Competent Authority Report

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

Cyphenothrin (PT 18)

CAS-No. 39515-40-7

Sumitomo Chemical (U.K.) PLC

DOCUMENT III-A

Study summaries

Section A5

Effectiveness section

Rapporteur: Hellas

November 2017

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)	Cockroaches, fleas, ants, spiders, flies mosquitoes, wasps, bed bugs and house ticks	X
5.2.2	Products, organisms or objects to be protected (IIA5.2)	Protects homes and public buildings; the products control nuisance and disease transmitting pests	
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)	Insect death following contact. See section 5.4.1 Mode of Action	X
5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)	Ready to use aerosols – 0.3% w/w Emulsifiable concentratre : 5% w/v in the concentrate 0.5 – 2 g/l in dilution through a sprayer	X
	PT18		
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	Mode of action	Cyphenothrin affects the nervous system of insects that causes pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of nerve membranes in insects and other invertebrates.	
5.4.2	Time delay	Knockdown is almost instantaneous.	
5.5	**Field of use envisaged (IIA5.5)**		

	MG03: Pest control	PT 18 – Insecticide for the control of flying and crawling insects	X
	Further specification	For professional use only	
5.6	**User (IIA5.6)**		
	Industrial	None	
	Professional	Professional Pest Control Operators to apply a ready to use aerosol or as an emusifiable concentrate diluted with water or kerosene applied through a knapsack/power sprayer or via a ULV applicator	X
	General public	None	
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

X

Cyphenothrin is a pyrethroid insecticide used only indoors by professional users; therefore its resistance status in the general pest population has not been widely investigated. It is a synthetic pyrethroid, with the same mode of action as other members of the group, so is anticipated to be subject to the same pressures regarding the potential development of resistance as the other synthetic pyrethroids.

A review by the WHO of Vector Resistance to Pesticides (Anon. 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread. Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2003), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).
Resistance is considered unlikely to occur as a result of the proposed uses of cyphenothrin. As a result of the scale of the proposed uses the proportion of the target population treated is small and selection pressure for the development of resistance is consequently low. No adverse effects on performance attributable to the development of resistance have been recorded during commercial use in Japan.

Staetz	2004	Insecticide Mode of Action Classification: A Key to Insecticide Resistance Management (v.3.3.2) Insecticide Resistance Action Committee (IRAC International), 2004
Brogdon & McAllister	1998	Insecticide Resistance and Vector Control Emerging Infectious Diseases; Vol. 4 No. 4, December 1998. http://www.cdc.gov/ncidod/EID/vol4no4/brogdon.htm

5.7.2 Management strategies

X

The principles of strategies for managing the development of resistance are similar for cyphenothrin as they are for other synthetic pyrethroids;

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- applications should always be made against the most susceptible stages in the pest life cycle
- where an extended period of control is required, treatments should be alternated with products with different modes of action
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	Likely tonnage is indicated in the Confidential Document enclosed as Appendix I.	X

