Bayer CropScience

Title

Request for Establishment of a New Exclusive Use Period Associated with Registration of New Public Health Use of Deltamethrin as Provided for Under FIFRA § 3(c)(1)(F)(vi)

Company Product Code

Deltamethrin (BES0668 Insecticide)

Authors

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Guideline Reference

US EPA OCSPP Guideline Number SUPP
EPA Questions and Answers Document – Exclusive Use Data Protection for Minor Use Registrations – Revised September 2012

Completion Date

September 6, 2013

Submitted By

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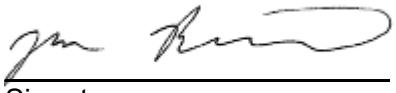
CLAIM OF CONFIDENTIALITY

Information claimed as confidential has been removed to a confidential attachment.

Company: Bayer CropScience

Company Agent: Jan Brill

Title: Manager, Registrations



Signature

September 6, 2013
Date

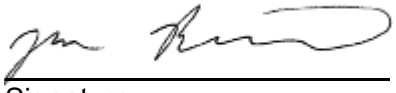
However, these data are the property of Bayer CropScience AG and, as such, are considered to be a trade secret and confidential for all purposes other than compliance with FIFRA § 10.

Submission of these data in compliance with FIFRA does not constitute a waiver of any rights to confidentiality which may exist under any other statute or in any country other than the USA.

Company: Bayer CropScience

Company Agent: Jan Brill

Title: Manager, Registrations



Signature

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STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

This report does not meet the requirements for EPA FIFRA Good Laboratory Practice Standards, 40 CFR Part 160, and differs in the following way:

(1) This document is informational, and is not the result of a study as defined by 40 CFR 160.3. Since the document does not report a study, no GLP (40 CFR 160 or Current OECD Principles of Good Laboratory Practices) statement is required as per PR Notice 2011-3 (VI)(C)(3), p. 11.

Sponsor/Submitter
Jan Brill
Manager, Registrations
Bayer CropScience

Signature

September 6, 2013
Date

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A. INTRODUCTION

Bayer CropScience, the primary registrant of the insecticide deltamethrin, is hereby requesting / petitioning the Environmental Protection Agency to establish a new Exclusive Use Period for data associated with new minor public health use of deltamethrin for Wide Area Mosquito Control by applying the provisions of FIFRA § 3(c)(1)(F)(vi).

FIFRA § 3(c)(1)(F)(vi) states that:

> *With respect to data submitted after the date of enactment of this clause by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a non-minor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.*

Deltamethrin Registrations and Exclusive Use status

Deltamethrin Technical (EPA Reg. No. 264-1006) is currently registered by Bayer CropScience LP. It was first granted US registration on March 2, 1994 under EPA Reg. No. 34147-7, which was subsequently transferred to the aforementioned EPA Reg. No. for Bayer CropScience in 2005. The formulated product registration application for BES0668 Insecticide that includes the minor (public health) use of deltamethrin for Wide Area Mosquito Control is being submitted concurrently with this petition. The exclusive use period for the original deltamethrin registration expired on March 2, 2004, and the data compensation period expired on March 2, 2009.

B. DELTAMETHRIN PUBLIC HEALTH USE FOR WIDE AREA MOSQUITO CONTROL

BES0668 Insecticide is a 2% deltamethrin containing liquid formulation that is designed to be applied as an ultra-low volume (ULV) application for the control of adult mosquitoes and other pestiferous fly species. This product introduces a new use pattern for deltamethrin; Wide Area Mosquito Control.

Mosquitoes are important pests that significantly impact human health, economies and enjoyment throughout much of the United States. Small numbers of mosquitoes annoy people. Large numbers negatively impact real estate values, adversely affect tourism and related business as well as harm pets and livestock. Most serious however, is when mosquitoes, even in small numbers, threaten public health as vectors of infectious disease, such as West Nile Virus (WNV), Eastern equine encephalitis (EEE), Saint Louis encephalitis (SLE), Western equine encephalitis (WEE) as well as diseases which threaten our borders, such as Malaria, Dengue Fever, and Yellow Fever.

Deltamethrin has a number of important public health uses worldwide to combat vector-borne diseases. It is one of the principal pesticides used to fight against malaria-carrying mosquitoes (both as an indoor spray and for the treatment of mosquito bed nets).

Aqua-K-Othrine, a very similar deltamethrin formulation when compared to BES0668 Insecticide was developed for use as a space spray to control mosquitoes more than 15 years ago. It has full World Health Organization Approval and is currently utilized in more than 30 countries outside the U.S., with a high level of safety and effectiveness.

EPA's rigorous pesticide review process ensures that state and local mosquito control departments have access to effective insecticides to reduce disease-carrying mosquito populations without posing unreasonable risk to human health and the environment.

Identification, Chemical Class and Mode of Action of the Active Ingredient

The insecticidal activity of deltamethrin and other pyrethroid insecticides is due to disrupting the kinetics of neuronal voltage-gated sodium ion channel (VGSC) closure following an action potential. This is also the principal mode of toxicity for this class of insecticides in mammals and other vertebrate species, expressed as transient, acute neurotoxic signs such as tremor or uncoordinated movements.

Chemical Name:

CAS: (S)-Cyano-3-phenoxybenzyl(1R, 3R)-3-(2,2-dibromovinyl)- 2,2-dimethyl cyclopropanecarboxylate

Common Name

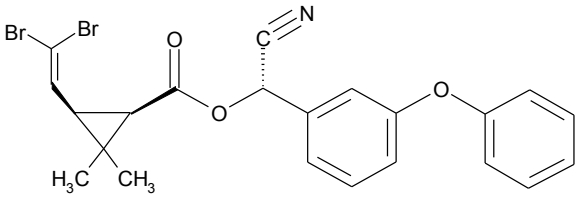
Deltamethrin

Chemical Abstract Service Registry Number

Deltamethrin: CAS Number 52918-63-5

Chemical Structure

Deltamethrin:



Proposed Use Pattern

BES0668 Insecticide is a liquid formulation containing 0.171 lb deltamethrin per gallon as the active ingredient. It is intended as a ULV application for control of adult mosquitoes, flies, gnats, and midges. Its primary use is for mosquito abatement districts for public health control of mosquito populations. This product is applied using ground equipment. Ground equipment is primarily truck-mounted ULV sprayers and mist blowers, but will also include backpack application capable of producing a spray droplet spectrum with a volume mean diameter less than 30 microns.

The application rates for BES0668 Insecticide are low and dependent on the pest pressure, population resistance and vegetation density (Table 1). The application rates range from 0.00045 lb a.i./A to 0.00134 lb a.i./A. A military-only use to control sand flies permits an application rate of 0.0018 lb a.i./A.

Table 1: Summary of Proposed Use Patterns for BES0668 Insecticide

Pest Pressure / Difficulty to Control	Application Rate Lb a.i./Acre
Low / Susceptible	0.00045
Moderate	0.00089
High / Hard to Kill	0.00134
Military-only	0.00180

C. TIMING OF REQUEST FOR ESTABLISHMENT OF A NEW EXCLUSIVITY PERIOD

In the USEPA Question & Answer document [http://www.epa.gov/opp00001/minoruse/exclusive-use-questions.pdf, Revised September 2012]; concerning Establishing a New Exclusive Use Period, the Agency confirms that "the applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph.

