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Environmental Protection Authority
Te Mana Rauhī Taiao

SUBMISSION FORM

Once you have completed this form
Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: submissions@epa.govt.nz

Once your submission has been received the submission becomes a public document and may be made publicly available to anyone who requests it. You may request that your contact details be kept confidential, but your name, organisation and your submission itself will become a public document.

Submission on application number:	APP202142
Name of submitter or contact for joint submission:	Timothy E Wilson
Organisation name (if on behalf of an organisation):	Arysta LifeScience
Postal address:	15401 Weston Parkway, Suite 150, Cary, North Carolina USA 27513
Telephone number:	(919) 678-4865
Email:	tim.wilson@arysta.com

☐ I wish to keep my contact details confidential

The EPA will deal with any personal information you supply in your submission in accordance with the Privacy Act 1993. We will use your contact details for the purposes of processing the application that it relates to (or in exceptional situations for other reasons permitted under the Privacy Act 1993). Where your submission is made publicly available, your contact details will be removed only if you have indicated this as your preference in the tick box above. We may also use your contact details for the purpose of requesting your participation in customer surveys.

The EPA is likely to post your submission on its website at www.epa.govt.nz. We also may make your submission available in response to a request under the Official Information Act 1982.

☐ I support the application

☐ I oppose the application

☒ I neither support or oppose the application

The reasons for making my submission are[1]:

Arysta LifeScience would like to take the opportunity to lodge a formal submission under Section 58 of APP202142 to the New Zealand EPA for information that Arysta LifeScience plans to generate in a semi-field pollinator study to address data gaps with the active ingredient acephate and the proposed non-contact period for pollinators.

☐ I wish to be heard in support of my submission (this means that you can speak at the hearing)

☒ I do not wish to be heard in support of my submission (this means that you cannot speak at the hearing)

I wish for the EPA to make the following decision:

Arysta LifeScience would also like to request an extension for the final decision on HS application APP202142 for acephate until the proposed study is complete in November 2014.

[1] Further information can be appended to your submission, if you are sending this submission electronically and attaching a file we accept the following formats – Microsoft Word, Text, PDF, ZIP, JPEG and JPG. The file must be not more than 8Mb.

Arysta LifeScience

Timothy E Wilson, Ph.D.
Global Regulatory Manager, Fungicides-Insecticides
Arysta LifeScience, LLC
15401 Weston Parkway, Suite 150
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September 15, 2014

Dr. Matthew Allen
New Zealand EPA
Level 10 215 Lambton Quay
Private Bag 63002
Wellington 6140, New Zealand
Matthew.Allen@epa.govt.nz
DDI +64 4 474 5553

Re: **Formal Submission Lodge Request under Section 58 in Response to Acephate Reassessment and EPA proposal [OPC reassessment (APP202142)] on altering the bee controls (non-contact periods) for acephate.**

Dear Mr. Allen,

Arysta LifeScience would like to take the opportunity to lodge a formal submission under Section 58 of APP202142 to the New Zealand EPA for information that Arysta LifeScience plans to generate in a semi-field pollinator study to address data gaps with the active ingredient acephate and the proposed non-contact period for pollinators.

In the proposed study, the objective is to determine the LD50 on honey bees for acephate applied as Orthene on a pre-flowering crop. The outcome should define the acceptable wait time between pre-bloom application on lemon trees and low honey bee mortality during active foraging at bloom time. Current testing guidelines for bee acute contact toxicity rely on exposure to treated foliage. After consulting with entomology experts and study designers it was proposed that spraying a pre-bloom crop followed by exposure would be a more appropriate test system to assess bee exposure on lemon trees and to address the assessment and proposals contained in APP202142.

According to experts bees spend very little time in contact foliage and instead are more likely to have contact with a treated flower. In consultation with grower groups in New Zealand, real world application methods, rates, and timing were taken into consideration in the proposed study design. The results of the proposed study will give NZ EPA a higher tier assessment and allow a more informed regulatory decision to be made. Our intent in proposing this study is to allow growers to safely continue to use a key tool to control lemon moth.

A detailed review of historical pollinator studies involving acephate indicate that most of the data is old and unequivocal in determining an appropriate non-contact period. Herein Arysta LifeScience has submitted a protocol to the NZ EPA for a field to laboratory study to assess the residual toxicity of acephate foliar application on honey bees (*A. mellifera*). Arysta would also like to request an extension for the final decision on HS application APP202142 for acephate until the proposed study is complete in November 2014.

