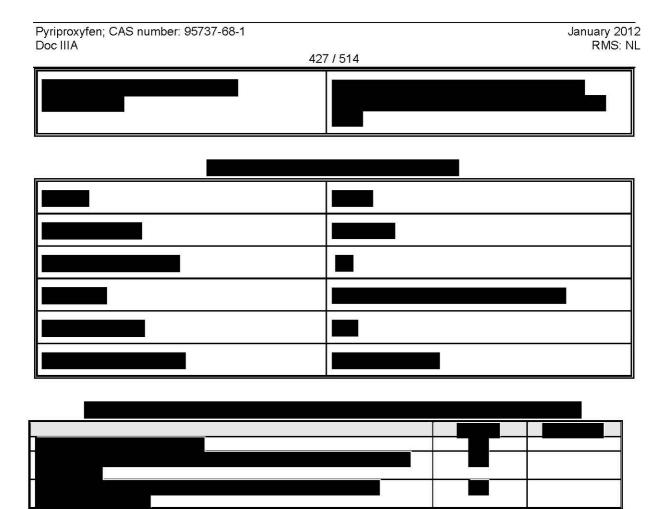
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7.5.3.3 Effects on reproduction of birds

Section A7.5.3.3/01 Annex Point IIIA XIII 1.3

Effects on reproduction of birds

Official 1 Reference use only 1.1 Reference Yes 1.2 Data protection 1.2.1 Data owner Sumitomo Chemical Company Ltd. 1.2.2 Data submitted to the MS after 13 May 2000 on existing a.s. for the 1.2.3 Criteria for data purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance Yes. US EPA Pesticide Assessment Guidelines §71-4 2.1 Guideline study 2.2 GLP

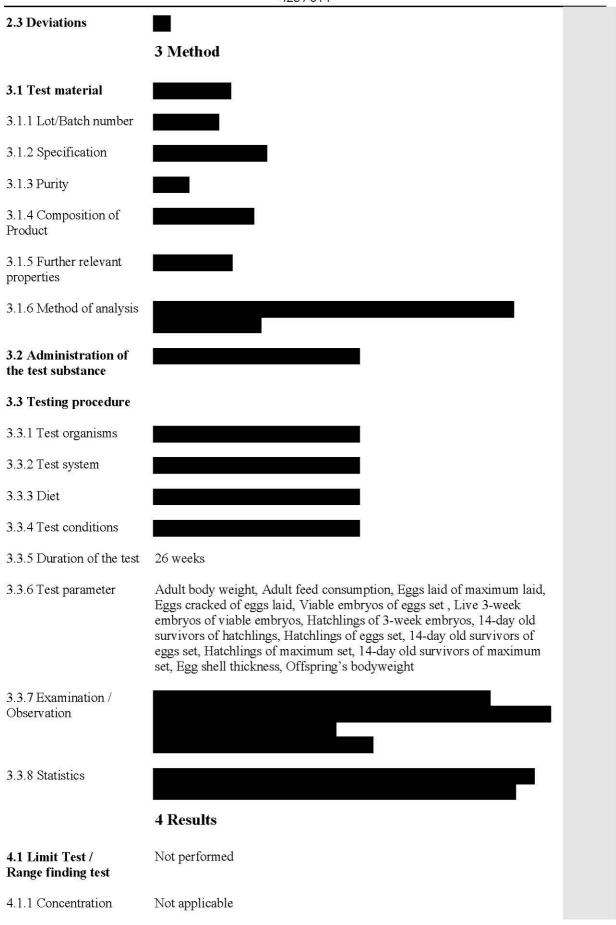
Pyriproxyfen; CAS number: 95737-68-1

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Pyriproxyfen; CAS number: 95737-68-1 January 2012
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4.1.2 Number/ percentage Not applicable of animals showing adverse effects

4.1.3 Nature of adverse effects

Not applicable

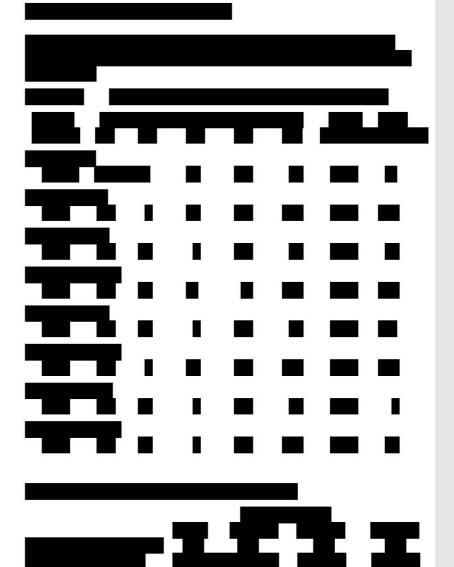
4.2 Results test substance

4.2.1 Applied concentrations

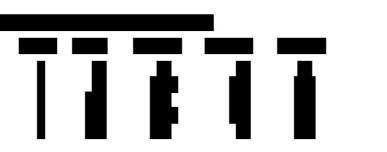
120, 360 and 600 ppm in food.

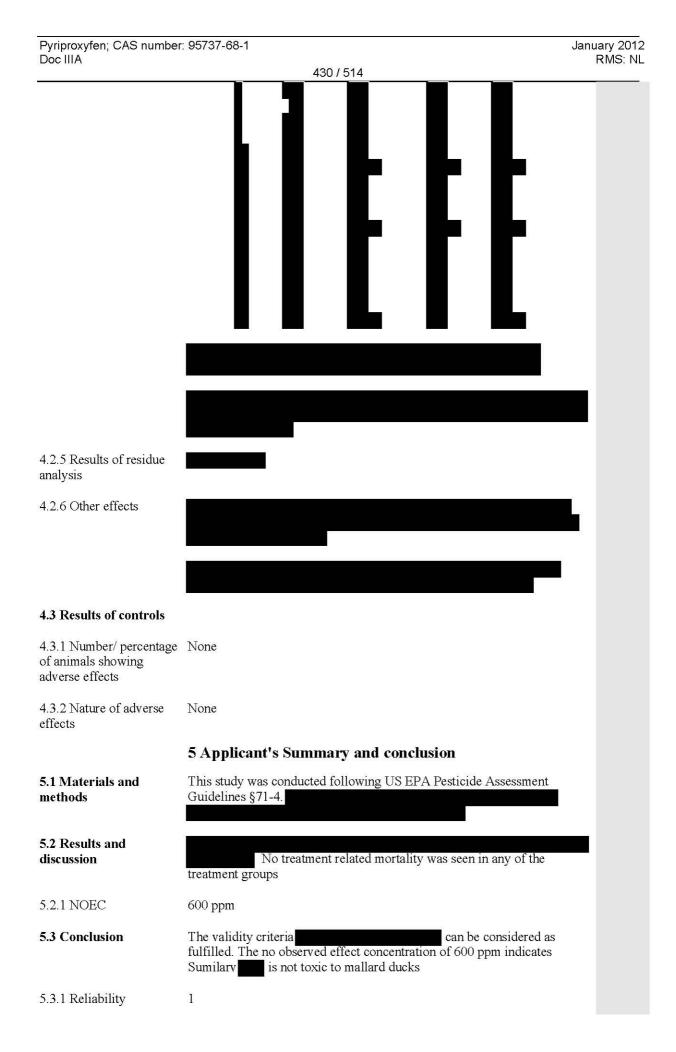
4.2.2 Effect data (Mortality and reproductivity)