As noted above, the exclusive use period for deltamethrin expired in 2004, and the data that Bayer is requesting to be covered by the new exclusivity period pertains solely to the minor use of the pesticide for Wide Area Mosquito Control.

D. CRITERIA FOR MINOR USE (PUBLIC HEALTH) CLASSIFICATION

The definition of a "minor use" as defined in FIFRA § 2(ll), as follows, pertains to exclusive use period for minor use registrations provisions.

> 2(ll) MINOR USE.—The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—
>
> > (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
> >
> > (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and
> >
> > > (A) there are insufficient efficacious alternative registered pesticides available for the use;
> > >
> > > (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
> > >
> > > (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
> > >
> > > (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

E. JUSTIFICATION FOR DELTAMETHRIN WIDE AREA MOSQUITO CONTROL USE BEING A MINOR USE

FIFRA § 2 (ll) (1); Test - Does not meet this criterion

Criterion: The total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

Explanation: Currently approximately 90 million acres are treated annually for Wide Area Mosquito Control to protect public health in the USA. Mosquito control agency's normally treat a specific area several times per year. If an individual acre is treated twice, it is counted as 2 treated acres. This exceeds the FIFRA "less than 300,000 acre" criterion.

FIFRA § 2 (ll) (2); Test - Meets criterion

Criterion: Based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and

Without the protection from generic entry to the market that is afforded by the New Exclusive Use Period, the Wide Area Mosquito Control use of deltamethrin does not provide sufficient economic incentive to support the costs to develop the data necessary for initial or continuing registration. A detailed justification of this follows;

See Cross Reference 1

FIFRA § 2 (ll) (2) (A); Test - Meets criterion

Criterion: There are insufficient efficacious alternative registered pesticides available for the use

As detailed in the attached Letter of Support from the IR-4 Project (see Appendix 4), the mosquito-control community in the United States has a very limited number of choices when adulticide applications are required to protect public health from mosquito-borne disease. Given the wide variety of diseases of both humans and animals that are vectored by mosquitoes in the USA, and in other parts of the world which potentially could move into the USA, it is vitally important to have as large a "toolbox" as possible in the event of disease outbreak. This reality is hampered by the considerable cost to register an active ingredient for mosquito control, and the relatively small market size to regain the costs of registration. Evidence of this is seen in the recent voluntary cancellations of Temephos for mosquito larviciding, and Resmethrin for adulticiding.

Bayer CropScience has recently faced this reality making the difficult decision to voluntarily cancel one of our own active ingredients (Resmethrin, letter issued in October 2012, can sell only through 2015) that is currently used only for Wide Area Mosquito Control. The reasons for cancellation were the relatively low market potential in public health use, the high costs to produce the active ingredient only for one use pattern, and the high costs to keep the products registered through the ReRegistration, Endocrine Disruptor Screening Program, and Registration Review processes. It is our intention to replace Resmethrin with Deltamethrin in our Wide Area Mosquito Control portfolio.

Error! Reference source not found. provides a summary of application parameters for deltamethrin and major competitive insecticides that are presently registered as mosquito adulticides.

Selection of competitive products (by active ingredient) was based on their dominance in the mosquito adulticide market, as shown by Kline consultants survey data for the calendar year 2012. The major competitors in this market are the pyrethroid permethrin and organophosphates malathion and naled. An additional significant competitive product in the market is the pyrethroid resmethrin, but resmethrin will soon leave the market in a voluntary cancellation as noted above. Combined, these four ingredients account for more than 75% of the total insecticide use in vector control and hold approximately 50% of the value in the market.

Table 2: Summary of Application Parameters for Deltamethrin and Competitive Insecticides as Mosquito Adulticides

Active Ingredient	Product Name	Chemical Class/Family	Percent Active Ingredient	Maximum Application Rate (lb a.i./acre)
Deltamethrin	**BES0668**	**Pyrethroid**	**2.0**	**0.0015**
Permethrin	Kontrol 4-4	Pyrethroid	4.6	0.007
Malathion	Fyfanon	Organophosphate	96.5	0.23
Naled	Dibrom	Organophosphate	87.4	0.1
Sumithrin / d-Phenothrin	Anvil 10+10 ULV	Pyrethroid	10.0	0.0036
Pyrethrins	Pyronyl Oil	Pyrethrins	5.0	0.0025
Resmethrin	Scourge	Pyrethroid	18.0	0.007
Etofenprox	Zenivex	Pyrethroid	20	0.007

*See Appendix 2 for further details on calculation of application rate.

Efficacy in non-resistant / manageable mosquito species

For comparison purposes, data for numerous competitive products were collected as in-house Bayer studies and peer-reviewed publications (Appendix 2) that followed equivalent testing guidelines. Table 3 details the comparative efficacy of such adulticides at distances that were selected for consistency and standard reporting across the various publications that were evaluated. Droplet size and application rates were taken into consideration for the purposes of this comparative study. Mosquito species in Table 3 (I.e. *Ae. sollicitans, Ae. taeniorhynchus, Ae. melanimon, C. pipiens, and Ae. aegypti*) are generally regarded as being more easily managed by conventional ULV-applications of adulticides.

While most competitor adulticides showed appropriate efficacy at 100 ft, a marked decrease in efficacy of all competitors was noted as the range increased to 300 ft. Only BES0668 was consistently effective with 100% mortality (24hr), from 100-300 ft. BES0668 demonstrates excellent efficacy in the control of manageable vectors, doing so at very low levels of A.I. that result in decreased efficacy of competitor adulticides.

Table 3: Efficacy (% Mortality, 24 Hr.) of Deltamethrin and Competitor Mosquito Adulticides on Manageable Vectors† When Applied from Ground-Based ULV.*

Active Ingredient	Product Name(s)	100 ft	200ft	300ft
Deltamethrin	**BES0668**	**100%**	**100%**	**100%**
Naled	Dibrom, Trumpet	99.5%	92.6%	89%
Permethrin	Aquapermanone, Permanone, Aguareslin, AquaKontrol, Biomist	86.4%	87.2%	76.4%
Pyrethrin	Pyrenone	90.2%	76%	NA
Resmethrin	Scourge	74.1%	64.7%	63.3%
Sumithrin	Duet, Anvil	99%	95.2%	88.5%

† *Ae. sollicitans, Ae. taeniorhynchus, Ae. melanimon, C. pipiens, and Ae. aegypti*

*Data was derived from 12 independent peer-reviewed studies, reference: Appendix 2. While application rates varied, data was compiled to reflect an average rate of 0.5 ± 0.05 g A.I. per ha with particle size ranging from 15.1-25.9 (VMD_{50}).

Efficacy in tolerant and/or hard to kill species of mosquitoes

In vector control programs there are mosquito species that are generally regarded as “hard to kill” (e.g. *C. quinquefasciatus* and *An. quadrimaculatus*). These mosquito species typically have well developed resistance to other organophosphate &/or pyrethroid insecticides and are of particular interest to abatement districts inasmuch as they require frequent applications to keep these populations in check. For the purposes of this report, results were combined from an equal distribution of laboratory colonies and wild-caught mosquito populations.

