	All six experimental colonies, exposed to PROTECT-B, were destroyed within 10 – 18 weeks. On day 3, ants were observed carrying the bait material to their nests. It was observed, on subsequent days, that the proportion of the bait in the nest increased while common food and the size of the nest decreased gradually. On day 7, no eggs were observed in the nest. As the developmental cycle progressed, the number of larvae and pupae decreased. This is due to females losing their ability to produce viable eggs and the development of stage-3 larvae being interrupted in parallel so that new generations do not develop.	Kocisova, A. (2001)
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	Colonies were exposed to PROTECT-B ant killer bait containing 0.5% S-Methoprene in a three storey building. The building contained 15 flats composed of brick and reinforced concrete located in the sub-basement, ground floor, first, second and third floor. Flat infestation levels varied from lightly to heavily infested.	Pharaoh ants were treated with the bait at a rate of 2 x 2g/20 m ² or 4 x 2g/20 m ² over a 12 week period. To assess the need for preliminary and final spraying prior to and following treatment with Protect-B, 6 flats were subjected to preliminary spraying with Protect-B household spray and a final spray, following bait treatment, with Protect-B cockroach	A bait dose of 2 x 2g/20 m ² is effective in controlling Pharaoh ants. By week 5, five flats were no longer infested while by week 12, ants were completely eliminated. Interviews conducted 6 weeks after final spraying revealed there were no Pharaoh ants in the building. Preliminary spraying is considered unnecessary as baits placed in flats which did not undergo preliminary spraying were as effective in controlling ants as those in which preliminary spraying was undertaken. Final spraying may provide protection against re-infestation (while it remains effective) and kill the few worker Pharaoh ants that may remain in the building.	Tajti, L. and Dudas, E. (1997)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*
					and ant killer aerosol		
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	Colonies were exposed to PROTECT-B ant killer bait containing 0.5% S-Methoprene in pantries of several student hostels at a university campus in Malaysia in which sanitary conditions were evaluated as being moderate to poor. Ant counts in flats prior to treatment ranged from 157.7 to 168.7%.	Three partially exposed sachets of PROTECT-B were placed at various locations within the pantries where ant trails were visible pre-sampling. Ants were exposed to the ant bait over a 12 week period.	Within 4 weeks of treatment with PROTECT-B granular ant bait, a reduction in ant numbers of > 87.6% was observed with complete elimination of by week 8. Such results were still evident by week 12. It was found that the granular formulation of Methoprene enhanced the distribution of toxicant from foraging workers to immature stages (compared to the reference paste formulation of hydramethylnon bait) as solid food is only ingestible by the larvae. In return the larvae regurgitated partially digested food to the workers to be distributed among colony members. This process possibly caused an inhibitory effect on the population growth thus eliminating the colony slowly. In addition, Methoprene possibly acted like pyriproxyfen, another bait incorporated with IGRs, which affected not only the larvae and pupae stages but also reduced egg production of queen thus decreasing number of workers produced in a longer period.	Lee C.Y. (2001)
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	Colonies were exposed to PROTECT-B ant bait containing 0.5% S-Methoprene in a high rise housing block containing 34 flats. Each flat was heavily infested.	The number of baits used per flat varied from 14 to 4. A total of 213 baits were placed throughout the building, in areas of recorded ant activity, as close as possible to existent trails over a 4 month period.	The first 2 months of treatment with PROTECT-B revealed no change, to the "naked eye", in the level of infestation. Following 3 months of treatment, ant numbers began to decrease significantly and by month 4, only isolated occurrences of ants were observed. In several flats ant queens were observed displaying distinct disoriented behaviour. Rather than moving in their usual purposeful and straightforward manner, they crawled in circles, changing direction occasionally and proceeding hesitantly, clearly uneasy as there were no apparent trails to guide them. Observations made two months after treatment had finished indicated that 100% control was provided with no ants observed.	Lachmuth, U. (1999)
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	Pharaoh ants were treated with the bait PROTECT-B containing	Five different baits were used in the first and third baited	Adult and brood size remained large for the first two months of the study. During the third month, brood size began to decrease with no brood observed in one brood	Gaynor, W.J. (2001)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*
			Brood, queens and workers	<p>0.5% S-Methoprene in a laboratory experiment in which three ant colonies were individually placed in two stacked plaster of paris chambers which were placed in a plastic container coated in Fluron® to prevent ants from escaping and placed on a metal tray filled with water to act as a further deterrent.</p> <p>The bait was placed in the corner of the plastic chamber opposite the food and water supply.</p>	containers and four baits were used in the second baited container. Ants were treated over an 18 week period.	<p>chamber, a very small amount observed in the second chamber and a more significant amount in the third. During the fourth month, brood size continued to decrease in the baited containers until none were observed in two of the brood chambers with only a small amount were observed in the third.</p> <p>Overall counts of dead ants removed from the baited containers (2120) was greater than those removed from the control containers (1290).</p> <p>Decreases in bait weight ranged from 0.02 g to 1.89 g.</p>	