4.2.3 Body weight



4.2.4 Food consumption





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5.3.2 Deficiencies No

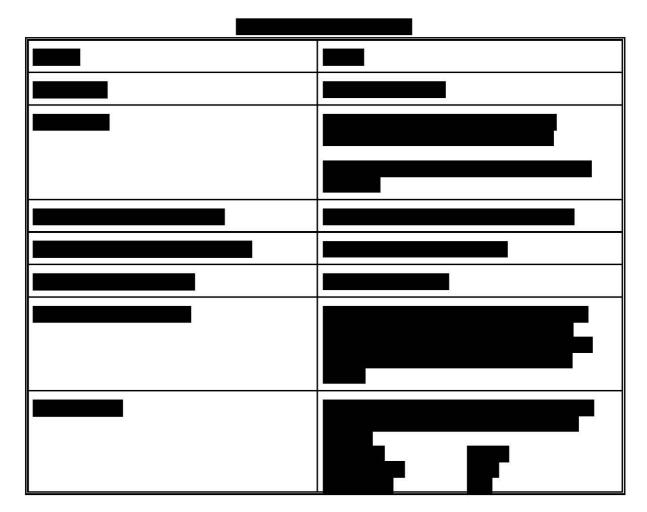
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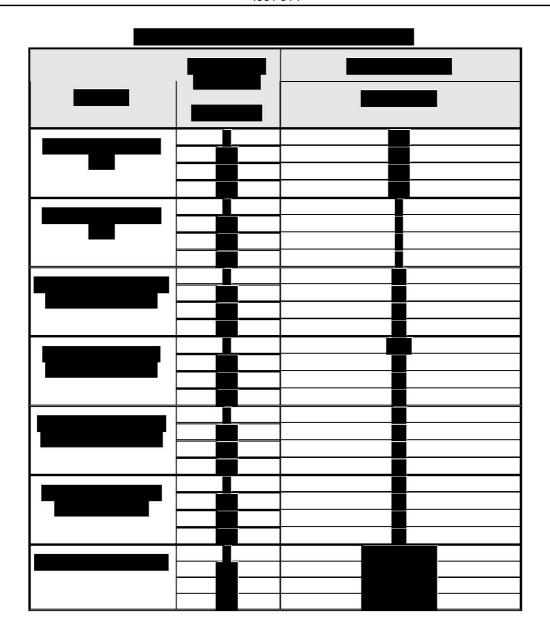
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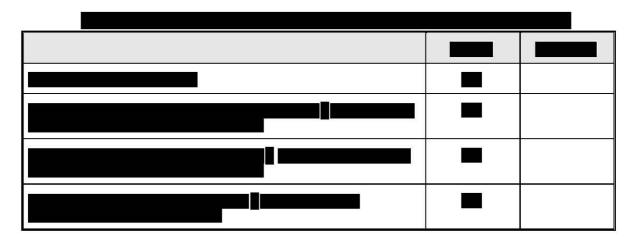
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3.3.3 Diet

Effects on reproduction of birds

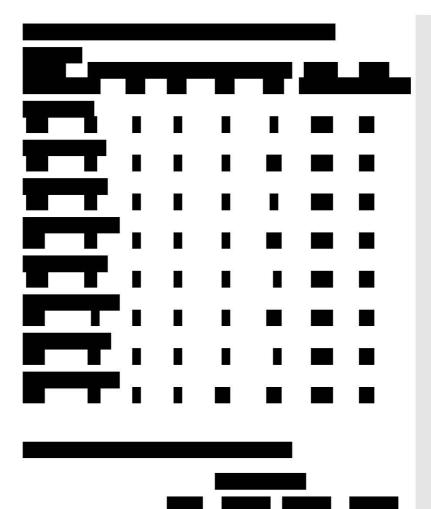
Official 1 Reference use only 1.1 Reference 1.2 Data protection Yes 1.2.1 Data owner Sumitomo Chemical Company Ltd. 1.2.2 1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance Yes. US EPA Pesticide Assessment Guidelines §71-4 2.1 Guideline study 2.2 GLP 2.3 Deviations 3 Method 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Administration of the test substance 3.3 Testing procedure 3.3.1 Test organisms 3.3.2 Test system

Pyriproxyfen; CAS number: 95737-68-1 January 2012

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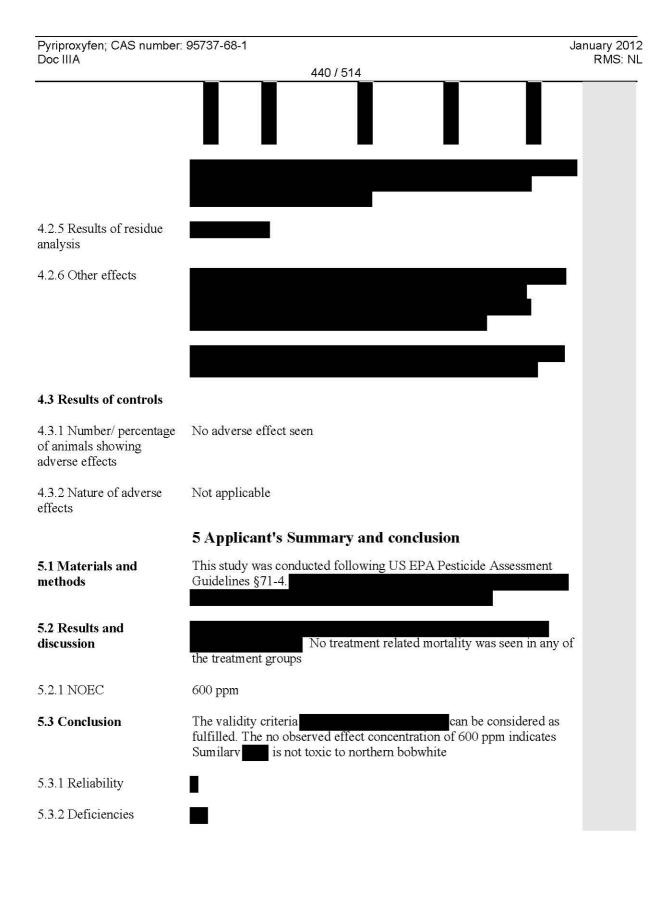
438 / 514 3.3.4 Test conditions 3.3.5 Duration of the test 22 weeks Parameters observed were; Adult body weight, Adult feed consumption, 3.3.6 Test parameter Eggs laid of maximum laid, Eggs cracked of eggs laid, Viable embryos of eggs set, Live 3-week embryos of viable embryos, Hatchlings of 3week embryos, 14-day old survivors of hatchlings, Hatchlings of eggs set, 14 day old survivors of eggs set, Hatchlings of maximum set, 14day old survivors of maximum set, Egg shell thickness, Offspring's body weight 3.3.7 Examination / Observation 3.3.8 Statistics 4 Results 4.1 Limit Test / Not performed Range finding test 4.1.1 Concentration Not applicable 4.1.2 Number/ percentage Not applicable of animals showing adverse effects 4.1.3 Nature of adverse Not applicable effects 4.2 Results test substance Non-entry field 0, 120, 360 and 600 ppm in food 4.2.1 Applied concentrations 4.2.2 Effect data (Mortality and reproductivity)

