TITLE

Request for Establishment of a New Exclusive Use Period (Provided by FIFRA § 3 (c) (1) (F) (VI)) for Oxytetracycline Hydrochloride on Olive for FireLine™ 45 WP

(EPA Reg. Nos.: 80990-6)

GUIDELINE REFERENCE

US Environmental Protection Agency Office of Pesticide Programs

Question and Answers – Exclusive Use Data Protection for Minor Use Registrations

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1. This document is informational and is not a result of a study as defined by 40 CFR 160.3. Since this is an informational document no data was required to be generated and reported under the Good Laboratory Practices Standard.

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Introduction

Olive knot, a major global bacterial disease affecting olive trees, is caused by an epiphytic bacterial pathogen, *Pseudomonas savastanoi* pv. *savastanoi* (*Psv*). Since the early 1900s, foliar treatments of copper-based bactericides have been relied upon to control olive knot disease. While copper resistance in *Psv* is relatively limited, to slow or prevent further development of copper resistance by *Psv*, the availability of a non-copper-based bactericide will be essential in the battle against this commercially significant disease.

FireLine™ 45 WP (EPA Reg. No. 80990-6) is a bactericide with oxytetracycline hydrochloride as its active ingredient. AgroSource Inc., registrant for FireLine™ 45 WP, requests exclusive use of the studies submitted in support of The IR-4 Project's request for a new minor use of oxytetracycline on olives per FIFRA § 3 (c) (1) (F) (VI) which states:

> "*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 registration 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*."

To the best knowledge of AgroSource, the exclusive use period for oxytetracycline has expired and that these data pertaining solely to the minor use of oxytetracycline on olives are eligible

for the provisions as indicated in FIFRA § 3 (c) (1) (F) (VI). Minor use for the purpose of extension of exclusive use registration provisions is defined by FIFRA §2 (II) as:

"*2 (II) 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."

A justification for minor use classification per FIFRA §2 (II) (2) (A) (C) or (D) follows below for the use of the oxytetracycline hydrochloride (active ingredient of Fireline™ 45 WP) on olives.

FIFRA §2 (II) (2) (A) – "*There are insufficient efficacious alternative registered pesticides available for the use.*"

Current University of California IPM Pest Management Guidelines[1] for olive knot disease (*Pseudomonas savastanoi* pv. *savastanoi*, *Psv*) list four products having the greatest IPM value for growers to consider. Of these, three are copper-based bactericides (fixed copper, Bordeaux mixture and copper sulfate) while the fourth, Gallex®, a liquid mixture of 2,4-xylenol and meta-cresol (components of coal tar), has anti-bacterial and anti-fungal properties. Gallex is typically applied as a 'paint' directly to the olive knot (gall) and is not generally applied as a foliar spray to trees.

In an effort to identify additional (non-copper based treatments for olive knot), Dr. Jim Adeskaveg has lead a multi-year (2014 – 2018) research effort for the California Olive Board and California Olive Commission under the Project Title: "Epidemiology and management of olive knot caused by *Pseudomonas savastanoi* pv. *savastanoi.*" [4, 5, 6-8]. The overall purpose of these ongoing studies has been to study the efficacy of bactericides, biopesticides, chemical, and other mechanisms to treat and control olive knot caused by *Psv*. Oxytetracycline was included in these studies and showed a high degree of efficacy *in vitro* against *Psv*; results also demonstrated each treatment mechanism must be optimized to maximize efficacy for the specific disease pathogen and host [5].

FIFRA §2 (II) (2) (C) – *The minor use pesticide plays or will play a significant part in managing pest resistance.*

The key component of effective resistance management is the ability to treat the pest with multiple (at least two) product each having a different Mode of Action (MoA) as defined by

[1] See "Olive, Olive Knot, Pathogen: *Pseudomonas savastanoi*" http://ipm.ucanr.edu/PMG/r583100411.html, accessed October 17, 2019.

the Fungicide Resistance Action Committee (FRAC). Oxytetracycline has been assigned FRAC Code 41 – which is different from the FRAC Codes assigned to all other currently registered pesticides for olive knot (see Table 1). Therefore, FireLine™ 45 WP (active ingredient: oxytetracycline hydrochloride) will play a significant part in managing the potential for resistance development in *Pseudomonas savastanoi* pv. *savastanoi.*

Table 1: Currently registered alternative active ingredients for control of olive knot in olives.

Crop Disease Pathogen	Classification	Active Ingredient	FRAC Code[2]
Olive **Olive Knot** ***Pseudomonas savastanoi* pv. *savastanoi* (*Psv*)**	Conventional Chemical Pesticide	2,4-xylenol + m-cresol	N/A
		Basic copper sulfate	Group M1
		Copper oxychloride + Copper hydroxide	Group M1
		Copper Hydroxide	Group M1
		Copper Octanoate	Group M1
		Copper Oxychloride	Group M1
		Copper sulfate pentahydrate	Group M1
		Cuprous Oxide	Group M1
	Biopesticide	*Bacillus subtilis* (and strain QST 713*)*	Group 44
		Laminarin	Group P4

[2] In cases were no FRAC Code is given it may be listed as: NC = not classified or N/A = not assigned.

FIFRA §2 (II) (2) (D) – *The minor use pesticide plays or will play a significant part in an integrated pest management program*.

Use of FireLine™ 45 WP (oxytetracycline hydrochloride, FRAC Group 41) as part of an Integrated Pest Management (IPM) program against *Psv* for control of olive knot disease provides enables multiple bactericides with differing Modes of Action (MoA) to be targeted at the pathogen. This is significant because currently available bactericides are nearly all copper-based products and therefore all have the same MoA (FRAC Group M01). With an over-reliance on copper-based bactericides for treatment of olive knot, the present situation has resulted in increased potential for copper resistance among phyllospheric bacterial populations and excessive copper loading in the environment. By including FireLine™ 45 WP into an IPM program the potential to significantly extend the longevity and increase the value of all active ingredients used in the management of in olive knot disease becomes available to olive growers.

Summary

Regarding the importance for the justification of oxytetracycline hydrochloride (a.i. of FireLine™ 45 WP) for minor use status per FIFRA §2 (II) (2) (A) (C) or (D); as stated previously above the following are important:

1) Current registered products for treatment of olive knot disease are limited to mainly copper-based bactericides and thus to a group of products having a single MoA against the pathogen. With the presence or potential of copper resistance the need for another bactericide having a MoA differing from copper is essential for the effective management of olive knot.

2) The MoA for oxytetracycline differs from that of copper, therefore oxytetracycline can play a significant role in the effective resistance management in the battle against olive knot disease in olives.

3) FireLine™ 45 WP contains the active ingredient oxytetracycline hydrochloride and has established bactericidal efficacy against the pathogen responsible for olive knot disease in olives.

4) The addition of FireLine™ 45 WP into an IPM program for control of olive knot in olives will reduce the amount of metallic copper added to the environment each season.

5) Oxytetracycline rapidly degrades in the environment and the rates and levels proposed will leave zero residue in the target crops with minimal to no lasting impact on the environment when employed in an integrated IPM management program.

Based on justifications in this document to fulfill FIFRA §2 (II) (2) (A) (C) or (D); AgroSource, Inc. submits that oxytetracycline hydrochloride application to olive meets the requirements for minor use. Accordingly, this justification of minor use for oxytetracycline hydrochloride on olive per FIFRA § 3 (c) (1) (F) (VI) supports approval of a new Exclusive Period for AgroSource data and studies provided in support of The IR-4 Project petition to expand the label of FireLine™ 45 WP to olives.

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