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2017
Materials and methods	**5.2.1** According to the submitted efficacy studies the representative products Pesguard LG OBA and Gokilaht 5EC have been tested against cockroach, ant, bedbug and flea species. However, spiders, flies, mosquitoes, wasps and ticks were not tested in the efficacy studies with the representative products, and therefore cannot be included included among target pest organisms of cyphenothrin. **5.3.2** It is stated that the likely concentrations at which the a.s. will be used are 0.5 – 2 g/l in dilution through a sprayer. However, considering the submitted efficacy studies with Gokilaht 5EC, the proposed concentrations for a.s. are: 1 - 1.25 gr as/lt in dilution with water and applied through a low pressure sprayer. **5.4.1** It could be added that cyphenothrin is a synthetic pyrethroid insecticide with contact and stomach action (Pesticide Manual, 13th edition). **5.2.1, 5.3.1 & 5.5** According to study B5.10/01, Gokilaht 5EC proved to be effective killing agent against German and American cockroaches by surface residual spray onto non-absorbent surfaces (e.g. overlaid plywood) for up to 12 weeks at a rate of 0.0625 gr a.i/ m^2. Moreover, Gokilaht 5EC proved to be effective as knockdown and killing agent against German cockroaches at 125 ml product diluted in water in 5 lt hand-held applicators for spraying 100 m^2 surfaces (equivalent to 0.0625 gr a.i./m^2). According to study B5.10/02, Gokilaht 5EC proved to be effective against black garden by directed spray onto the insects at 1 ml product diluted in 50 ml water for spraying 1 m^2 (equivalent to 0.05 gr a.i./m^2). Hence, based on the results of studies B5.10/01 and B.5.10/02 with Gokilaht 5EC, cyphenothrin proved to be effective as direct spray against German cockroaches and surface residual spray (including crack and crevice treatment) against German and American cockroaches at 0.0625 gr a.i./m^2, and direct spray against black garden ants at 0.05 gr a.i./m^2. In 2016, the applicant provided two new efficacy studies, a field study (B5.10.2/08) and a laboratory study (B5.10.02/09), with the representative product Pesguard LG OBA in order to support the new/revised intended use of the product, namely indoor application by professionals as surface spot, crack and crevice treatment at 6.6 gr product/m^2 against German cockroaches (*Blattella germanica*), bed bugs (*Cimex lectularius*) and cat fleas (*Ctenocephalides felis*). Since Pesguard LG OBA contains two active substances (0.3% cyphenothrin and 0.1% imiprothrin w/w), the laboratory study was also provided to prove the innate effect of cyphenothrin as indoor spot, crack and crevice treatment at 6.6 g Pesguard LG OBA/ m^2. These studies were discussed in Efficacy WG-I 2017 (early discussion) and as a

follow up in Efficacy WG-III 2017. The EFF WG-III agreed with the evaluation made by the eCA for both efficacy studies.

In the laboratory study B5.10.02/09, tests were conducted using Pesguard LG OBA and Pesguard LG OBA containing only cyphenothrin as active substance at 0.3% or 0.1% (without imiprothrin) by increasing the content of one solvent in order to replace imiprothrin. A series of bioassays were performed to assess the direct and residual efficacy of Pesguard LG OBA (0.3% cyphenothrin and 0.1% imiprothrin w/w), New Formulation (High Level) (0.3% cyphenothrin w/w) and New Formulation (Low Level) (0.1% cyphenothrin w/w) against German cockroaches (*Blattella germanica*), bed bugs (*Cimex lectularius*) and cat fleas (*Ctenocephalides felis*) in terms of knockdown and mortality.
For the direct spray efficacy evaluation, the tested products were applied at a single rate of approximately 0.15g directly onto the insects in a container from a height of approximately 30cm. For the residual efficacy evaluation, treatments were applied directly onto ceramic (non-porous) and plywood (porous) surfaces at a rate of 6.6g per m^2.
In terms of direct spray, all tested products resulted in 100% knockdown within 30 minutes and 100% mortality 2-3 days post treatment for all test species.
Following exposure of cockroaches to Pesguard LG OBA and New formulation 0.3% on treated plywood aged up to 3 months, residual treatments showed low levels of mortality + knockdown (0-40%). However, contact of cockroaches with Pesguard LG OBA and New formulation 0.3% on treated ceramic substrates aged 1 and 2 days resulted in 80-95% mortality.
Following contact of bedbugs with Pesguard LG OBA and New formulation 0.3% on treated plywood aged 2 days, there were 97% affected (51% knocked down + 46% dead) and 100% affected (67.5% knocked down + 32.5% dead) insects, respectively. Contact of bedbugs on ceramic 1 and 2 day aged deposits resulted in 100% mortality of bed bugs.
Following contact of fleas with Pesguard LG OBA and New formulation 0.3% on treated plywood aged 1 day to 3 months, low levels of efficacy were observed, thus 0-10% knocked down and 5-38% dead insects. Contact of fleas on the ceramic 1 and 2 day aged deposits resulted in 100% mortality of fleas. Contact of fleas with Pesguard LG OBA and New formulation 0.3% on treated ceramic tiles aged 1 week resulted in 64% and 85.9% mortality, respectively.