4.2.3 Body weight



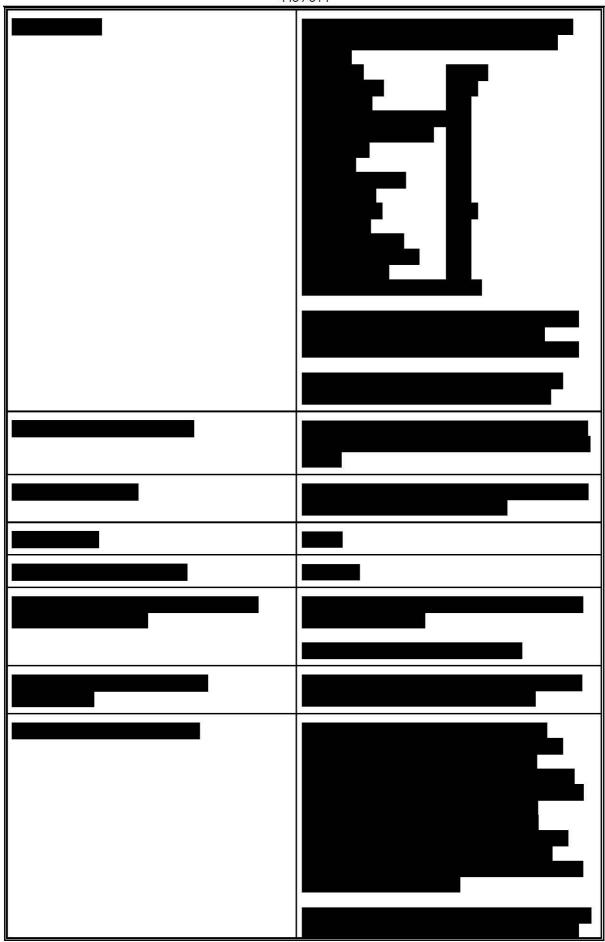
4.2.4 Food consumption

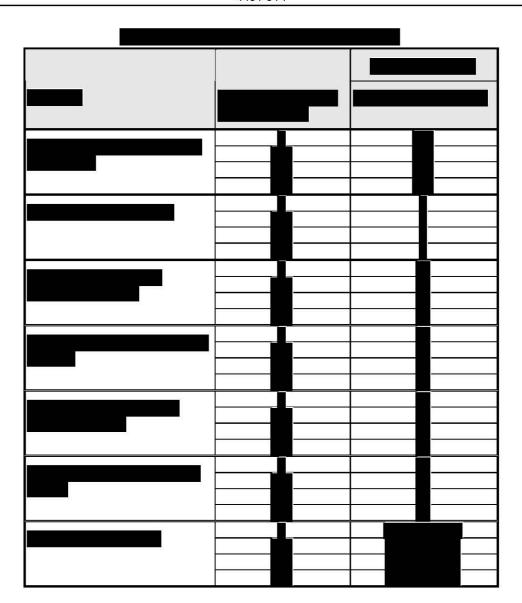




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7.5.4 Effects on Honeybees

7.5.4.1 Acute toxicity to honey bees and other beneficial arthropods for example predators

A7.5.4.1/01	Honey Bee, acute toxicity test		
	1 Reference	Official use only	
1.1 Reference		•	
1.2 Data protection	Yes		
1.2.1 Data owner	Sumitomo Chemical Company Ltd.		
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I		
	2 Guidelines and Quality Assurance		
2.1 Guideline study	Yes		
	EPPO Guideline Number: 170 (1992) OECD Guidelines 213/214		
2.2 GLP			
2.3 Deviations			
	3 Method		
3.1 Test material			
3.1.1 Lot/Batch number			
3.1.2 Specification			
3.1.3 Purity			
3.1.4 Composition of Product			
3.1.5 Further relevant properties			
3.1.6 Method of analysis			
3.2 Reference substance	Yes, Dimethoate		
3.2.1 Method of analysis for			

Pyriproxyfen; CAS number: 95737-68-1 January 2012 Doc IIIA RMS: NL 447 / 514 reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration 48 hours 3.3.7 Test parameter Mortality 3.3.8 Examination Observations made at 4, 24 and 48 hours 3.3.9 Monitoring of test substance concentration 3.3.10 Statistics 4 Results 4.1 1 Limit Test / Performed Range finding test 4.1.1 Concentration 4.1.2 Number/ percentage of animals showing adverse effects

January 2012 RMS: NL Pyriproxyfen; CAS number: 95737-68-1 Doc IIIA 448 / 514 10.0 4.1.3 Nature of adverse effects 4.2 Results test substance 4.2.1 Applied concentrations 4.2.2 Effect data (Mortality) 4.2.3 Concentration / effect curve 4.2.4 Other effects 4.3 Results of controls 4.3.1 Mortality 4.3.2 Number/ percentage of Bees showing adverse effects 4.3.3 Nature of adverse effects Performed 4.4 Test with reference substance

Pyriproxyfen; CAS number: 95737-68-1 January 2012

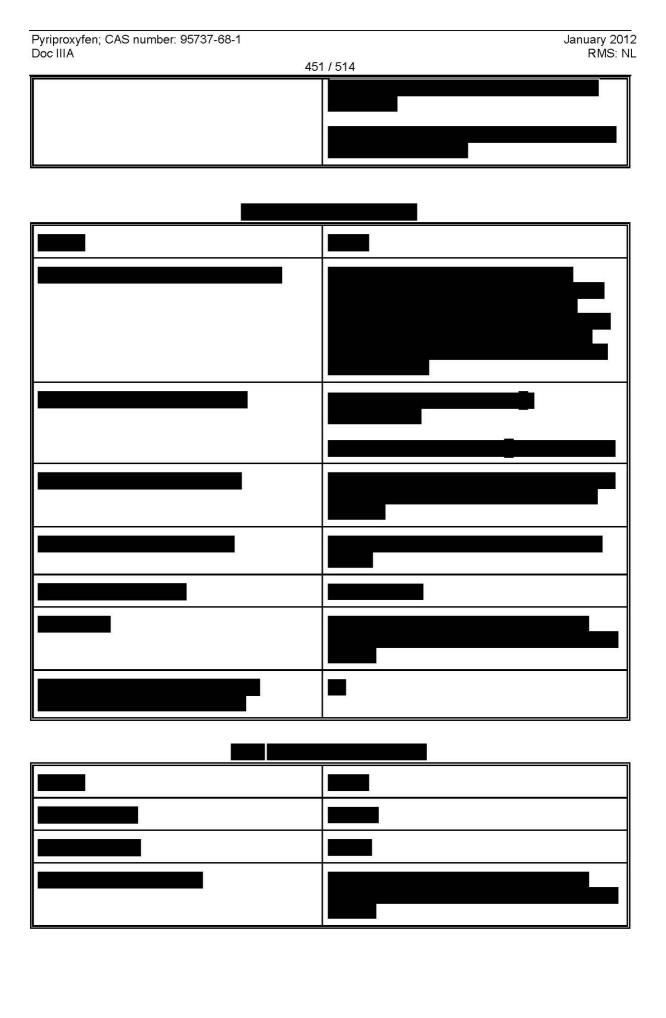
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449 / 514 4.4.1 Concentrations 4.4.2 Results 5 Applicant's Summary and conclusion 5.1 Materials and methods The acute contact and oral toxicity tests for Honeybees with pyriproxyfen were conducted in accordance with EPPO Guideline Number 170 and OECD Guidelines 213/214 In the contact test a single 1µl dose was applied to honey bees and the bees were observed for signs of mortality and toxicity for 48 hours. In the oral test honeybees were exposed to pyriproxyfen in sucrose solution and observed for signs of mortality and toxicity for 48 hours The 48-hour mortalities were low at the all levels tested. As the 5.2 Results and discussion maximum required dose tested is $100 \,\mu g$ a.i./bee the 48 hour LD₅₀ was empirically estimated to be greater than 100 µg a.i./bee 5.2.1 LC₀ Not applicable 5.2.2 LC₅₀ >100 μg a.i./bee $5.2.3 \ LC_{100}$ Not applicable This study met the validity criteria of OECD guideline 213 and 214 5.3 Conclusion 5.3.1 Other Conclusions 5.3.2 Reliability

