



**US Environmental Protection Agency Office of
Pesticide Programs**

**SePRO's Petition to Establish a New 10-Year
Exclusive Use Period for Data Supporting New
Minor Uses**

September 26, 2018

Report Title:

Petition to Establish a New 10-Year Exclusive Use Period for Data Supporting New Minor Uses

Active Ingredient:

Fluridone

EPA Guideline:

None

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COMPANY: SePRO Corporation

COMPANY
REPRESENTATIVE:



26 September 2018

Laurent C. Mézin, Ph.D.
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Date

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26 September 2018

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SePRO Corporation

Sonar Technical (EPA Registration Number 67690-6)
Fluridone Technical (EPA Registration Number 67690-31)
Fluridone Technical (EPA Registration Number 67690-63)

Petition to Establish a New 10-Year Exclusive Use Period for Data Supporting New Minor Uses

Products: Brake
EPA Registration Number 67690-78

Executive Summary

SePRO Corporation (SePRO) is petitioning the EPA to establish a new 10-year exclusive use period for all data being submitted to support the use of fluridone on the following minor use crops: avocado, pomegranate, pistachio, mandarin, and cherries/peaches/plums (stone fruit crop group). Pursuant to FIFRA Section 3(c)(1)(F)(VI) a new 10-year exclusive use period can be obtained for the minor use-specific data generated by a registrant to register a minor use after the initial exclusive use period expires.

Introduction

Fluridone (1-Methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone) was registered with the EPA in 1986 as a new active ingredient for aquatic weed control, which is classified as a minor use. This was the only EPA registered use for the active ingredient until the Agency approved the use on cotton in 2016. SePRO acquired the active ingredient (including registrations and the supporting database) from Dow Elanco in 1993 and became the primary registrant. SePRO currently has three technical grade active ingredient (TGAI) fluridone registrations and 17 typical end-use product (TEP) fluridone registrations. Please refer to Table 1 for a listing of all current SePRO registrations for products containing fluridone.

Fluridone (initially developed under the numbered compound code name of EL171) was initially developed in the US as a potential cotton herbicide by Eli Lilly. This use was never submitted to EPA due to economic reasons (i.e., it was too expensive to produce and sell in the cotton market). Fluridone is a systemic herbicide used to manage aquatic weeds in ponds, lakes, and other aquatic sites. It inhibits carotene synthesis, which causes the loss of chlorophyll. It is typically applied to large-scale areas or the whole water body because it requires a contact time of >45 days to be effective. It is highly regarded as having a very good safety profile and is one of most widely used aquatic herbicides for large scale management of aquatic weeds in sensitive environments. The EPA approved labeling allows for a single treatment of up to 90 ppb for a whole pond and 150 ppb for lakes and other sites, with a maximum cumulative application of 150 ppb per growth cycle and up to 2 pounds per acre on dewatered aquatic sites. There are no direct application food uses for fluridone; however, fluridone treated water can be used to irrigate food crops and pastures and is approved for use in potable water up to 150 ppb. There are

a number of tolerances established under 40 CFR Part 180.420 (refer to Table 2 for a full listing of the fluridone tolerances). The Agency reassessed the fluridone tolerances on September 20, 2004 (Tolerance Reassessment Document).

In 2016 the EPA approved the use of fluridone in cotton and granted the appropriate tolerances under 40 CFR Part 180.420. Additionally, it granted a minor use determination and established a new exclusive use period for this use under FIFRA 2(l)(2) (EPA, DP#423484).

The EPA is also in-process of completing Registration Review for fluridone. It is anticipated to have a final decision in 2019.

Current EPA Fluridone Regulatory Status

Fluridone is currently registered with EPA as an aquatic and terrestrial herbicide.

Based upon the initial date of EPA registration for fluridone (1986), the initial data protection (exclusive use and data compensation) for the original supporting data has expired. As noted above, the EPA established a new 10-year exclusive use period for data supporting cotton in 2016.

Basis for Minor Use Classification Request

FIFRA 2(l) defines “minor use” as follows:

“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.”

The new proposed uses of fluridone on avocado, pomegranate, pistachio, mandarin, and cherries/peaches/plums (stone fruit crop group) meets FIFRA 2(l)(1). All of the new crops meet the definition of a minor use, based on US acreage less than 300,000 acres. The following supports this conclusion.

FIFRA Minor Use-Acreage

Based upon a review of USDA data each of the identified new uses meet the definition of a minor use. Additionally, USDA data from the 2012 Census of Agriculture provides crop acreage information for each of the crops of interest. The following table summarizes the 2012 crop acreage in the USA. The data demonstrate that each of the crops of interest are well below the minor use threshold of 300,000 acres:

Minor Use Crop	2012 Acreage¹
Avocado	73,534
Pomegranate	32,887
Pistachio	232,653
Mandarin (also includes tangerine)	42,289
Cherries	155,029
Peaches	128,480
Plum	88,122

¹USDA National Agricultural Statistics, 2012 Census of Agriculture, Crop Acreage

Based upon the above information, all new crops meet the definition of minor use.