We trust that you will find this response in order; however, should there be any questions please contact me at 919-678-4865 or via email at tim.wilson@arysta.com

Arysta LifeScience

Timothy E Wilson, Ph.D.
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E-mail: tim.wilson@arysta.com

Sincerely,

Timothy E Wilson, Ph.D.
Global Regulatory Affairs Manager
Arysta LifeScience, LLC

SMITHERS VISCIENT
Carolina Research Center
2900 Quakenbush Road, Snow Camp, NC 27349 August 2014

STUDY PROTOCOL

Non-GLP Translational Field-to-Lab Study to Assess the Residual Toxicity of Acephate Applied as a Foliar Application on Honey Bees (*A. mellifera*)

TO BE COMPLETED BY THE STUDY SPONSOR:

Study Sponsor: Arysta LifeScience Management Company, LLC

Address: 15401 Weston Parkway, Suite 150, Cary, NC 27513

Phone: **919-678-4865**

Study Monitor: Tim Wilson **E-mail:** tim.wilson@arysta.com

Sponsor Protocol/Project No.: NA

Test Substance Name(s): Acephate

Purity: **Batch or Lot #:**

Additional Comments and Modifications:

Sponsor Approval: **Date:**

TO BE COMPLETED BY SMITHERS VISCIENT LABORATORIES BEFORE EXPERIMENT INITIATION:

Testing Facility: Smithers Viscient, CRC, 2900 Quakenbush Rd., Snow Camp, NC 27349

Study Director: Jessica Louque Study No.:

Test Concentrations: 1600 g FP/ha

Proposed Experimental Dates: (Start) September 2014 (Termination) October 2014

Study Director Signature **Study Initiation Date**

1.0 OBJECTIVE

The objective of this study is to determine the LD_{50} on honey bees for acephate applied as Orthene on a pre-flowering crop of cucumbers. The outcome should define the acceptable wait time between pre-bloom application on lemon trees and low honey bee mortality during active foraging at bloom time.

2.0 SUMMARY AND SCOPE

This study will consist of 1 rate of Orthene applied to cucumber as a foliar application. Flower buds will be sprayed at various points pre-bloom and bees will be exposed to flowers until the LD_{50} has been reached. Bees will be caged in small containers and monitored for a 48-hour time period after the beginning of exposure. Prior to exposure, adult honey bees will be captured and placed into containers approximately 24-48 hours before application. Cages will continuously have access to food, with the exception of the immediate exposure phase.

3.0 MATERIALS AND METHODS

3.1 Chemical System

3.1.1 Test substance

The test substance will be Orthene, and will be provided to Smithers Viscient (SMV) Carolina Research Center (CRC) by the Study Sponsor. The CRC test material center will receive the test substance, inspect the packaging and evaluate the condition of the container. If the packaging is damaged, the Study Sponsor will be advised. The test substance will be given a testing facility identification number and stored in a locked compartment according to label or Sponsor-provided specifications. An accurate record of product use will be maintained as specified by U.S. EPA Good Laboratory Practices (GLP) Guidelines, although this study will not be audited. Storage temperature will be monitored and recorded.

Test Substance:	
Lot or Batch #:	
Expiration Date:	
Formulation:	
SMV ID#:	

Treatment	Rate	Water
UTC	water only	2000 L/ha
TRT1	1600 g/ha	

3.1.2 Test Substance Application Procedures and Application Rates

The application rate will be 1600 grams of Formulated Product (FP) per hectare, or 1552 grams of Active Ingredient (acephate) per hectare. Tank mix will be made with 2000 Liters per hectare for the application. The Test Substance will be applied with a boom sprayer.

3.2 Test System

3.2.1 Species

Honey bees, *Apis mellifera*, will be used in this study with 10 adult bees per test cage with 5 test cages per treatment.

Honey bees will be procured from Smithers Viscient apiaries. Honey bees will be randomly selected for the study and cannot be individually marked. The test will be carried out with young adult worker bees derived from a healthy colony. The bees will be collected randomly from the outer combs of the colony or in front of the hive.

3.2.2 Justification of test system

Honey bees are ecologically and economically important pollinators that have also proven sensitive to some pesticides. They can be maintained in artificial colonies (hives) and thereby avail themselves in adult, eggs, and larval life stages and their hive products (honey, nectar, pollen, and beeswax) to monitoring and collection. They have been identified by the U.S. Environmental Protection Agency as an appropriate surrogate for evaluating pesticide risks to bees and insect pollinators in general.

3.2.3 Test System Acclimation

Adult bees will be captured and installed into container cages approximately 12-24 hours prior to the application initiation. Immediately upon containment and stabilization, sugar solution will be provided to the bees.

3.3 Test conditions

3.3.1. Cages

The bee containment cages are white plastic 5" cubes with ventilated mesh sides. One side has an opening for a lid that holds a feeding trough for sugar solutions.