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5.3.3 Deficiencies

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Table A7.5.4.1-07: Validity criteria for acute honeybee according to OECD 213/214

A7.5.4.1/02 Honey Bee, acute toxicity test 1 Reference

Official use only 1.1 Reference Yes 1.2 Data protection Sumitomo Chemical Company Ltd. 1.2.1 Data owner 1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance 2.1 Guideline study Yes BATDT (Bee Adult Toxicity Dusting Test) method 2.2 GLP 2.3 Deviations 3 Method 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Reference substance

Pyriproxyfen; CAS number: 95737-68-1 January 2012 Doc IIIA RMS: NL 454 / 514 3.2.1 Method of analysis for reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration 96 hours 3.3.7 Test parameter Mortality 3.3.8 Examination Observations made at 24, 48, 72 and 96 hours

3.3.9 Monitoring of test substance concentration

3.3.10 Statistics

4 Results

4.1 1 Limit Test / Range finding test

Not performed

4.1.1 Concentration

Not applicable

4.1.2 Number/percentage of animals showing adverse effects

Not applicable

4.1.3 Nature of adverse effects

Not applicable

4.2 Results test substance

4.2.1 Applied concentrations 0 and 100 µg a.i./bee

4.2.2 Effect data (Mortality)



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4.2.3 Concentration / effect curve

4.2.4 Other effects

4.3 Results of controls

4.3.1 Mortality

4.3.2 Number/ percentage of Bees showing adverse effects

4.3.3 Nature of adverse effects

4.4 Test with reference substance

4.4.1 Concentrations

4.4.2 Results

5 Applicant's Summary and conclusion

5.1 Materials and methods

The bee adult toxicity dusting test was performed according to the BATDT (Bee Adult Toxicity Dusting Test) method.



5.2 Results and discussion

No treatment-related mortality was observed at a dose level of 100 μg a.s./bee

5.2.1 LC₀ Not applicable

5.2.2 LC₅₀ >100 μg a.i./bee

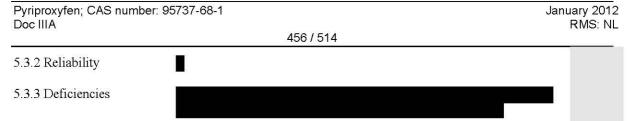
 $5.2.3 \, LC_{100}$ Not applicable

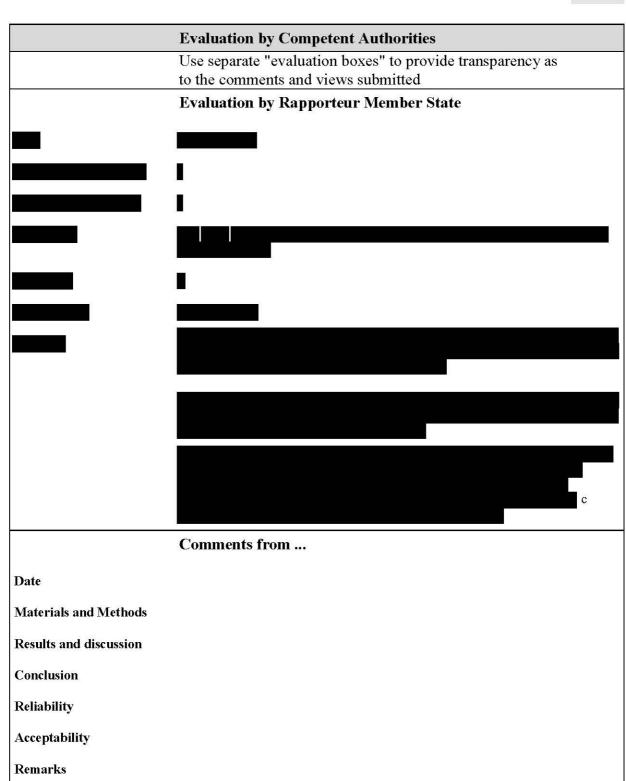
5.3 Conclusion This study was performed to the BATDT (Bee Adult Toxicity Dusting

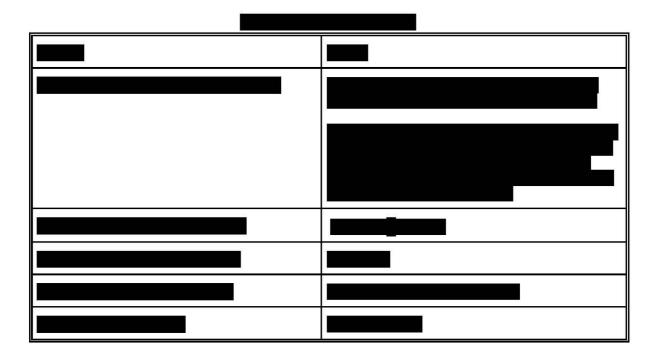
Test) method. A toxic standard was not used simultaneously with this test. However the reported LD_{50} for Dimethoate using this method is