The data of Table 4 reports the results from the comparative study of BES0668 with competitor adulticides. At all ranges, BES0668-Deltamethrin proved to be more effective than all competitors with the highest percent mortality. Where some competitor adulticides may have limited control at 100ft, most are ineffective (<70% control) as the range from application increases to 200 and 300ft, respectively.

Table 4: Efficacy (% Mortality, 24 Hr.) of Deltamethrin and Competitor Mosquito Adulticides on Hard to Kill Vectors† When Applied from Ground-Based ULV.*

Active Ingredient	Product Name(s)	100 ft	200ft	300ft
Deltamethrin	**BES0668**	**96.1%**	**92.7%**	**82.9%**
Naled	Dibrom, Trumpet	19.4%	20.4%	14.6%
Permethrin	Aquapermanone, Permanone, Aguareslin, AquaKontrol, Biomist	69.4%	60.6%	54.1%
Resmethrin	Scourge	76.5%	73.3%	61.3%
Sumithrin	Duet, Anvil	82.6%	79.9%	81.3%

†*C. quinquefasciatus* and *An. quadrimaculatus* (*C. quinquefasciatus* from Deltamethrin studies were acquired from a laboratory colony)

*Data was derived from 12 independent peer-reviewed studies, reference: Appendix 2. While application rates varied, data was compiled to reflect an average rate of 0.5 ± 0.05 g A.I. per ha with particle size ranging from 15.1-20.6 (VMD_{50}).

FIFRA § 2 (ll) (2) (B); Test - Meets criterion

Criterion: The alternatives to the pesticide use pose greater risks to the environment or human health

Full details of the risk reduction can be found in the Reduced Risk Rationale being submitted concurrently with this request and can be found under MRIDs 49114119 & 49114120. The decision on whether or not this application qualifies for Reduced Risk Classification will be decided before the decision on this petition will be finalized.

The following is a summary of the benefits extracted from those documents;

Deltamethrin and its end-use product BES0668 Insecticide meet a number of the criteria cited in PR Notice 97-3 to qualify for Reduced-Risk status. Only one of the competitive compounds (etofenprox) that deltamethrin is compared to for Reduced-Risk selection is designated as a Reduced-Risk compound. Moreover, etofenprox-containing products are limited in this market, with the major active ingredients for this use in terms of market share being permethrin and malathion. Deltamethrin has distinct advantages over these major competitive compounds. The most significant advantages that deltamethrin brings to reduced-risk criteria are as follows:

- The toxicological database for deltamethrin is essentially complete, according to current EPA requirements, and does not indicate any particular concerns. Deltamethrin has a favorable toxicological profile and presents lower risk to human health by reducing the use of compounds that are listed as “likely human carcinogens” (permethrin and resmethrin), as having “suggestive evidence of carcinogenicity” (pyrethrins and malathion) or compounds that are used with the synergist piperonyl butoxide

(permethrin, sumithrin, pyrethrins and resmethrin), which is listed as a "possible human carcinogen". Deltamethrin would also reduce the use of organophosphorus (OP) insecticides (naled and malathion). Both naled and a metabolite dichlorvos (DDVP) produce delayed-onset polyneuropathy (OPIDP) after a single dose. Finally, BES0668 would also reduce the use of pesticides for which there is evidence of mutagenicity (malathion and naled), developmental toxicity (sumithrin) and heightened sensitivity of the neonate or fetus (malathion, sumithrin and pyrethrins).

- Unlike other pyrethroid competitors, BES0668 Insecticide does not require use of the synergist piperonyl butoxide, which is listed as a "possible human carcinogen".
- BES0668 Insecticide, when used as directed on the label, provides a favorable margin of safety in regard to risks to most non-target organisms. Compared to competitive insecticides, BES0668 offers reduced risk (based on Tier I risk quotients) to: (1) fish (over malathion, permethrin, and resmethrin); (2) freshwater invertebrates (over malathion, naled, and permethrin); (3) marine invertebrates (over etofenprox and permethrin); (4) birds (over naled); and (5) honey bees (over etofenprox, malathion, naled, permethrin, and pyrethrins).
- The application rate for BES0668 is less than half to 75- times lower (100 times lower when considering PBO as an active ingredient) than competitive products.
- BES0668 Insecticide is applied using a proprietary aqueous formulation not available to its competitors. This formulation is known as FFAST (Film Forming Aqueous Spray Technology) and is designed to reduce the evaporation rate of water during the ULV application, such that the small spray droplets imitate the behavior of oil-based formulations.
- The use of BES0668 Insecticide as either an undiluted or water-diluted application eliminates (human and environmental) exposure to oil-based diluents used in competitive products; thereby reducing exposure to some oils as potential irritants. This also reduces the possibility of application equipment failure caused by some oils used to dilute competitive products and allows clean-up with water rather than organic solvents.

FIFRA § 2 (ll) (2) (C) Test; Meets criterion

Criterion: The minor use pesticide plays or will play a significant part in managing pest resistance; or

FIFRA § 2 (ll) (2) (D) Test; Meets criterion

Criterion: The minor use pesticide plays or will play a significant part in an integrated pest management program.

Both criteria are addressed below;

The introduction of BES0688 to control mosquitoes will bring significant benefits for resistance management and integrated pest management, including the following:

- A much-needed new tool in vector management, replacing an expiring tool, Resmethrin.

  The mosquito-control community in the United States, together with their stakeholders, has a very limited number of choices when adulticide applications are required to protect public health from mosquito-vectored disease. For a very long time, the international success of deltamethrin in mosquito control has been well known and Bayer has repeatedly been asked to make this effective mosquito adulticide available to the U.S. market.

- An excellent fit in integrated vector management strategies.

  Deltamethrin has a number of important public health uses worldwide to combat vector-borne diseases. It is one of the principal pesticides used to fight malaria-carrying mosquitoes (both as an indoor spray and for the treatment of mosquito bed nets). Aqua-K-Othrine is a very similar deltamethrin formulation that has been used for many years in Europe, Australia and other markets outside the U.S., with a high level of safety and effectiveness. Aqua-K-Othrine has full WHO Approval for use as a space spray to control mosquitoes.

- Despite limited instances of pyrethroid resistance in mosquitoes in the United States, the pyrethroids still are important tools to help manage resistance to organophosphates such as naled, & malathion, which is more common in some of the tougher-to-control mosquito species, like the southern house mosquito.

- BES0668 Insecticide can be used to effectively control mosquitoes at incredibly low application rates, resulting in extremely low levels of active substance (< 1.0 g AI per acre for normal application) entering the environment after application. This will be a benefit both to public health and non-target organisms in the environment. With high levels of efficacy, BES0668 Insecticide will satisfy demand for more thorough vector suppression during disease outbreaks, as experienced in the West Nile virus flare during 2012. Moreover, this high level of performance can be achieved using a water-based spray, at application rates that are much lower than competing adulticides and without the synergist piperonyl butoxide. All of these factors help to mitigate negative perceptions of area-wide adulticide applications, which can only be beneficial to the public-health mission of municipal mosquito abatement programs and can demonstrate greater margins of safety; thereby, decreasing the hazard and risk of mosquito abatement.

