

**Section A5.3/01**  
**Annex Point IIA5.10**  
**TNsG: Pt. I-A5.10,**  
**Pt. III-Ch. 6**

**Efficacy Data**  
**Laboratory Direct Spray Test**

		Official use only
<b>1 REFERENCE</b>		
<b>1.1 Reference</b>	<p>██████████ Biological efficacy of imiprothrin oil-based aerosol formulation against cockroaches. Sumitomo Chemical Co., Ltd, Agricultural Chemicals Research Laboratory, 4-2-1, Takatsukasa, Takarazuka-shi, Hyogo, Japan. ██████████</p> <p>Experimental test dates: 10 July 1989 to 29 July 1989.            English report issue: 20 December 1996.</p>	
<b>1.2 Data protection</b>	Yes	
1.2.1 Data owner	Sumitomo Chemical Co. (SCC) Ltd, Japan	
1.2.2		
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
<b>1.3 Guideline study</b>	<p>No</p> <p>One methodology was followed, this was designed to show knockdown and toxicity after direct spray. The test was based on Sumitomo's own technical test methodology.</p> <p>Although the test method was not specifically based on any standard test guideline the basic test procedure was acceptable when compared with the following method and the test design is considered valid and acceptable.</p> <p>PSD Efficacy Guideline 207: Hand Held Aerosols and Ready to use Sprays against Crawling Insects (March 2000)</p>	X
<b>1.4 Deviations</b>	<p>Deviation when compared to the PSD test method are listed below.</p> <p>Deviations from PSD Guideline 207</p> <p>No batch number of test product was recorded.            Spray deposit in mg was recorded but spray times were not presented.            No untreated control was included in the test.            No analytical check was made on the test formulation.            No details were presented for the inert compounds in the commercial reference products.</p> <p>These deviations are not considered to have affected the validity of the test method used.</p>	X
<b>2 METHOD</b>		
<b>2.1 Test Substance</b>	Imiprothrin : 0.05, 0.1, 0.2 and 0.4% w/w oil-based aerosol as given in section 2	
2.1.1 Trade name/ proposed trade name	Not applicable	

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2.1.2	Composition of Product tested	% w/w [REDACTED]	X
2.1.3	Physical state and nature	Liquid (oil-based formulation) applied as aerosol spray.	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Not applicable	
2.2	<b>Reference substance</b>	d-tetramethrin aerosol: d-tetramethrin 0.25, 0.5, 1.0 and 2.0% w/w [REDACTED]	X
2.2.1	Method of analysis for reference substance	Not applicable	
2.3	<b>Testing procedure</b>		
2.3.1	Test population / inoculum / test organism	Given in Table A5.3/01-1.1	X
2.3.2	Test system	Given in Table A5.3/01-1.2	
2.3.3	Application of TS	Given in Table A5.3/01-1.3	
2.3.4	Test conditions	Given in Table A5.3/01-1.4	
2.3.5	Duration of the test / Exposure time	Direct spray: Knockdown over 20 minutes Mortality after 72 hours	
2.3.6	Number of replicates performed	Five	
2.3.7	Controls	No untreated control included in test design. A d-tetramethrin aerosol product was tested as a representative standard reference compound, containing various concentrations of d-tetramethrin (0.25, 0.5, 1.0 and 2.0% w/w).	X
2.4	<b>Examination</b>		
2.4.1	Effect investigated	Knockdown Kill	
2.4.2	Method for recording / scoring of the effect	Knockdown was recorded by counting the number of immobilised cockroaches over the specified time period. Mortality was assessed by counting the number of dead cockroaches	

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- after a set time.
- 2.4.3 Intervals of examination Knockdown assessed over 20 minutes, at 0.2, 0.3, 0.5, 0.7, 1.0, 1.5, 2.0, 3.0, 5.0, 7.0, 10, 15 and 20 minutes for the German cockroach, and at 0.7, 1.0, 1.5, 2.0, 3.0, 5.0, 7.0, 10, 15 and 20 minutes for the American cockroach.  
Mortality was recorded after 72 hours.
- 2.4.4 Statistics Bliss probit method
- 2.4.5 Post monitoring of the test organism Yes  
Mortality was assessed after 72 hours.