0.188µg a.i./bee

5.3.1 Other Conclusions None







Pyriproxyfen; CAS number: 95737-68-1

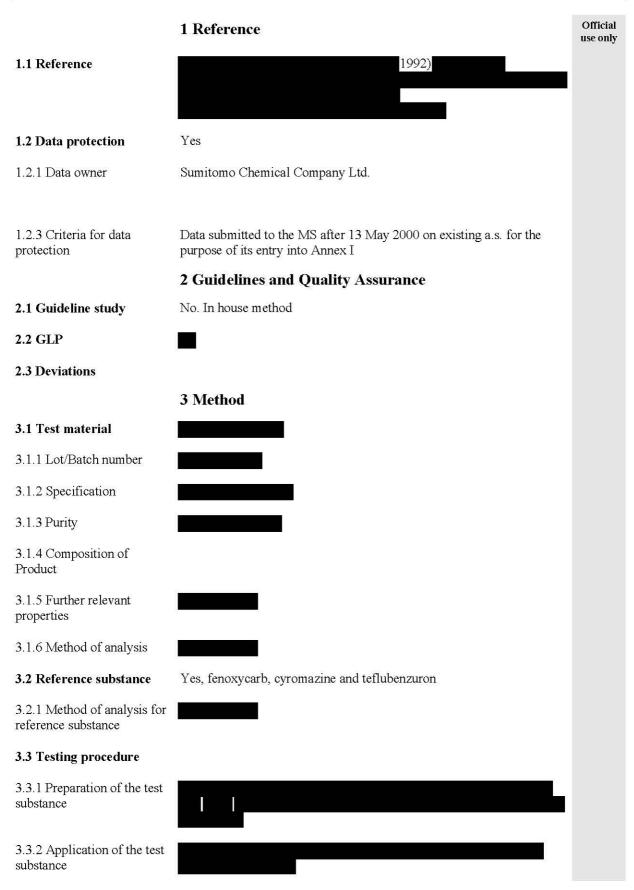
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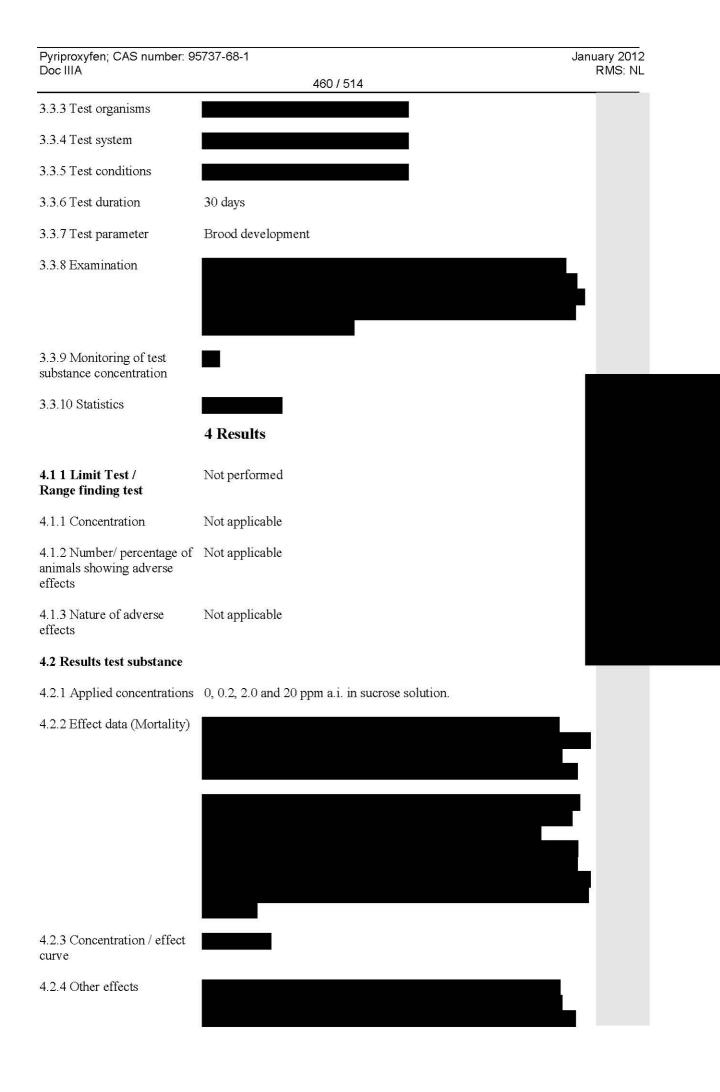
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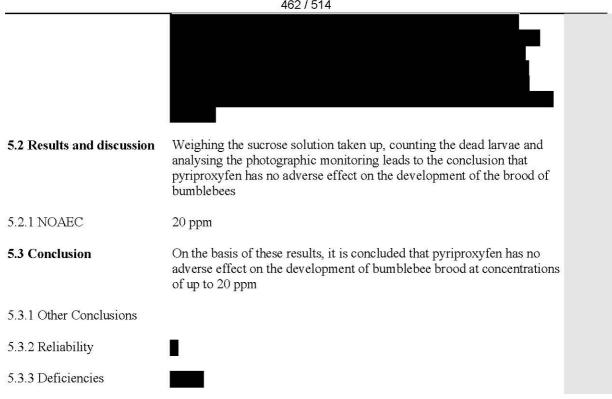
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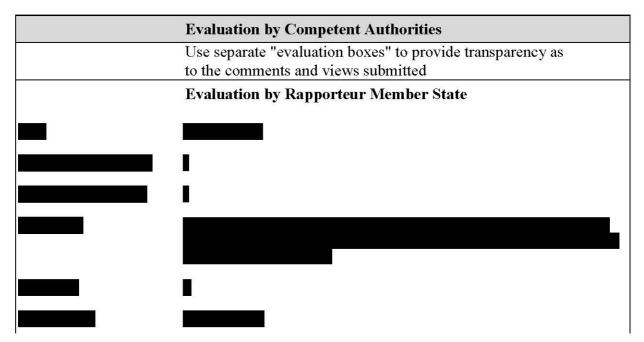
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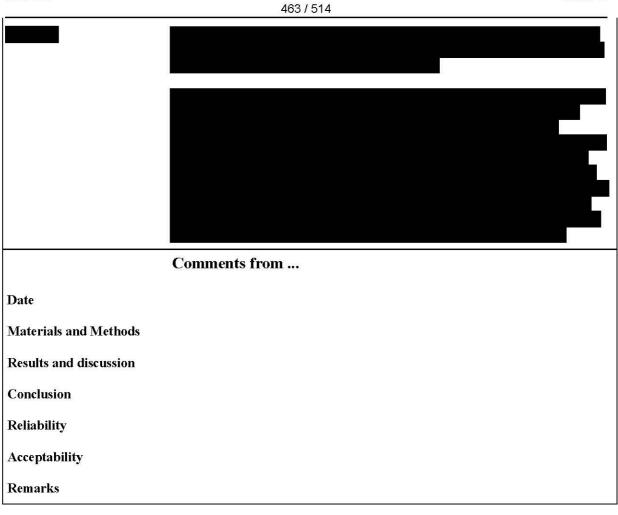
A7.5.4.1/03 Honey Bee, Brood development test