F. CONCLUSIONS

In conclusion, the preceding discussion shows that the registration of deltamethrin for Wide Area Mosquito Control qualifies as a public health minor use, and clearly meets the FIFRA § 3(c)(1)(F)(vi) criteria for granting a new 10 year exclusive data use period. Deltamethrin, when used in Public Health Mosquito Control programs, effectively controls adult mosquitoes, including the primary disease vector species. These pests are the vector for multiple debilitating diseases including West Nile Virus, Eastern equine encephalitis, Saint Louis encephalitis, Western equine encephalitis, as well as diseases which threaten our borders, such as Malaria, Dengue Fever, and Yellow Fever. Additionally, deltamethrin offers lower risk to humans and/or the environment than alternative insecticides (often organophosphates, or other pyrethroids, most of which are synergized with piperonyl butoxide). With its lower use rate per acre, and control of key pests, not only is chemical use minimized, but exposure to applicators and non-target organisms is also reduced. Deltamethrin use for Wide Area Mosquito Control is supported by both the Department of Defense, and the IR-4 Project (see Appendix 4). Deltamethrin brings an effective and alternative mode of action for control of mosquitoes. Its level of control and long distance efficacy is equal to or better than present standards that frequently include the abovementioned alternative insecticides. Deltamethrin will replace and/or complement some of these currently used products, some of which have already shown signs of resistance development.

Bayer's mission is *Science for a Better Life*® and few products fit this objective better than BES0668 Insecticide. The Department of Defense asked Bayer to register deltamethrin for wide area vector control in the United States and Public Mosquito Abatement Districts need new and improved products for controlling mosquitoes. As a long term supporter of, and investor in, the

public health mosquito abatement industry, Bayer will devote substantial resources to successfully bring BES0668 Insecticide to the market, provide effective and sustainable product stewardship, and training in how to best use the product. . We will continue to invest in research and development of new vector control solutions, as long as our efforts do not benefit other companies more than our own. A new Exclusive Use Period for the data supporting deltamethrin will enable Bayer to recoup the costs for bringing this product to market in a financially viable period of time, and enable us to continue to invest in research and development supporting the mosquito control industry. Without it, our generic competitors will benefit substantially more than Bayer from our development, and greatly reduce our ability to continue to invest in this important business.

EPA had the vision to foresee the need for a 10 year exclusive on data for minor use needs to encourage potential registrants to invest in research and products where there's an important need yet poor financial return. We believe Bayer's financial investment in this initiative is deserving of a 10 year exclusive and thank EPA for their consideration regarding this matter.

G. APPENDIX 1: PROPOSED PRODUCT LABEL

BES0668 Insecticide [Mosquito Image]

Alternate Brand Names: DeltaGard Public Health Insecticide; DeltaGard Mosquito Insecticide; Cirrus Public Health Insecticide; Nobel Public Health Insecticide; Govern Public Health Insecticide; Imperium Public Health Insecticide

FOR WIDE AREA MOSQUITO CONTROL USE ONLY BY FEDERAL, STATE, TRIBAL, OR LOCAL GOVERNMENT OFFICIALS RESPONSIBLE FOR PUBLIC HEALTH OR VECTOR CONTROL, OR BY PERSONS CERTIFIED IN THE APPROPRIATE CATEGORY, OR OTHERWISE AUTHORIZED BY THE STATE OR TRIBAL LEAD PESTICIDE REGULATORY AGENCY TO PERFORM ADULT MOSQUITO CONTROL APPLICATIONS, OR BY PERSONS UNDER THEIR DIRECT SUPERVISION, OR AS ALLOWED BY STATE REGULATIONS FOR PERSONS TREATING PRIVATE PROPERTY.

[FOR THE CONTROL OF FLIES AND MOSQUITOES IN AND AROUND POULTRY AND LIVESTOCK FACILITIES.]

ACTIVE INGREDIENT:	
Deltamethrin	2.0 %
OTHER INGREDIENTS :	98.0%
TOTAL :	100.0%

Contains 0.17 pounds of Deltamethrin per gallon

EPA Reg. No. 432-XXXX EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel For Additional Precautionary Statements

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information, Call 1-800-331-2867

FIRST AID	
If swallowed:	• Call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything to an unconscious person.
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for immediate treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Personal Protective Equipment (PPE)

Mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

User Safety Requirements

Follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fresh water and estuarine fish and invertebrates. Runoff from treated areas into a body of water may be hazardous to fish and aquatic invertebrates.

Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes, or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate water when disposing of equipment rinsate or wash waters.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow drift when bees are actively visiting the treatment area, except when applications are made to prevent or control a threat to public and / or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes, or the occurrence of mosquito-borne disease in animal or human populations**,** or if specifically approved by the state or tribe during a natural disaster recovery effort.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

SHAKE OR AGITATE THOROUGHLY BEFORE USE: Product (either diluted or undiluted) must be thoroughly agitated before use. Avoid prolonged storage of excess formulation in application equipment.

NOTICE: This concentrate is for dilution with water only; it cannot be diluted in oil.

WIDE AREA AND SPACE SPRAY APPLICATION RATES AND CONDITIONS

Do not exceed 0.036 pounds of AI per acre per year to any site. Do not make more than 25 applications per site per year. More frequent applications and more than 25 applications per site may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

BES0668 INSECTICIDE is approved for application as an Ultra-Low Volume (ULV) aerosol to control flying or resting adult mosquitoes and flies in residential, industrial, urban, recreational, municipal, agricultural and other areas where adult mosquitoes and flies are found. This product is used for control of mosquitoes and flies in areas such as residential areas, industrial areas, urban areas (such as utility tunnels, sewers, storm drains and catch basins, pipe chases, basements, underground passages, parking decks, crawl spaces, or uninhabited buildings), parks, campsites, woodlands, athletic fields, golf courses, playgrounds, recreational and overgrown waste areas, roadsides, swamps, marshes, tidal areas, corrals, feed lots, swine lots, poultry ranges, zoos, animal quarters, barns, orchards, dumps, junkyards, tire dumps, and other areas where adult mosquitoes and flies may be found.

This product may be applied over any and all crops or agricultural areas, including range grasses and pastures for the control of adult mosquitoes within or adjacent to the treatment areas

For best results, apply when insects are most active and meteorological conditions are conducive to keeping the spray cloud in the air column close to the ground. An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning is recommended. Apply when wind speed is equal to or greater than 1 mph.

GROUND APPLICATION INSTRUCTIONS

This product is recommended for application with hand-held, backpack, portable & truck mounted ULV sprayers and portable and vehicle mounted mist-blowers for wide area applications, to control adult mosquitoes, black flies, gnats, biting and non-biting midges, stable flies, horse flies, deer flies, sheep flies, horn flies, and nuisance flying insects such as houseflies or blow flies.