Based on the results of study B5.10.02/09, the representative product Pesguard LG OBA and New formulation containing 0.3% cyphenothrin proved to be effective against German cockroaches, bedbugs and fleas as direct treatment onto the insects and surface treatment at 6.6 g product /m^2 when applied on non-porous surfaces with a residual activity of 1-2 days post treatment.
This study proves also innate effect of cyphenothrin at 6.6 g Pesguard LG OBA/m^2 (0.0198 g cyphenothrin/ m^2) as a spot, crack and crevice treatment against German cockroaches, bedbugs and fleas for Union-List inclusion purposes. At product authorization stage additional data should be required to support efficacy of the biocidal products in terms of duration of residual effect, residual effect on porous surfaces and field studies with spot, crack and crevice treatment against claimed target organisms.

5.6
It is stated that cyphenothrin will be applied by PCOs in emusifiable concentrate formulations diluted with water or kerosene applied through a knapsack/power sprayer or via a ULV applicator. However, in the submitted efficacy studies the supportive biocidal product Gokilaht 5EC has not been tested with ULV applicators and therefore ULV method of application of cyphenothrin cannot be

included. Additionally, Gokilaht 5EC has not been tested in formulations after dilution with kerosene, and therefore dilution of cyphenothrin formulations with kerosene is not recommented.

5.7.1

According to [redacted] some cases of resistance of housefly adults on cyphenothrin have been reported.
Moreover, there is reason to expect resistance development in insects (e.g. cockroaches and ants), in particular when cyphenothrin is used as surface treatment because of the persistent activity on surfaces over time. The selection pressure can be high and continuous use of the a.s. may lead to resistance in due time.

Therefore, the conclusion that" Resistance is considered unlikely to occur as a result of the proposed uses of cyphenothrin" has no sound justification and most likely will prove incorrect in time.

[redacted] The status and seasonal changes of organophosphate and pyrethroidresistance in Turkisl house fly, Musca domestica L. (Diptera: Muscidae). Journal of Vector Ecology. 31: (1): 58-64.

5.7.2

There is reason to expect resistance development in insects, when the a.s. is used in particular because of the persistent activity on surfaces over time. The selection pressure can be high and continuous use of the a.s. may lead to resistance in due time. Alteration with products based on other a.s. is probably the best way to avoid resistance development.
So, the phrase "Because of the anticipated low level of selection pressure from the proposed uses, no specific strategy for management of the development of resistance is required" will be removed.
According to the Arthropod Pesticide Resistance Database provided by IRAC (http://www.pesticideresistance.org/search.php) some resistance cases of cyphenothrin have been reported against houseflies (*Musca domestica*) and whiteflies (*Bemisia tabaci*). Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocide uses of cyphenothrin.

5.8

Likely tonnage is indicated in Confidential Doc-IIIA, section A5 Efficacy.

Conclusion	Applicant's version is adopted considering the comments written above
Reliability	The reliability indicator for all efficacy studies with Pesguard LG OBA is considered to be 1, apart from study B5.10.2/06, which is proposed to be 2. The reliability indicator for the efficacy studies with the Gokilaht 5 EC is considered to be 2.
Acceptability	All efficacy studies with the representative products (Pesguard LG OBA and Gokilaht 5 EC) are acceptable
Remarks	None
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 5.3: Summary Table of Experimental Data on The Effectiveness of The Active Substance Against Target Organisms At Different Fields Of Use Envisaged, Where Applicable

	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [] Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	All efficacy data have been conducted with the formulations and are included in the respective Documents IIIB.	
Undertaking of intended data submission [ ]		
	EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A10 – Summary and Evaluation of Sections 2 to 9

10.4 Section A5 Effectiveness against Target Organisms and Intended Uses

Function
Insecticide PT 18: For the control of crawling insects

Field of use envisaged
For use by professional pest control operators, in ready to use aerosols or as an emusifiable concentrate diluted with water and applied through a knapsack/power sprayer applicator.

Effects on target organisms
Cyphenothrin kills insects by affecting the nervous system of insects to cause pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of nerve membranes in insects and other invertebrates.