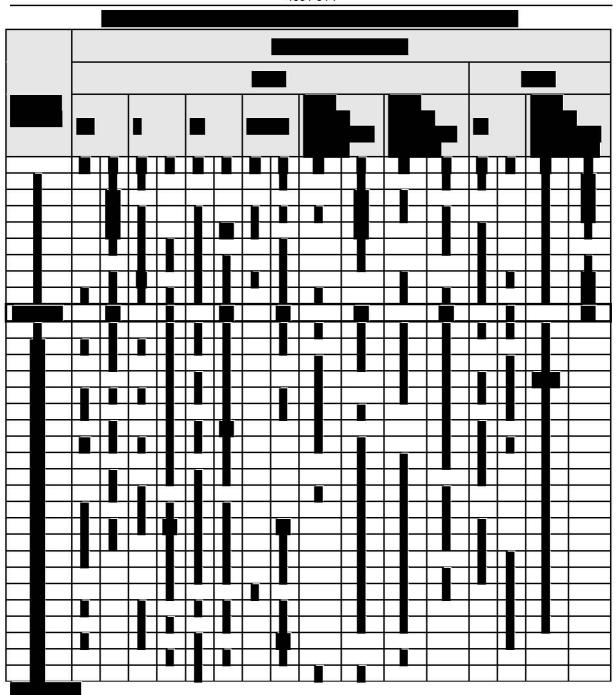


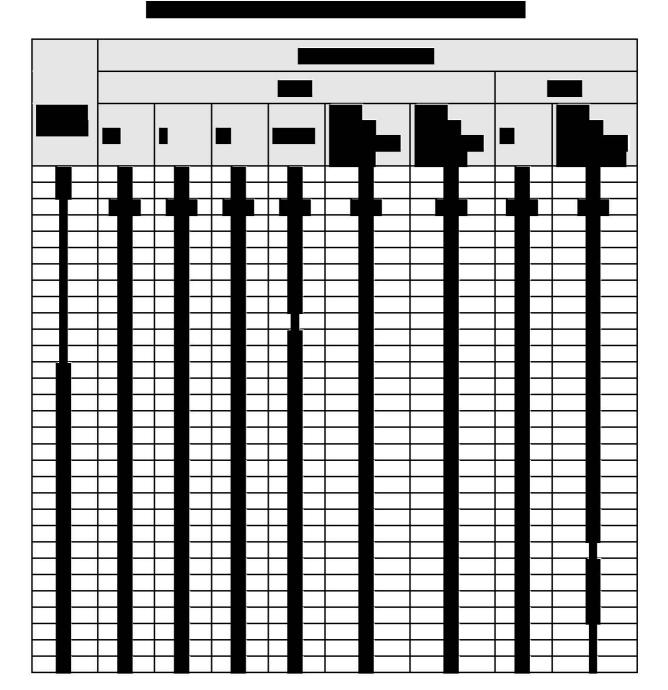




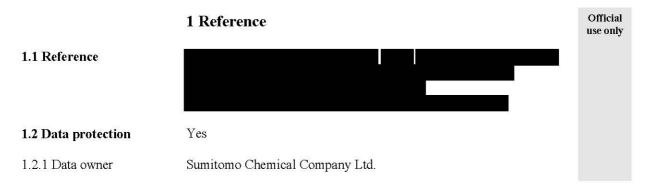


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A7.5.4.1/04 Honey Bee, Brood development test



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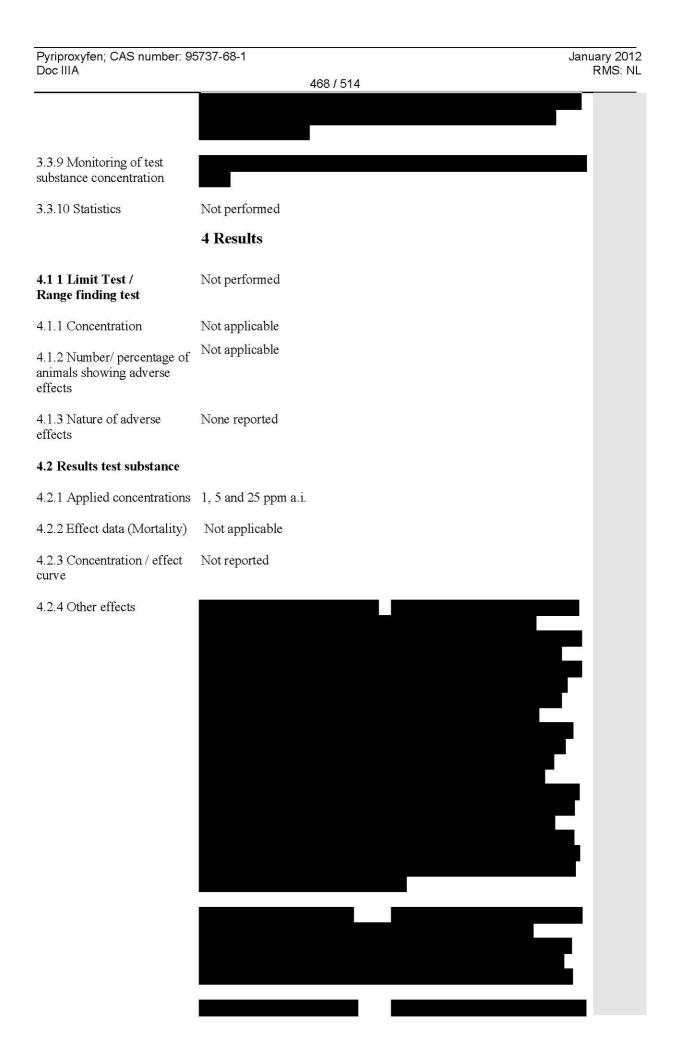
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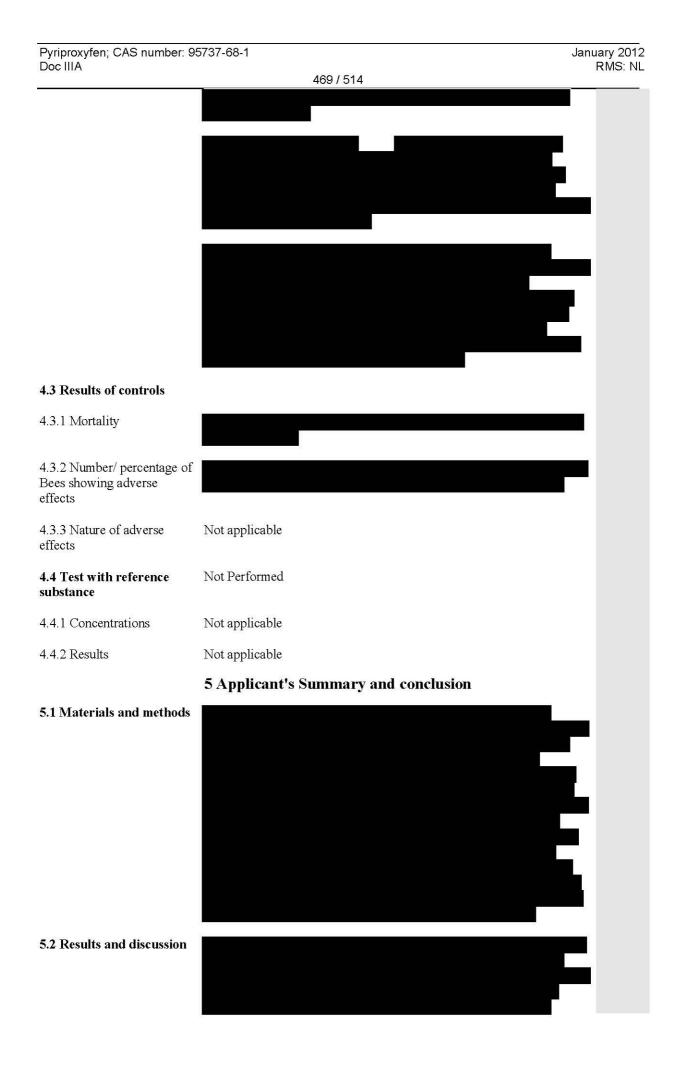
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1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance 2.1 Guideline study No. In house method 2.2 GLP 2.3 Deviations 3 Method 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Reference substance 3.2.1 Method of analysis for reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration 30 days Brood development 3.3.7 Test parameter 3.3.8 Examination





