



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 26, 2020

Beth Mitchell
Regulatory Affairs Manager
SePRO Corporation
11550 N. Meridian Street, Suite 600
Carmel, IN 46032-4562

Subject: Exclusive Use Protection Request for Minor Use Crop Data - REVISED
Product Name: SONAR TECHNICAL
EPA Registration No. 67690-6
Decision: 544753
Application Date: 9/26/2018

Dear Ms. Mitchell:

This letter corrects an error on the May 18, 2020 letter that responded to the petition requesting that data associated with the minor use registrations of fluridone on avocado, pomegranate, pistachio, mandarin, and cherries/peaches/plums (stone fruit crop group 12-12) each receive a ten-year exclusive-use protection period. Specifically, this letter corrects the date for which exclusive use protection expires for the minor use data subject to the letter. EPA is granting the request for an exclusive-use data protection of ten years to protect the supporting minor use data (MRIDs 50679101-50679107) until **September 26, 2028** under EPA Registration No. 67690-6. **This letter supersedes the previous agency letter dated May 18, 2020 sent in response to your request for exclusive use protection for the minor use crop data specified below in the Determination section of this letter.**

SePRO Corporation cited FIFRA section 3(c)(1)(F)(vi) as the authority for the Agency to make such a determination. The 1996 Food Quality Protection Act ("FQPA") amendments to FIFRA incorporated this subsection under 3(c)(1)(F), the section that provides for protection of certain data submitted in support of pesticide registrations. FIFRA section 3 (c)(1)(F)(vi) sets forth the criteria for extending the period of exclusive-use protection for minor use data.

FIFRA section 3(c)(1)(F)(vi) and its implementing regulations¹ specifically describe the set of data that are eligible for exclusive-use protection. A study submitted by an applicant or registrant to support an

¹ 40 CFR §152.83(b) Exclusive use period for certain minor use data. A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met: (1) The study relates solely to a minor use of a pesticide. (2) The applicant or registrant at the time the new use is requested has notified the administrator that any exclusive use period for the

amendment adding a new minor use to an existing registration that does not retain any period of exclusive use is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the conditions are met. The following are our considerations for determining whether the data associated with the requested registration are eligible for a new ten-year period of exclusive use protection.

First, the data associated with this registration do pertain solely to registrations of minor uses. The minor use definition of crops grown on less than 300,000 acres in the US applies here (FIFRA section 2(II)(1)). Second, the data were submitted after the exclusive-use period for the first registration of the new chemical had expired. The initial registration for fluridone was granted on March 31, 1986. Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B). Fourth, the data was submitted concurrently with the application for the new minor uses, in compliance with FIFRA section 3(c)(1)(F)(vi). Finally, the data were not generated by IR-4. Data generated by IR-4 are not entitled to exclusive-use protection (see 40 CFR 152.94(b)).

DETERMINATION

The Agency concludes that the data supporting the uses of fluridone on avocado, pomegranate, pistachio, mandarin (tangerine), and the stone fruit crop group 12-12 qualify for the requested ten-year period of exclusive-use protection. EPA concludes that avocado, pomegranate, pistachios, mandarin (tangerine), and stone fruit crop group 12-12 are minor uses and are grown on less than 300,000 bearing age acres as defined by FIFRA § 2(II)(1) and that the other criteria have been met (as described above). Therefore, the Agency GRANTS your request for a new 10 year exclusive-use protection of these data (MRIDs 50679101-50679107). If the Agency receives a me-too application for this pesticide and use combination during this exclusive-use data protection period citing SePRO's data for which SePRO has not given a letter of authorization, those applications will be denied. Exclusive-use protection for data, which complies with 40 CFR 152.83(b), submitted in support of these registrations will expire September 26, 2028, 10 years from the date of application. In addition, if the minor use registration which is supported by these data 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 provision of FIFRA section 3(c)(1)(F)(vi).

pesticide has expired and that the study is eligible for exclusive use treatment. (3) Less than 10 years have passed since the study was submitted to EPA. (4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B). (5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use. See also, Federal Register 79, 6825.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Goodis". The signature is fluid and cursive, with a large initial "M" and "G".

Michael Goodis, PE
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Attachment: BEAD. June 6, 2019. REVISED: Minor Use Status of Avocado, Pomegranate, Pistachio, Mandarin, and Stone Fruit for a New Exclusive Use Period for Protection of Data for Fluridone (DP 450617)