DROPLET SIZE DETERMINATION FOR GROUND APPLICATION EQUIPMENT

This proprietary FFAST (Film Forming Aqueous Spray Technology) formulation greatly reduces the evaporation rate of water from the sprayed droplets and allows the water-based spray cloud to behave as that produced by a typical oil-based formulation. This enables the spray droplets to maintain optimum size and stability while drifting through the target area.

Spray equipment must be adjusted so that the volume median diameter (VMD) is between 8 - 30 microns ($8\mu \leq D_{v0.5} \leq 30\mu$) and that 90% of the spray is contained in droplets smaller than 50 microns ($D_{v\,0.9} < 50\mu m$). Directions from the equipment manufacturer or vendor or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

ULV NON-THERMAL AEROSOL (COLD FOG):

Apply through any non-thermal ULV application equipment capable of producing the required droplet spectrum. Base acreage calculations on the equipment manufacturer's recommended swath width. Apply at a rate not to exceed 0.0014 pounds of deltamethrin per acre in any given 24-hour period. An optimum swath is created when this product is applied from a truck that is being driven perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area.

This product may be applied through ULV Cold Aerosol Generators, or other equipment designed for non-thermal ULV aerosol applications. The desired application rate may be obtained under different conditions by altering the dilution rate of this product, the flow rate of the insecticide from the application equipment and the vehicle speed. Examples are given in the following table:

Flow Rate based on a 300 foot swath width (Fluid Ounces Per Minute)

Application Rate (lb deltamethrin/ Acre)	Vehicle Speed (MPH)	Undiluted	Diluted 1 + 1	Diluted 1 + 2	Diluted 1 + 3	Diluted 1 + 4
0.00045	5	1.01	2.02	3.03	4.04	5.05
	10	2.02	4.04	6.06	8.08	10.11
	15	3.03	6.06	9.10	12.13	15.16
	20	4.04	8.08	12.13	16.17	20.21
0.00089	5	2.02	4.04	6.06	8.08	10.11
	10	4.04	8.08	12.13	16.17	20.21
	15	6.06	12.13	18.19	24.25	30.32
	20	8.08	16.17	24.25	32.34	40.42
0.00134	5	3.04	6.09	9.13	12.17	15.22
	10	6.09	12.17	18.26	24.34	30.43
	15	9.13	18.26	27.39	36.52	45.65
	20	12.17	24.34	36.52	48.69	60.86

Where dense vegetation or a public health emergency is present, the use of higher rates and/or slower speeds is recommended.

When targeting organophosphate resistant or other difficult to control species of mosquitoes or flies use of the high label rate is recommended.

PORTABLE, BACKPACK OR HAND CARRIED ULV APPLICATION: Apply through non-thermal ULV application equipment and base acreage calculations on a 50 foot swath. At a pace of 2 MPH (2.9 ft/sec) apply 1 ounce per minute of BES0668 INSECTICIDE diluted as follows: for an application rate of 0.00045 pounds of Deltamethrin per acre dilute 1 to 14, for an application rate of 0.00089 pounds of deltamethrin per acre dilute 1 to 6.5, for an application rate of 0.00134 pounds of deltamethrin per acre dilute 1 to 4. Based on the above dilution and application rates apply 5 ounces of diluted product while walking 870 feet (290 yards)

FLY AND MOSQUITO CONTROL IN INDOOR/OUTDOOR LIVESTOCK AND POULTRY FACILITIES: This product is recommended for application with hand-held, backpack, portable & truck mounted ULV sprayers and portable and vehicle mounted mist-blowers for wide area applications, to control mosquitoes, black flies, gnats, biting and non-biting midges, stable flies, horse flies, deer flies, sheep flies, horn flies, and nuisance pests such as face flies or blow flies.
For the treatment of livestock and poultry facilities (e.g., cattle, dairy and livestock barns, goat houses, horse stables/barns, loafing sheds, poultry houses, shade houses, stables, swine houses, feedlots, manure piles, swine yards, corrals, stockyards, holding pens and other animal facilities where flies become pests and quick knockdown is needed.

This product may be applied undiluted, but to maximize efficacy against larger fly species (e.g., blow flies, flesh flies) it is recommended to dilute in water (1 + 1) before application, increasing the droplet density in the ULV cloud.

Indoors, reduce air movement as much as possible before applying by closing doors, windows and other openings; if animals are present, ventilate the treated area immediately following application. When treating indoors, cover any exposed drinking water, drinking fountains, and animal feed before application. Outdoors, apply when insects are most active, usually in late afternoon when there is little wind. Pay particular attention to areas where flies congregate, such as around feed bunks, fences, and on the exterior walls of buildings. Animals may be present during treatment.

[Optional text]

United States Department of Defense use for control of Phlebotomine Sand Flies.

BES0668 INSECTICIDE may be applied by United States military personal or applicators under direct U.S. military supervision for control of Plebotomine sand flies by ground or aerial ULV application.

APPLICATION RATE: For effective control, apply this product diluted or undiluted at a rate of 0.0018 pounds of active ingredient per acre (equals 2 grams per hectare).

GROUND APPLICATION INSTRUCTIONS: Adjust spray equipment so that the volume median diameter is less than 30 Microns and that 90% of the spray consists of droplets smaller than 50 microns

AERIAL APPLICATION INSTRUCTIONS: Do not apply by fixed wing aircraft at a height less than 100 feet, or by helicopter at a height less than 75 feet.

For best results, treat when insects are most active and meteorological conditions are conducive to keeping the spray cloud in the air column close to the ground. In order to compensate for windy conditions and ensure drift onto the target area, aerial application with aircraft equipped with Global Positioning Systems (GPS) is recommended.

DROPLET SIZE DETERMINATION FOR AERIAL APPLICATION EQUIPMENT:

The effects of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

Aerial Application made at ≤ 200 feet above ground elevation:

Spray equipment must be adjusted so that the volume median diameter produced is less than 60 microns (D_v 0.5 < 60 µm) and that 90% of the spray is contained in droplets smaller than 115 microns (D_v 0.9 < 115 µm).

Aerial Application made at >200 feet above ground elevation:

Spray equipment must be adjusted so that the volume median diameter produced is less than 80 microns (D_v 0.5 < 80 µm) and that 90% of the spray is contained in droplets smaller than 160 microns (D_v 0.9 < 160 µm).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE AND SPILL PROCEDURES: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling:

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 pounds)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

Refillable container: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience LP. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DeltaGard is a registered trademark and FFAST is a trademark of the Bayer Group

Net Contents:

PRODUCED FOR

Bayer Environmental Science

Bayer Environmental Science
A Division of Bayer CropScience LP
PO BOX 12014, 2 T. W. Alexander Drive
Research Triangle Park, NC 27709

Marketing Claims:

- For Effective Control of Adult Mosquitoes (Including organophosphate resistant species), Midges (biting and non-biting), and Flies
- For use as a Space Spray by Ground Application to Control Adult Mosquitoes and Flies
- Unique Formulation Allows Dilution with Water Rather Than Oil
- [Contains] [Requires] no [synergist] [piperonyl butoxide] [PBO]
- Contains no [Volatile Organic Compounds] [VOCs]
- Low odor
- EPA Reduced Risk Classification
- Uses Water as a Diluent
- Fast and Effective Control of Adult Mosquitoes and Flies
- Lower application rates than other pyrethroid based formulations used in mosquito control
- Low use rates
- Provides Quick Knockdown and Effective Control of Mosquitoes, Flies, Gnats, Biting and Non-Biting Midges
- For Ground Application
- A FFAST™ Formulation
- May be Applied Undiluted or Diluted in Water
- ULV application provides excellent control at Rates Up to 0.00134 Pounds Deltamethrin per Acre
- ULV application provides excellent control at Rates As low as 0.00045 Pounds Deltamethrin per Acre
- Provides quick, permanent knockdown of Adult Mosquitoes and Flies
- Excellent toxicity profile

H. APPENDIX 2: REFERENCES

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Weathersbee, A. A., III, M. V. Meisch, A. Inman, and D. A. Dame. "ACTIVITY OF LAMBDA-CYHALOTHRIN APPLIED AS AN ULTRALOW VOLUME GROUND TREATMENT AGAINST ANOPHELES QUADRIMACULATIS ADULTS." Journal of American Mosquito Control Association 7.2 (1991): 238-41.

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Brown, James R. and Rui-De Xue. “GROUND APPLICATION OF AQUARESLIN AND AQUAKONTROL AGAINST ANOPHELES QUADRIMACULATUS, AEDES AEGYPTI AND AEDES ALBOPICTUS.” Journal of American Mosquito Control Association 27.3 (2011): 330-32.

I. APPENDIX 3 – LIST OF STUDIES REQUESTED FOR EXCLUSIVE USE

Study	Guideline No.	EPA MRID No.
Vandock, K. P.; A summary of laboratory and field efficacy trials for BES0668 insecticide against important public health pests; Department of Mosquito and Rodent Control, Lake Charles, LA, USA; Report No.: US0377; Document No.: M-463444-01-2; July 26, 2013; Pages: 11	810.3400	49114101
Zhai, J.; Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of patriot adulticide using ground ULV sprayer against Aedes aegypti mosquitoes in Florida; Eurofins Agroscience Services Inc., Mebane, NC, USA; Report No.: S11-00013; Document No.: M-465171-01-1; February 20, 2013; Pages: 207	810.1000 810.3400	49114102
Zhai, J.; Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of patriot adulticide using ground ULV sprayer against Aedes Sollicitans mosquitoes in Texas; Eurofins Agroscience Services Inc., Mebane, NC, USA; Report No.: S11-00014; Document No.: M-465233-01-1; February 20, 2013; Pages: 218	810.1000 810.3400	49114103
Zhai, J.; Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of patriot adulticide using ground ULV sprayer against Aedes sp. and Culex sp. mosquitoes in California; Eurofins Agroscience Services Inc., Mebane, NC, USA; Report No.: S11-00015; Document No.: M-465239-01-1; February 20, 2013; Pages: 199	810.1000 810.3400	49114104
Zhai, J. (2013); Field GLP study to determine efficacy, droplet spectrum, spray drift and deposition of Patriot adulticide using ground ULV sprayer against Anopheles sp. and Culex sp. mosquitoes in North Carolina; Eurofins Agroscience Services, Mebane, NC, Study No. S11-00016, 208 pages	810.1000 810.3400	49114105
Zhai, J.; Field demonstration study to determine efficacy of Patriot adulticide using ground ULV sprayer against field-collected Culex quinquefasciatus mosquitoes in Louisiana; Eurofins Agroscience Services Inc., Mebane, NC, USA; Report No.: S12-03042; Document No.: M-465250-01-1; December 10, 2012; Pages: 23	810.1000 810.3400	49114106
Zhai, J.; Field GLP studies to determine efficacy of Patriot adulticide using ground ULV sprayer against fly species in North Carolina; Eurofins Agroscience Services Inc., Mebane, NC, USA; Report No.: S12-00017; Document No.: M-465246-01-1; February 20, 2013; Pages: 114	810.1000 810.3000 810.3400	49114107
Baker, B.; Product chemistry of BES 0668 insecticide; Bayer CropScience LP, Kansas City, MO, USA; Report No.: BR 2730; Document No.: M-463440-01-1; August 29, 2013; Pages: 157	830 Series	49114108
Xu, T.; Dyer, D.; Deltamethrin - Aquatic field dissipation study waiver request; Bayer CropScience LP, RTP, NC, USA; Report No.: US0176; Document No.: M-408146-01-2; May 11, 2011; Pages: 75	835.6200	49114110
Perez-Ovilla, et al, (2013); Environmental Fate, Ecological and Drinking Water Exposure Assessment for Deltamethrin Use as Adulticide; Bayer CropScience, RTP, NC; Report No. MEDAY003; DART Reference No. M-461870-01-1; 41 pages	835.SUPP	49114111
Krolski, M. E.; Deltamethrin - Magnitude of the residue in/on alfalfa, leaf lettuce, and grass following Ultra Low Volume (ULV) spray for Mosquito Control; Bayer CropScience LP, RTP, NC, USA; Report No.: RADAN008; Document No.: M-462353-01-1; August 23, 2013; Pages: 788	860.1500	49114112
Merrill, D.; BES 0668 insecticide - Acute oral toxicity up and down procedure in rats; Product Satety Laboratories, Dayton, NJ, USA; Report No.: 36669; Document No.: M-461371-01-1; July 29, 2013; Pages: 17	870.1100	49114113

Study	Guideline No.	EPA MRID No.
Merrill, D.; BES 0668 insecticide - Acute dermal toxicity study in rats - Limit test; Product Satety Laboratories, Dayton, NJ, USA; Report No.: 36670; Document No.: M-461375-01-1; July 29, 2013; Pages: 15	870.1200	49114114
Merrill, D.; BES 0668 insecticide - Acute inhalation toxicity study in rats - Limit test; Product Satety Laboratories, Dayton, NJ, USA; Report No.: 36671; Document No.: M-461389-01-1; July 29, 2013; Pages: 23	870.1300	49114115
Merrill, D.; BES 0668 insecticide - Primary eye irritation study in rabbits; Product Safety Labs, Dayton, NJ, USA; Report No.: 36672; Document No.: M-461608-01-1; July 29, 2013; Pages: 15	870.2400	49114116
Merrill, D.; BES 0668 insecticide - Primary skin irritation study in rabbits; Product Safety Labs, Dayton, NJ, USA; Report No.: 36673; Document No.: M-461612-01-1; July 29, 2013; Pages: 15	870.2500	49114117
Merrill, D.; BES 0668 insecticide - Local lymph node assay (LLNA) in mice; Product Safety Labs, Dayton, NJ, USA; Report No.: 36674; Document No.: M-461616-01-1; July 29, 2013; Pages: 25	870.2600	49114118
Sheets, L., et al (2013); Reduced Risk Rationale for the Use of Deltamethrin in Wide Area Mosquito Control for Application by Commercial Applicators (Part I); Bayer CropScience, RTP, NC, Report No. US0356, 127 pages.	SUPP	49114119
Morrison, G., et al (2013); Resistance Management, Comparative Performance, and Market Analysis for BES0668 Insecticide; Reduced Risk Rationale for the Use of Deltamethrin in Wide Area Mosquito Control for Application by Commercial Applicators (Part II); Bayer CropScience, RTP, NC, Report No. US0357, 23 p. with 7 p. Confidential Appendix.	SUPP	49114120