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5.2.1 NOAEC 25 ppm

5.3 Conclusion No adverse effects were observed on honey bee colonies when fed

artificial pollen containing up to 25 ppm pyriproxyfen. It was suggested that this could be due to low transport of the test materials from the worker bees to the brood and/or high biodegradability of the test

material

5.3.1 Other Conclusions None

5.3.2 Reliability

5.3.3 Deficiencies

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A7.5.4.1/05 Non Target Arthropod, acute toxicity and reproduction test

Official 1 Reference use only 1.1 Reference Yes 1.2 Data protection Sumitomo Chemical Company Ltd. 1.2.1 Data owner 1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance 2.1 Guideline study Yes 2.2 GLP Yes 2.3 Deviations 3 Method 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification

Pyriproxyfen; CAS number: 95737-68-1 January 2012 RMS: NL Doc IIIA 476 / 514 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Reference substance Yes, Perfektion (Dimethoate) 3.2.1 Method of analysis for Not reported reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration Exposure phase 48 hours. Wasps were transferred for the fecundity test for a parasitisation period for 24 hours after which the surviving wasps were removed from the cylinder. After 10 days the number of aphid mummies was recorded 3.3.7 Test parameter Mortality and reproduction 3.3.8 Examination Exposure phase: 2, 24 and 48 hours Reproduction phase: Number of living, dead and missing parasitoids recorded at 24 hours. After ten days the wasps were removed from the units, the number of parasitized aphids was assessed 3.3.9 Monitoring of test substance concentration 3.3.10 Statistics 4 Results Performed 4.1 1 Limit Test /

Range finding test

4.2.5 Other effects

4.3.1 Mortality

4.3 Results of controls

Pyriproxyfen; CAS number: 95737-68-1

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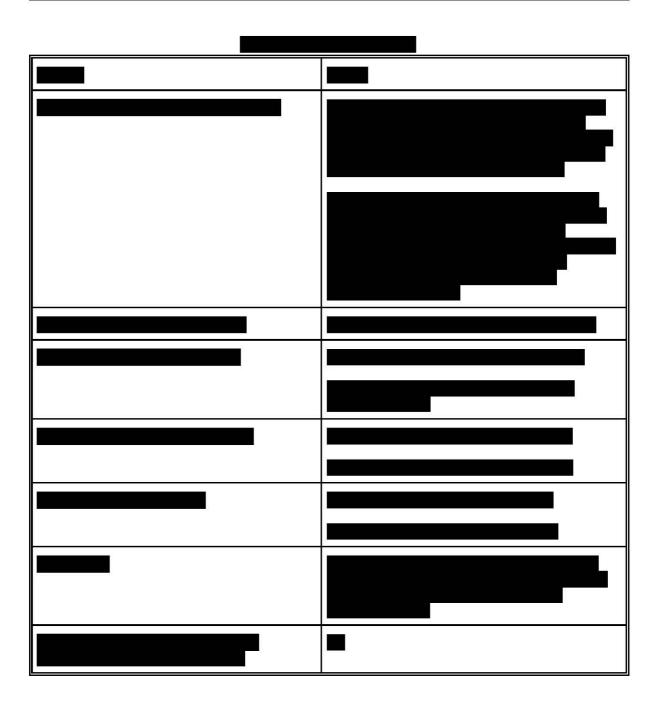
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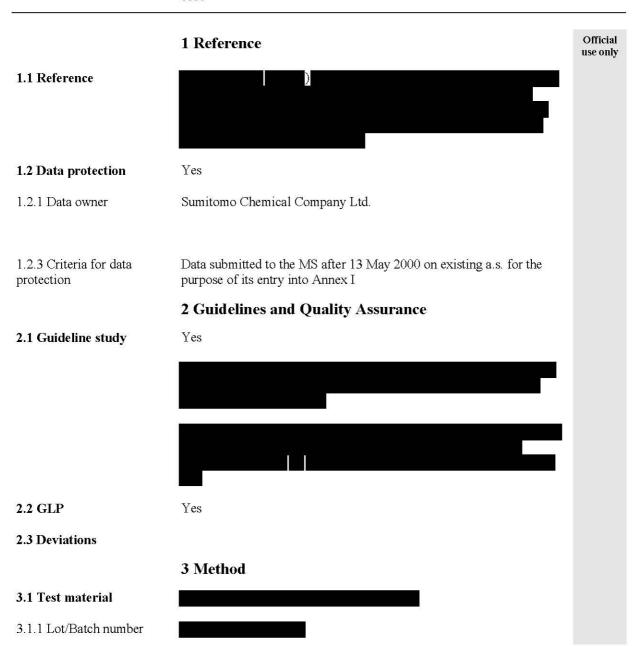
4.3.2 Number/percentage of animals showing adverse effects 4.3.3 Nature of adverse effects 4.4 Test with reference substance 4.4.1 Concentrations 4.4.2 Results 5 Applicant's Summary and conclusion The Mortality and reproductive behaviour of Aphidius rhopalosiphi 5.1 Materials and methods were recorded following 48 hour exposure to Following exposure, fecundity was assessed 10 days after the wasps had parasitized aphids over a 24 hour period 5.2 Results and discussion In the morality test, after 48 hours there was no mortality seen in the control, 32.25 and the 62.5 g a.i./ha groups. 20% of the aphids in the 125 g a.i./ha were either killed or affected. In the 250 g/a.i./ha 50% of the aphids were dead and only 3.3% were unaffected In the reproduction phase of the study the 125 g a.i./ha showed a significant reduction in parasitisation rate compared to the control. As such the NOEC for this study was 62.5 g a.i./ha 5.2.1 NOEC 62.5 g a.i./ha 5.2.2 LOEC 125 g a.i./ha $5.2.3 \, LC_{50}$ 213 g a.i./ha (95% confidence limits 150.9 to 265.2 g a.i./ha) 5.2.4 LC₁₀₀ Not reported 5.3 Conclusion This study met the required validity criteria. 0% mortality was seen in the exposure phase for the control group and 100% mortality was seen in the toxic standard (see table A7.5.4.1-34). The control group produced greater than 5 mummies per female wasp 5.3.1 Other Conclusions Not applicable 5.3.2 Reliability 5.3.3 Deficiencies