### 3 RESULTS

3.1 Efficacy	Concentration			
	%w/w	KT <sub>50</sub>	KT <sub>90</sub>	%Kill
German cockroach	0.05	1.1	2.2	14
	0.1	0.62	1.4	34
	0.2	0.45	0.95	64
	0.4	0.35	0.79	96
American cockroach	0.05	>20	>20	7
	0.1	8.5	>20	3
	0.2	3.6	15	43
	0.4	2.2	7.2	67

- KT<sub>50</sub> and KT<sub>90</sub> times are in minutes.
- 3.1.1 Dose/Efficacy curve Not reported.
- 3.1.2 Begin and duration of effects Knockdown of the German cockroaches - a maximum KT<sub>50</sub> value of 1.1 minutes for the 0.05% w/w treatment after direct spray.  
Knockdown of the American cockroaches - KT<sub>50</sub> values of 2.2 to >20 minutes after direct spray.  
Mortality was 96% in German cockroaches and 67% in American cockroaches within 72 hours at the top concentration of imiprothrin (0.4% w/w).
- 3.1.3 Observed effects in the post monitoring phase None recorded other than mortality.
- 3.2 Effects against organisms or objects to be protected Not applicable.
- 3.3 Other effects None observed.

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3.4	Efficacy of the reference substance	<u>d-Tetramethrin:</u>	Concentration			
			% w/w	KT <sub>50</sub>	KT <sub>90</sub>	%Kill
		German cockroach	0.25	2.6	7.4	6
			0.5	1.3	3.1	14
			1.0	0.65	1.6	70
			2.0	0.54	1.2	100
		American cockroach	0.25	>20	>20	7
			0.5	>20	>20	0
			1.0	14	>20	23
			2.0	5.4	>20	57
		KT <sub>50</sub> and KT <sub>90</sub> times are in minutes.				
3.5	Tabular and/or graphical presentation of the summarised results	Data given in Tables A5.3/01 - 1.5 and A5.3/01 - 1.6				X
3.6	Efficacy limiting factors					
3.6.1	Occurrences of resistances	None No evidence was seen from the test results to indicate the occurrence of resistance. For further information on the possible occurrence of resistance see Section IIA5.7.				
3.6.2	Other limiting factors	None				
<b>4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS</b>						
4.1	Reasons for laboratory testing	A basic laboratory test was performed to demonstrate knockdown and kill effects of direct spray. This data could not be generated in a controlled manner under field test conditions.				
4.2	Intended actual scale of biocide application	Not applicable				
4.3	Relevance compared to field conditions					
4.3.1	Application method	Imiprothrin is intended as a spot, crack and crevice treatment with application by aerosol spray. Aerosol spray application was used in the test, giving direct spray to the insect.				X

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4.3.2	Test organism	Imiprothrin aerosol will be used against cockroaches. The German cockroach ( <i>Blattella germanica</i> ) is a key indicator test species for efficacy against cockroaches. The much larger American cockroach, <i>Periplaneta americana</i> , gives a good indication of effects against less sensitive species. Both species are potential target species under field use.
4.3.3	Observed effect	Rapid knockdown and kill effects after direct spray to the insect were observed in this test and are required efficacy properties for the treatment of cockroach infestation under field conditions. Rapid knockdown prevents the insects from escaping before picking up an effective dose.
4.4	Relevance for read-across	Not applicable
<b>5 PARTICIPANT 'S SUMMARY AND CONCLUSION</b>		
5.1	Materials and methods	<p>Direct spray test, methodology described in report.</p> <p>Imiprothrin oil-based aerosol was tested against German and American cockroaches in a direct spray test. Cockroaches were placed in a plastic container (14 cm diameter and 7 cm high) with a wire net base. The container was placed in the bottom of a glass cylinder (20 cm in diameter and 60 cm in height). Spray application was made from the top of the cylinder and a lid added. After 30 seconds the cockroaches were removed and knockdown was observed over the following 20 minutes. Cockroaches were then transferred to clean containers and mortality was assessed after 72 hours.</p> <p>German cockroach, <i>Blattella germanica</i>: 5 male and 5 females per replicate were tested using 200 mg spray.</p> <p>American cockroach, <i>Periplaneta americana</i>: 5 male and 5 female were tested per replicate using 450 mg spray.</p>
5.2	Reliability	<p>█</p> <p>Only endpoint data was summarised and no replicate data was presented.</p>