3.3.2 Feed

During containment, bees will have access to a solution of sugar at 20-50% until the time of exposure. Food will be removed during the addition of plant material to the cage, but will be replaced as soon as exposure begins.

3.5 Study design

Cucumbers will be grown in tented enclosures to minimize outside exposure to the testing area. Application will take place between BBCH 50-60 to ensure the spray does not fall on open flowers. For each exposure period, flowers will be removed from plants and placed into the bottom of each bee containment cage. Flowers will remain in the bottom of the cage for the duration of the 48 hour observation phase. Bees will have access to fresh food at all times during the study, with the exception of the introduction of the flowers to the cage.

3.5.1 Replication and control of bias

Each treatment will have 5 replications, for a total of 50 bees per treatment block. Untreated replicates will be handled in the same way as treated replicates, with the only difference being that there is no exposure to any test material. Only one untreated control group will be used instead of an untreated control per treatment block. ID codes have been created to avoid confusion over the large quantity of replicates. Identification numbers can be found in the table below:

Treatment	Rep	Block	Identification
Untreated Control	R1	0	C1R1
Untreated Control	R2	0	C1R2
Untreated Control	R3	0	C1R3
Untreated Control	R4	0	C1R4
Untreated Control	R5	0	C1R5
Treatment 1	R1	-7	T1R1-7
Treatment 1	R2	-7	T1R2-7
Treatment 1	R3	-7	T1R3-7
Treatment 1	R4	-7	T1R4-7
Treatment 1	R5	-7	T1R5-7
Treatment 1	R1	-6	T1R1-6
Treatment 1	R2	-6	T1R2-6
Treatment 1	R3	-6	T1R3-6
Treatment 1	R4	-6	T1R4-6
Treatment 1	R5	-6	T1R5-6
Treatment 1	R1	-5	T1R1-5
Treatment 1	R2	-5	T1R2-5
Treatment 1	R3	-5	T1R3-5
Treatment 1	R4	-5	T1R4-5
Treatment 1	R5	-5	T1R5-5

Treatment	Rep	Block	Identification
Treatment 1	R1	-4	T1R1-4
Treatment 1	R2	-4	T1R2-4
Treatment 1	R3	-4	T1R3-4
Treatment 1	R4	-4	T1R4-4
Treatment 1	R5	-4	T1R5-5
Treatment 1	R1	-3	T1R1-3
Treatment 1	R2	-3	T1R2-3
Treatment 1	R3	-3	T1R3-3
Treatment 1	R4	-3	T1R4-3
Treatment 1	R5	-3	T1R5-3
Treatment 1	R1	-2	T1R1-2
Treatment 1	R2	-2	T1R2-2
Treatment 1	R3	-2	T1R3-2
Treatment 1	R4	-2	T1R4-2
Treatment 1	R5	-2	T1R5-2
Treatment 1	R1	-1	T1R1-1
Treatment 1	R2	-1	T1R2-1
Treatment 1	R3	-1	T1R3-1
Treatment 1	R4	-1	T1R4-1
Treatment 1	R5	-1	T1R5-1

3.5.2 Study Duration and Schedule

The study will last approximately 14 days. Application will take place on Day -10 until Day -1, and exposure times will begin on Day 0.

Timing	Event
Day -10	Application of Test Substance on Block D-10
Day -9	Application of Test Substance on Block D-9
Day -8	Application of Test Substance on Block D-8
Day -7	Application of Test Substance on Block D-7
Day -6	Application of Test Substance on Block D-6
Day -5	Application of Test Substance on Block D-5
Day -4	Application of Test Substance on Block D-4
Day -3	Application of Test Substance on Block D-3
Day -2	Application of Test Substance on Block D-2
Day -1	Application of Test Substance on Block D-1 Bees are introduced to the cages for exposure
Day 0	BBCH 61, or flowers opening - exposure begins
Day 1	First observation on all bees
Day 2	Second observation on all bees

3.5.3 Variables to be measured

Mortality counts will be considered in the evaluations, and will be compared to the untreated control group. Testing will only occur on the most recent 7 days of applications prior to the bloom period. A total of 10 days is to be sprayed to account for any variability in the bloom progression or climactic conditions that prevent applications or alter the crop growth.

4.0 STATISTICAL ANALYSIS

Basic statistics will be performed using a version of Microsoft Excel. Any additional analysis will be performed at the request of the Sponsor.

5.0 RECORDS TO BE MAINTAINED

Records to be maintained will include, but will not be limited to, correspondence and other documents related to the interpretation and evaluation of data, and all raw data and documentation generated as a result of the study.

6.0 REPORTING

A final data summary will be produced at the end of the lab phase. It will include basic study design, photos of the lab phase, results of the evaluations, and any statistical output generated from the study.