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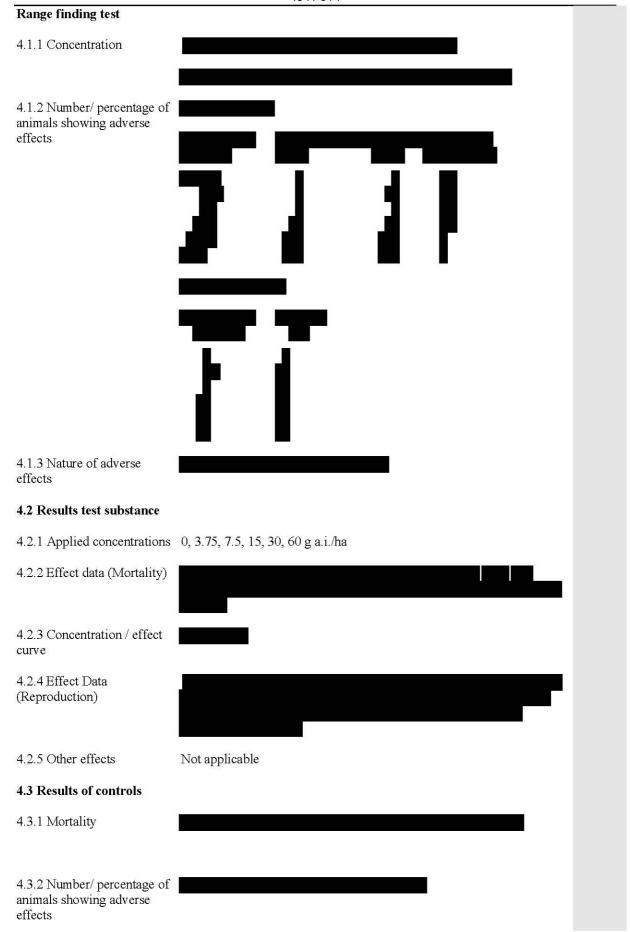


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A7.5.4.1/06 Non Target Arthropod, acute toxicity and reproduction test



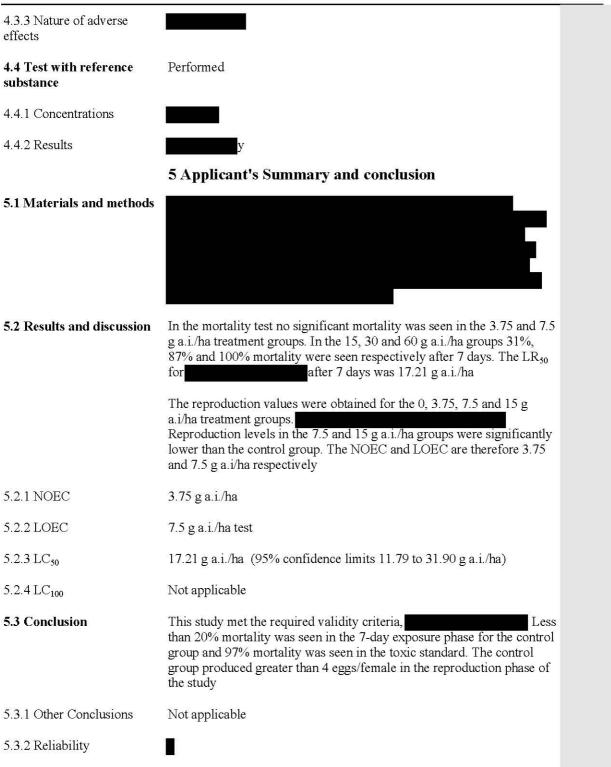
Pyriproxyfen; CAS number: 95737-68-1 January 2012 RMS: NL Doc IIIA 483 / 514 3.1.2 Specification 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Reference substance Yes, Perfektion (Dimethoate) 3.2.1 Method of analysis for reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration The mortality phase lasted for 7 days. A reproduction assessment was carried out for a further 7 days in all treatments with a minimum of 50% survival Mortality and reproduction 3.3.7 Test parameter 3.3.8 Examination Mortality phase: 3 and 7 days Reproduction phase: The sex of the mites was determined from day 7 onwards. The number of eggs and hatched larvae were recorded on days 7, 9, 11 and 14 of the assessment 3.3.9 Monitoring of test substance concentration 3.3.10 Statistics 4 Results 4.1 1 Limit Test / Performed



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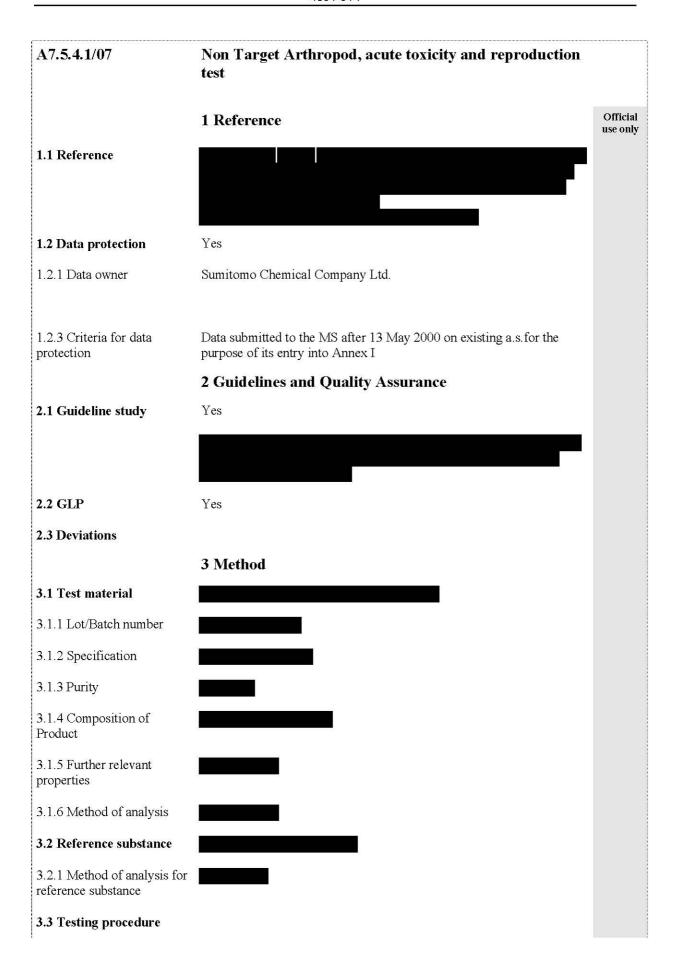
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5.3.3 Deficiencies

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Pyriproxyfen; CAS number: 95737-68-1 January 2012 RMS: NL

Doc IIIA 490 / 514 3.3.1 Preparation of the test substance 3.3.2 Application of the test substance 3.3.3 Test organisms 3.3.4 Test system 3.3.5 Test conditions 3.3.6 Test duration The mortality phase lasted for 9 days. A mating period of 4 days took place and then a reproduction assessment of 4 days took place 3.3.7 Test parameter Mortality and reproduction 3.3.8 Examination Mortality phase: 9 days 3.3.9 Monitoring of test substance concentration 3.3.10 Statistics 4 Results 4.1 1 Limit Test / Performed

Range finding test

4.1.1 Concentration