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	<p>Pharaoh ants were treated with the bait Faratox-Babolna containing 0.5% S-Methoprene in the rooms of 38 flats in an apartment block. Flats were positioned in a vertical row in which at least one resident had Pharaoh ants in the flat. The bait was delivered in the form of two bait station types (bait station A with one inlet or bait station B with one inlet and outlet).</p> <p>The initial level of infestation was such that single workers were observed everyday.</p>	The number of baiting stations ranged from 2 to 5 (with an average of 3.3) per flat in the first inspection and 1 to 6 (with an average of 2.4) in the second inspection. Ants were treated over a 20 week period.	Faratox-Babolna provided 100% control of Pharaoh ants following treatment over a 20 week period. Methoprene contained in the baits killed developing larvae and prevented adult ants from emerging from the pupal stage. It also sterilised queens thus preventing the supply of new workers and causing colonies to deteriorate slowly.	Doniec, J. (1996)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>) Brood, queens and workers	The efficacy of BIOPRENE ant bait containing 0.5% S-Methoprene was investigated in a plastic chamber furnished similarly to a breeding chamber and coated with Fluon-PTFE to prevent ants from escaping. A hollowed beech-wood ant nest was placed in the chamber with three feeding dishes containing sugar, fresh dead cockroaches and finely ground dried dog food, placed at equal distances from the ant nest. Colonies consisted of several queens, 200 - 300 workers and several progenies.	Ants were treated over a 13 week period with one bait per chamber.	<p>The number of queens in the nest increased for the first three weeks, but began to decrease from the fourth week. Numbers remained stable for a number of weeks but again began to decrease in the eight week as they left the nest and spread in the chamber. By the twelfth and thirteenth week of the experiment, just one queen was observed. The number of queens in the nest ranged from 4 at study initiation to 1 at study termination.</p> <p>Worker numbers increased during the first and second week but began to gradually decrease from the fourth week. From the eighth week, more straggling workers were observed outside of the nest as pupae and larvae diminished. Worker numbers ranged from 250 at study initiation to just 1 at study termination.</p> <p>During the first three weeks of the experiment, no changes in pupae and larvae conglomerates were noted. However, by week three they began to decrease and were completely eliminated by week seven.</p>	Schmidt, J. and Szilágyi, J. (2004)
Insecticide	MG03	S-Methoprene	Pharaoh ants (<i>Monomorium pharaonis</i>)	Pharaoh ants were treated with PROTECT-B Pharaoh's Ant Killer Bait containing 0.5% S-Methoprene in kitchens and other rooms equipped with plumbing within a number of flats located in houses in Poland, Switzerland and Hungary.	Ants were treated with six to ten ant baits in each flat over 5 months in Poland and Switzerland and 3 months in Hungary.	<p>In Poland worker ants were found to be considerably reduced by week two and completely eliminated by week ten while in Switzerland ant numbers began to decrease significantly from the third month of the study with complete elimination by the fifth month. In Hungary, ant populations began to decrease in the fourth week with a sharp decrease observed in the ninth week and complete elimination by week 12.</p> <p>In Switzerland and Hungary, queens were observed which showed distinct disorientated behaviour. They crawled in circles, frequently changing direction without displaying the usual purposeful straightforward movement. They proceeded hesitantly, unable to find apparent trails to guide them.</p>	Urbán, A. and Varjas, L. (1999)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*
						PROTECT-B Pharaoh's Ant Killer Bait was readily consumed and carried into the nest by ant workers. The interest of ants in visiting the bait slightly decreased after the third to fourth week; however, this did not influence the success of the bait in eliminating Pharaoh ants.	

* References:

- 1) Doniec, J. (1996), Results of field investigation of Pharaoh ants (*Monomorium pharaonis*) in Poland in 1995 – 1996, Bábolna Bioenvironmental Centre Ltd.
- 2) Gaynor, W.J. (2001), Efficacy evaluation of a methoprene-based bait against the pharaoh ant, Bábolna Bioenvironmental Centre Ltd.
- 3) Kocisova, A. (2001), Insecticidal effectiveness of PROTECT-B bait against Pharaoh ants (*Monomorium pharaonis* L.), Bábolna Bioenvironmental Centre Ltd.
- 4) Lachmuth, U. (1999), Treatment against *Monomorium pharaonis* with PROTECT-B pharaoh ant killer granular bait, Bábolna Bioenvironmental Centre Ltd.
- 5) Lee C.Y. (2001), Field performance of a methoprene granular bait against Pharaoh ants *Monomorium pharaonis*, Bábolna Bioenvironmental Centre Ltd.
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- 7) Tajti, L. and Dudas, E. (1997), Final report on field experiment on Protect-B Pharaoh ant killer bait, Bábolna Bioenvironmental Centre Ltd.
- 8) Urbán, A. and Varjas, L. (1999), Efficacy of Protect-B ready-to-use Methoprene based Pharaoh ant killer bait under field conditions, Bábolna Bioenvironmental Centre Ltd.