Conclusion

Based upon FIFRA 2(l)(1) and the above information, SePRO confirms that use of fluridone on avocado, pomegranate, pistachio, mandarin, and cherries/peaches/plums (stone fruit crop group) meet the definition of a minor use. Pursuant to FIFRA Section 3(c)(1)(F)(VI) a new 10-year exclusive use period can be granted for the data supporting the minor uses noted above. SePRO requests that EPA issue a new 10-year exclusive use period for the submitted data to support avocado, pomegranate, pistachio, mandarin, and cherries/peaches/plums (stone fruit crop group).

Table 1. SePRO Corporation Fluridone EPA Registrations

EPA Registration Number	Product Name	Percent Active Ingredient
67690-3	Sonar SRP/5P	5.0
67690-4	Sonar A.S.	41.7
67690-6	Sonar Technical	99.2
67690-12	Sonar X	5.0
67690-21	Sonar Q Quick Release	5.0
67690-30	Fluridone SC	41.7
67690-31	Fluridone Technical	99.2
67690-32	Fluridone SRP	5.0
67690-45	SonarOne	5.0
67690-48	Sonar Extra	3.79
67690-54	Sonar Genesis	6.3
67690-61	Sonar H4C	2.7
67690-63	Fluridone Technical	99.3
67690-64	WhiteCap SC	41.7
67690-65	WhiteCap RTU	3.79
67690-66	WhiteCap WDG	5.0
67690-73	Brake F2	17.26
67690-74	Brake FX Herbicide	6.3
67690-75	Brake F16 Herbicide	11.7
67690-78	Brake	13.76

Table 2. Fluridone Tolerances Established Under 40 CFR Part 180.420

(a) General. (1) Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, and its bound residues, calculated as the stoichiometric equivalent of fluridone, in or on the commodity.

Commodity	Parts per million
Crayfish	0.5
Fish	0.5

(2) Tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.1
Cattle, liver	0.1
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Cotton, gin byproducts	0.1
Cotton, undelinted seed	0.1
Egg	0.05
Goat, fat	0.05
Goat, kidney	0.1
Goat, liver	0.1
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, kidney	0.1
Hog, liver	0.1
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, kidney	0.1
Horse, liver	0.1
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.05

Poultry, fat	0.05
Poultry, kidney	0.01
Poultry, liver	0.01
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, kidney	0.1
Sheep, liver	0.1
Sheep, meat	0.05
Sheep, meat byproducts	0.05

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Reserved]

(d) Indirect or inadvertent residues. Tolerances are established for indirect or inadvertent residues of the herbicide fluridone, including its metabolites and degradates, in or on the irrigated crop commodities and crop groupings in the table in this paragraph, resulting from use of irrigation water containing residues of 0.15 parts per million following applications of fluridone on or around aquatic sites. Where tolerances are established at higher levels from other uses of fluridone on the crops in the table in this paragraph, the higher tolerance also applies to residues in or on the irrigated commodity. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only fluridone, 1-methyl-3-phenyl-5-(3-(trifluoromethyl)phenyl)-4(1*H*)-pyridinone, in or on the commodity.

Commodity	Parts per million
Animal feed, nongrass, group 18	0.15
Avocado	0.1
Berry, group 13	0.1
Cranberry	0.1
Fruit, citrus, group 10	0.1
Fruit, pome, group 11	0.1
Fruit, stone, group 12	0.1
Grain, cereal, forage, fodder and straw, group 16	0.1
Grain, cereal, group 15	0.1
Grape	0.1
Grass, forage	0.15
Hop, dried cones	0.1
Nut, tree, group 14	0.1
Okra	0.1
Strawberry	0.1
Vegetable, brassica, leafy, group 5	0.1
Vegetable, cucurbit, group 9	0.1

Vegetable, fruiting, group 8	0.1
Vegetable, leafy, except brassica, group 4	0.1
Vegetable, leaves of root and tuber, group 2	0.1
Vegetable, legume, group 6	0.1
Vegetable, root and tuber, group 1	0.1

[76 FR 23495, Apr. 27, 2011, as amended at 77 FR 66720, Nov. 7, 2012; 80 FR 18143, Apr. 3, 2015; 81 FR 7987, Feb. 17, 2016; 81 FR 72539, Oct. 20, 2016]

References

USDA National Agricultural Statistics, 2012 Census of Agriculture, Crop Acreage.