X

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**5.3 Assessment of efficacy, data analysis and interpretation**

Imiprothrin oil-based aerosol had a rapid knockdown effect, especially against the German cockroach (*Blattella germanica*). Results for both species compared favourably with those for the reference synthetic pyrethroid d-tetramethrin, with quicker knockdown times observed at lower concentrations.

The 3-day mortality data indicate that imiprothrin has a limited killing efficacy at the lower concentrations, while knockdown at this dose was very efficient in comparison with the reference d-tetramethrin.

The results demonstrate a clear dose reponse, with an increase in concentration of Imiprothrin from 0.05% to 0.4% w/w directly resulting in decreased knockdown times and greater killing efficacy.  $KT_{50}$  values decreased from 1.1 to 0.35 minutes for the German cockroach and from >20 to 2.2 minutes for the American cockroach as the Imiprothrin concentration increased.

Section 9.2.2 (Laboratory studies) of TNsG for Annex I Inclusion (Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002) states that the efficacy of an active substance may be demonstrated by a "screening" laboratory test using either the undiluted active substance, the active substance in a solvent carrier or the active substance presented in a simple formulation. In this study, the efficacy of Imiprothrin was demonstrated using the active substance presented in a simple oil-based formulation. The dose response achieved in the study, confirms that Imiprothrin was the active insecticidal ingredient in the oil-based spray formulation, as the efficacy against cockroaches was dependent on the Imiprothrin concentration. Furthermore, the differences in efficacy against cockroaches occurred whilst the concentrations of the other ingredients (deodorised kerosene, alkylbenzene, LPG) remained constant.

**5.4 Conclusion**

Imiprothrin in a simple oil-based aerosol was tested at a range of concentrations (0.05 to 0.4% w/w) by direct spray against German, *Blattella germanica* and American, *Periplaneta americana* cockroaches. Imiprothrin oil-based aerosol had a rapid knockdown effect, especially against the German cockroach (*Blattella germanica*). Results for both species compared favourably with those for the reference synthetic pyrethroid d-tetramethrin, with quicker knockdown times observed at lower concentrations.

When applied in a simple oil-based aerosol spray at a range of concentrations in a direct spray laboratory test, Imiprothrin demonstrated the insecticidal properties required for use as an effective cockroach control treatment.

**5.5 Proposed efficacy specification**

Imiprothrin will be used as a spot crack and crevice treatment against cockroaches.

**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

**EVALUATION BY RAPPORTEUR MEMBER STATE**

Date

11/05/07

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**Materials and Methods**

Participant's version is considered acceptable noting the following:

**2.1.2** The active substance is not present in water or a simple solvent solution. The Participant has provided a justification for this. The UK CA accepts that the deodorised kerosene is acting as a carrier and the LPG as a propellant, but no explanation has been provided for the role of the alkylbenzene, which makes up the balance of the solution. However, the Participant's explanation is that increased effects (decreasing  $KT_{50}$  values) are seen as the concentration of imiprothrin increases, whilst the other ingredients remain constant (with the exception of alkylbenzene, which decreases slightly to allow for the increase in a.s. concentration. The UK CA can therefore accept this justification for the a.s. being present in an oil-based aerosol and not a simple water or solvent carrier. However, the Participant was asked to provide a justification for the lack of an untreated control (so synergistic effects could be discounted). This consisted of a literature search, confirming that the non-active ingredients in the formulation did not have any biocidal effects. This was acceptable to the UK CA.

**2.2** The non-active ingredients for the reference substance differed from the test substance. The composition for the reference substance did not contain alkylbenzene and deodorised kerosene was used as the balance material to make the formulation up to 100 %.