J. APPENDIX 4 – LETTER OF SUPPORT FROM IR-4 PROJECT

The IR-4 Project
Pest Management Solutions for Specialty Crops and Minor Uses

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540
732.932.9575 fax 609.514.2612
www.ir4.rutgers.edu

Ms. Lois Rossi
Director, Registration Division
Office of Pesticide Programs
US Environmental Protection Agency
Washington, DC

Re: New Exclusive Use Period for Data for New Public Health Minor Uses for Deltamethrin (BES0668 Insecticide)

September 30, 2013

Dear Ms. Rossi,

The purpose of this letter is to formally state the IR-4 Project's support for EPA's consideration of establishment of a new exclusive use period for the data developed by Bayer Environmental Sciences to add new public health minor uses for deltamethrin. The specific product application is for BES0668 Insecticide, an aqueous formulation of 2% deltamethrin intended for area-wide control of public health pests including mosquitoes, sand flies, and other biting flies and midges. The IR-4 Project has not generated any of the relevant data, but has a strong interest in facilitating the development and registration of innovative vector control products.

As you know, the IR-4 Project was established in 1963 by the State Agricultural Experiment Stations to provide a mechanism to develop the data required by the regulatory authorities to support registration on high value, low acreage crops, and has grown to also broadly support minor uses of pesticides such as for public health vector control. The IR-4 Project has developed formal schemes to prioritize potential solutions to address pest management voids in specialty crops and other minor uses. During these processes, the participants include many factors in selecting projects including this guidance: "Consideration of priorities should include the availability and efficacy of alternative pest management products, the potential pest damage from the target pest, the performance of the proposed product in managing the target pest and the compatibility of the proposed product in new and existing Integrated Pest Management Programs." The IR-4 Project has received specific requests for assistance from publicly funded vector control programs operating in the U.S. and abroad to facilitate the registration of BES0668 Insecticide vs. mosquitoes and sand flies, and we believe that this proposal meets our criteria for support.

Deltamethrin has been registered in the U.S. since 1994, and we understand that any exclusive use periods for this A.I. have expired. Deltamethrin-based products are registered in the U.S. for public health uses including vs. mosquitoes, ticks, and bed bugs, but the use patterns have been very limited. While recommended by WHO for both indoor and outdoor space spraying vs. mosquitoes, deltamethrin public health pesticides have not been previously registered for area-wide spraying in the U.S.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-NIFA, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

IR-4 appreciates the opportunity to work with modern products like BES0668 Insecticide that are effective against a range of public health pests at very lose dose rates. We are optimistic that our efforts will help provide vector control programs with a valuable addition to their chemical control tool box, and we support Bayer's request for establishment of an exclusive use period for the data they generate towards this end.

Please let me know if you need additional information or if we can answer any additional questions.

Sincerely yours,

Jerry Baron, Ph.D.
IR-4 Executive Director

Karl Malamud-Roam, Ph.D.
IR-4 Public Health Pesticides Program Manager

Cc:
Mr. Jan Brill, Bayer Environmental Sciences
Mr. Gordon Morrison, Bayer Environmental Sciences
Ms. Susan Jennings, EPA

CONFIDENTIAL BUSINESS INFORMATION (CBI) SECTION

Title

Request for Establishment of a New Exclusive Use Period Associated with Registration of New Public Health Use of Deltamethrin as Provided for Under FIFRA § 3(c)(1)(F)(vi)

Company Product Code

Deltamethrin (BES0668 Insecticide)

Authors

Jan Brill
Gordon Morrison

Guideline Reference

US EPA OCSPP Guideline Number SUPP
EPA Questions and Answers Document – Exclusive Use Data Protection for Minor Use Registrations – Revised September 2012

Completion Date

September 6, 2013

Submitted By

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive,
Research Triangle Park, NC 27709, USA

CROSS REFERENCE PAGE

Cross Reference No. 1:

The cross-reference number noted on the placeholder page is used in place of the following pages.

Page	Reason for Deletion	FIFRA Reference
8 - 12	Description of Production & Sales	§10(d)(2)

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA section 10(d)(2) is identified by cross-reference to a confidential attachment. As required by Pesticide Registration (PR) Notices 86-5 and 2011-3, justification supporting the confidentiality claim is presented below:

1. "Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality."

   Bayer Response: The confidential components are clearly designated within the confidential attachment to the report.

2. "Cite the reasons why the cited passage qualifies for confidential treatment."

   Bayer Response: The confidential attachment contains sensitive Bayer CropScience product marketing and sales information that qualifies for confidential treatment under FIFRA Section 10(d)(2).

3. "Indicate the length of time -- until a specific date or event, or permanently -- for which the information should be treated as confidential."

   Bayer Response: Bayer CropScience considers this information confidential indefinitely, with no time limitations.

4. "Identify the measures taken to guard against undesired disclosure of this information."

   Bayer Response: All sales information is treated and maintained within Bayer CropScience as business confidential and not distributed outside the Bayer secured firewall.

5. "Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures."

   Bayer Response: Bayer CropScience has not disclosed this sales information to the public, and it has not been distributed outside the Bayer firewall, nor shared with anyone who is not a Bayer employee or as a consultant under secrecy agreement.

6. "Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information."

   Bayer Response: None known.

7. "If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial."

   Bayer Response: Disclosure of business confidential sales information would cause substantial competitive harm by providing our competitors with an intimate knowledge of our business knowledge pertaining to the subject compound and its associated markets.

8. "If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how."

   Bayer Response: The indicated business confidential sales information is voluntarily submitted to EPA, in order to support the reduced risk petition submitted to EPA. Public disclosure of the referenced information by the EPA would definitely weigh negatively on our willingness to provide such information in the future.

ECONOMIC JUSTIFICATION FOR NEW EXCLUSIVE USE PERIOD

K. INTRODUCTION

Historically, BCS did not develop deltamethrin in the United States for Wide Area Mosquito Control use because the costs to register this use pattern would not meet the company's return on investment criteria for new product development. In addition, Bayer has been supporting mosquito control professionals as the exclusive supplier of the active ingredient resmethrin under the brand name Scourge®. Capable of controlling the most difficult mosquito species, Scourge provides mosquito abatement districts with a product they can depend upon.

Unfortunately, due to the high cost of goods and low profitability of Scourge, Bayer could not financially justify the costs (estimated to be in the range of $1.5 to $2.5 million, or higher if Tier 2 EDSP triggered) to preserve resmethrin through the FQPA reregistration & Endocrine Disruption Screening Program processes. As a result, BCS made the difficult decision to voluntary cancel the registration of our Scourge products in October 2012, and will no longer sell Scourge after Dec 31, 2015.

Development of deltamethrin for mosquito control in the United States creates a similar dilemma for Bayer. The high cost to bring BES0668 to market without a new Exclusive Use Period of the supporting data does not meet the company's financial return criteria and will make it difficult to recoup the initial investment in a reasonable time frame.