**2.3.1** Blattela should read Blattella in Table A5.3/01 1.1.

**2.3.7** The Participant states that no untreated control was included in the test design. However, as the UK CA has accepted the above justification, no further testing will be requested.

**5.1** The number of *P. americana* used in the test was not 5 males and 5 females, but 3 males and 3 females.

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**Results and Discussion**

Participant's version is considered acceptable noting the following:

**3.5** There was 100 % knockdown after 20 mins of *B. germanica* using both imiprothrin and the reference substance at each concentration. However, mortality of *B. germanica*, when using imiprothrin, was between 14 and 96 % after 72 h. Therefore, the UK CA notes these results suggest that recovery has occurred. There was only 4 % recovery at the highest test concentration (0.4 % w/w) and the UK CA notes that the a.s. will be used in a product at 0.5 % w/w, and so assumes that negligible recovery will occur.

Knockdown of *P. americana* was between 47 and 97 % at 20 mins for the 4 concentrations. However, mortality at 72 h was between 3 and 67 %. This meant that recovery again took place. At the highest concentration (0.4 % w/w), 30 % recovery occurred. As knockdown is only a short term reversible effect, this is not a high consideration for efficacy. Efficacy is more concerned in mortality as an innate effect.

In Table A5.3/01 1.6, *Peripanta* should read *Periplaneta*.

**4.3.1** Application was by aerosol spray directly onto the insect. This is not simulating how it will actually be used when formulated (spot, crack and crevice treatment). However, the UK CA accepts that innate efficacy has been demonstrated and that is all that is needed for the a.s..

The UK CA considers the test method to be acceptable. The efficacy template does not require the Participant to state a number for the reliability indicator. However, although the study was not conducted according to a formal internationally accepted test standard, the methodology used and the reporting of the results are considered acceptable. Therefore, the UK Competent Authority considers the reliability indicator to be 2 (see below) due to some reporting deficiencies.

**Conclusion**

Participant's version is considered acceptable.

**Reliability**

■

**Acceptability**

Acceptable

**Remarks**

**1.3** The Participant states that no guideline was followed. The UK CA considers this to be acceptable because efficacy studies are not required to be conducted to guidelines.

**1.4** The Participant has stated that there were deviations when the method used was compared to a recognised guideline. The UK CA does not have any concerns about these deviations for the reason stated above.

Innate efficacy of the a.s has been shown against *B. germanica*, one of the target species, which is acceptable for Annex 1 inclusion to be recommended.

All data and endpoints presented in the study summary have been checked against the original study and are correct.

The full list of intended uses of the representative product and active substance have been included in Document I, Section 2.1.2 and Document I, Appendix II.

**Date**

**COMMENTS FROM ... (specify)**

*Give date of comments submitted*

**Comments**

*Discuss if deviating from view of rapporteur member state*

**Summary and conclusion**

*Discuss if deviating from view of rapporteur member state*

Tables for Method

**Table A5.3/01-1.1 Test organism**

Criteria	Details
Species	<i>Blattella germanica</i> German cockroach <i>Periplaneta americana</i> American cockroach
Strain	Insecticide susceptible strain
Source	Sumitomo Chemical Co. Ltd in house laboratory culture
Laboratory culture	yes
Stage of life cycle and stage of stadia	<i>B. germanica</i> = adults (10-20 days old) <i>P. americana</i> = adults (3-6 weeks old)
Mixed age population	No - only adults were tested
Other specification	50:50 male:female
Number of organisms tested	400 German cockroach 240 American cockroach
Method of cultivation	Not specified
Pre-treatment of test organisms before exposure	None
Initial density/number of test organisms in the test system	Ten German cockroaches (5 male + 5 female) or six American cockroaches (3 male + 3 female) per container.