Bayer costs incurred (to date) to support Wide Area Mosquito Use registration application

L. COSTS TO SUPPORT APPLICATION FOR REGISTRATION FOR BES0668

Product Chemistry Data Costs	$144,000
Acute Toxicity Data Costs	$38,000
Product Performance Data Costs	$605,000
Aquatic Dissipation Waiver Request	$15,000
Reduced Risk Document Preparation	$205,000
Residue Trials and Tolerance Petition	$271,000
Dossier Preparation & PRIA Fees	$75,000
Total Cost	$1,353,000

M. ECONOMIC SITUATION WITHOUT NEW EXCLUSIVE USE PERIOD:

- BES0668 is a FFAST (Film Forming Aqueous Spray Technology) formulation. This technology, developed by Bayer, improves performance by reducing the speed of evaporation of water droplets in the spray cloud, allowing it to remain efficacious for a longer period of time. Because this technology is off patent, generic suppliers will be able to closely copy Bayer's formulation. Or worse, from an environmental perspective, they will utilize a solvent based formulation in order to lower the cost still further, while exposing the applicators, residents, and environment to a solvent based spray cloud rather than water.
- Generic competition will almost certainly enter the market as early as one year after the launch of BES0668. Typical adoption practices of the Mosquito Abatement Districts show that the first year is a trial year for any new product. Mosquito abatement districts will use this testing period with deltamethrin to determine whether or not it will become part of their continuing control program. This means end users will have the option to purchase generic product the second mosquito season after the launch of BES0668 crippling our ability to build brand loyalty and recoup our investment, while enabling generic companies to benefit greatly from our investment.
- The public bidding process, which accounts for approximately 80% of the volume sold in the mosquito control market favors lower cost generic products. Bid specifications require municipalities to purchase the lowest priced product that meets bid specifications. Because bid prices are open to the public, History has shown that generic companies gain market share by dropping price immediately, thereby removing value from the market quickly.
- It is estimated that lower cost generic products from companies that do not perform basic research or provide significant industry support will eventually capture 80 - 90% percent of the total deltamethrin market for mosquito control, depending on whether Bayer gains the new exclusive use period. This projection is based on the historical situation in the market with permethrin where Bayer, who developed the use pattern and had a significant period of exclusivity initially, now supplies just 20 percent of the permethrin market on a branded basis and generic companies supply 80% (see table 1). The additional share loss to generic deltamethrin (to 90%) is expected if Bayer is not granted the new exclusive use period during which we can secure some brand loyalty, and when we could have our improved formulation worked into bid specifications.
- Bayer sales and profit estimate under this scenario where generic competition enters the market in year 2 is listed in table 6. Payback of the initial investment of $1.3 million is estimated to be 7 years.

Table 5: Market Share of Permethrin in the professional Mosquito Control Market CY 2012

Company	Permethrin Brand Name	Generic	Acres Treated (000)	% of Total Acres Treated
Univar	Kontrol	Yes	18424	47%
Clarke	Biomist	Yes	8964	23%
Bayer	**Permanone, Aqua-Reslin**	**No**	**7699**	**20%**
AllPro	Aqualuer, AquaHault	Yes	4070	10%
Total			39157	100%

- Kline® 2012 syndicated market research report

N. ECONOMIC SITUATION WITH NEW EXCLUSIVE USE PERIOD :

- Generic competition is still expected, however not until the 4th year after the launch of BES0688 due the time it would take for a generic company to generate their own supporting data and gain federal and state registration approvals.
- Bayer sales and profit estimates under this scenario are listed in table 7. As you can see from the figures, with the Exclusive Use Period, we can recover our investment by year 3, with a financially acceptable total value at the end of the 10 year period of almost 13 Mio$ (with generics making 21 Mio$ during the same time period). Without the exclusive use period, it will take roughly 7 years to recoup our costs, with less than half of the top-line value (5.6 Mio$, vs. 31.7 Mio$ for generics), and our profit will barely cover the data development cost. With such a low return without the exclusive use protection, and most of the sales and profit going to generic competitors, it will be difficult for Bayer to maintain our commitment to continued development of new products and solutions for use by Mosquito Abatement Districts. This would not be a benefit for public health, or for the continuing need for a useful and efficacious toolbox for MADs.

Table 6: Financial estimate without 10 year exclusive use of data

	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7		Year 8		Year 9		Year 10		10 yr Total
Product	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	$ Value
Bayer BES0668	100%	$ 347	60%	$ 956	20%	$ 601	15%	$ 599	15%	$ 711	10%	$ 474	10%	$ 474	10%	$ 474	10%	$ 474	10%	$ 474	$ 5,583
Generic Deltamethin	0%	$ -	40%	$ 637	80%	$ 2,406	85%	$ 3,396	85%	$ 4,027	90%	$ 4,264	90%	$ 4,264	90%	$ 4,264	90%	$ 4,264	90%	$4,264	$ 31,786
Total	100%	$ 347	100%	$ 1,594	100%	$ 3,007	100%	$ 3,996	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$4,738	$ 37,369
Bayer standard cost/ac		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20	
Bayer total cost of goods		$ 126		$ 546		$ 401		$ 479		$ 569		$ 379		$ 379		$ 379		$ 379		$ 379	
Bayer Profit		**$ 221**		**$ 410**		**$ 200**		**$ 120**		**$ 142**		**$ 95**		**$ 95**		**$ 95**		**$ 95**		**$ 95**	**$ 1,567**

- Generics enter market year 2 before Bayer can establish brand loyalty for BES0668
- Standard cost of goods remains constant
- Market size remains constant at 90,268,000 treated acres

Table 7: Financial estimate with 10 year exclusive use of data

	Year 1		Year 2		Year 3		Year 4		Year 5		Year 6		Year 7		Year 8		Year 9		Year 10		10 yr Total
Product	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	Share	$ Value	$ Value
Bayer BES0668	100%	$ 347	100%	$ 1,199	100%	$ 2,063	70%	$ 1,524	50%	$ 2,369	30%	$ 1,421	20%	$ 948	20%	$ 948	20%	$ 948	20%	$ 948	$ 12,714
Generic Deltamethin	0%	$ -	0%	$ -	0%	$ -	30%	$ 653	50%	$ 2,369	70%	$ 3,316	80%	$ 3,790	80%	$ 3,790	80%	$ 3,790	80%	$3,790	$ 21,499
Total	100%	$ 347	100%	$ 1,199	100%	$ 2,063	100%	$ 2,177	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$ 4,738	100%	$4,738	$ 34,213
Bayer standard cost/ac		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20		$ 0.20	
Bayer total cost of goods		$ 126		$ 436		$ 750		$ 1,016		$ 1,895		$ 1,137		$ 758		$ 758		$ 758		$ 758	
Bayer Profit		**$ 221**		**$ 763**		**$ 1,313**		**$ 508**		**$ 474**		**$ 284**		**$ 190**		**$ 190**		**$ 190**		**$ 190**	**$ 4,321**

- Generics enter market year 4 allowing Bayer to gain brand loyalty
- Standard cost of goods remains constant
- Market size remains constant at 90,268,000 treated acres