**Table A5.3/01-1.2 Test system**

Criteria	Details
Culturing apparatus / test chamber	Glass cylinder (20 cm diameter and 60 cm height) Plastic container (14 cm diameter and 7 cm height) with a wire net at the bottom The plastic container containing the cockroaches was placed at the centre of the bottom of the glass cylinder and application made from the upper end of the cylinder.
Number of vessels / concentration	Five replicates per species
Test culture media and/or carrier material	Applied directly to the cockroaches
Nutrient supply	Not applicable
Measuring equipment	Not applicable

Table A5.3/01-1.3 Application of test substance

Criteria	Details
Application procedure	Cockroaches were placed in the plastic container which was placed at the centre of the bottom of the glass cylinder. Aerosol spray was directly sprayed to the insects from the upper end of the cylinder, the upper end was then covered with a glass lid.
Delivery method	Aerosol spray
Dosage rate	Direct spray using 200 mg <i>B. germanica</i> 450 mg <i>P. americana</i> Imiprothrin concentrations tested: 0.05, 0.1, 0.2, 0.4% w/w. d-Tetramethrin concentrations tested: 0.25, 0.5, 1.0, 2.0% w/w.
Carrier	[REDACTED]
Concentration of liquid carrier	[REDACTED]
Liquid carrier control	None
Other procedures	None

Table A5.3/01-1.4 Test conditions

Criteria	Details
Substrate	Direct spray to the cockroaches
Incubation temperature	25 ± 2°C
Moisture	Relative humidity of 60 ± 10%
Aeration	no
Method of exposure	Exposed to direct spray and removed to clean container after 20 minutes
Ageing of samples	Not applicable
Other conditions	None

**Table A5.3/01 - 1.5 Efficacy of imiprothrin oil-based aerosol to German cockroach (*Blattella germanica*) in comparison with d-tetramethrin by direct spray method**

Treatment (a.i.)	conc. %w/w	% knockdown-down insects at (min)												
		0.2	0.3	0.5	0.7	1.0	1.5	2.0	3.0	5.0	7.0	10	15	20
imiprothrin	0.05	0	0	8	24	44	70	88	100	100	100	100	100	100
	0.1	0	14	36	54	82	92	98	100	100	100	100	100	100
	0.2	4	32	56	72	94	100	100	100	100	100	100	100	100
	0.4	18	44	84	100	100	100	100	100	100	100	100	100	100
d-tetramethrin	0.25	0	0	2	2	14	22	38	62	78	86	100	100	100
	0.5	0	2	10	20	38	58	72	92	100	100	100	100	100
	1.0	4	14	38	56	78	98	100	100	100	100	100	100	100
	2.0	6	20	46	58	82	98	100	100	100	100	100	100	100

Treatment (a.i.)	conc. %w/w	KT <sub>50</sub> min.	KT <sub>90</sub> min.	Mortality %
imiprothrin	0.05	1.1	2.2	14
	0.1	0.62	1.4	34
	0.2	0.45	0.95	64
	0.4	0.35	0.79	96
d-tetramethrin	0.25	2.6	7.4	6
	0.5	1.3	3.1	14
	1.0	0.65	1.6	70
	2.0	0.54	1.2	100

**Table A5.3/01 - 1.6 Efficacy of imiprothrin oil-based aerosol to American cockroach (*Periplanta americana*) in comparison with d-tetramethrin by direct spray method**

Treatment (a.i.)	conc. %w/w	% knockdown-down insects at (min)									
		0.7	1.0	1.5	2.0	3.0	5.0	7.0	10	15	20
imiprothrin	0.05	0	0	0	0	0	10	23	30	33	47
	0.1	0	0	3	20	30	40	47	50	57	77
	0.2	0	10	23	30	43	67	77	83	83	93
	0.4	10	17	27	53	77	83	93	93	97	97
d-tetramethrin	0.25	0	0	0	0	0	0	3	10	13	20
	0.5	0	0	0	0	0	3	10	13	13	23
	1.0	0	0	3	13	27	33	33	37	50	60
	2.0	4	13	20	30	30	57	63	67	67	83

Treatment (a.i.)	Conc. %w/w	KT <sub>50</sub> min.	KT <sub>90</sub> min.	Mortality %
imiprothrin	0.05	>20	>20	7
	0.1	8.5	>20	3
	0.2	3.6	15	43
	0.4	2.2	7.2	67
d-tetramethrin	0.25	>20	>20	7
	0.5	>20	>20	0
	1.0	14	>20	23
	2.0	5.4	>20	57