



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

**Exclusive Use
Extension Request
Response Letter for
Tetraconazole**

April 8, 2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Jonathan Janis, Regulatory Manager, NAFTA
Isagro S.P.A., D/B/A Isagro USA, Inc.
430 Davis Drive, Suite 240
Morrisville, NC 27560

Subject: Tetraconazole
Exclusive-use period extension for data protection from April 14, 2015 to April 14, 2016
Tetraconazole Technical; EPA Reg. No. 80289-1

Dear Mr. Janis:

This letter responds to your request dated May 14, 2014 that data associated with the April 14, 2005 original registration for the active ingredient tetraconazole, receive a two year extension of the original ten year exclusive-use protection period, from April 14, 2015 to April 14, 2017. The Agency is granting a one year extension until April 14, 2016 of exclusive-use data protection for selected data under EPA Registration No. 80289-1.

On October 17, 2014, Sipcam Agro USA, Inc. submitted a letter to the Agency in opposition to Isagro S.P.A., D/B/A Isagro USA, Inc.'s petition to extend the exclusive use period for tetraconazole. Subsequently on December 14, 2014, Isagro S.P.A., D/B/A Isagro USA, Inc. submitted a letter to the Agency responding to Sipcam Agro USA, Inc.'s opposition letter. One point that Sipcam Agro USA, Inc. includes in their letter is that Isagro S.P.A., D/B/A Isagro USA, Inc. has not provided any evidence that they are marketing *Mettle 125 ME Fungicide* (EPA registration No. 80289-8) for the minor uses listed in crop group 13-07F. In its response to the opposition letter, Isagro S.P.A., D/B/A Isagro USA, Inc. states that *Mettle 125 ME Fungicide* is marketed and that any grower can purchase the product for any use in accordance with the label. Isagro S.P.A., D/B/A Isagro USA, Inc. also stated that the product is marketed, sold and used for both major and minor crops and stake holders and growers have not raised any concerns or issues regarding the availability of the product for their production needs. The Agency has considered both of the letters and supporting documentation received to date. The Agency has a final printed label for *Mettle 125 ME Fungicide* and amur river grape, hardy kiwifruit, maypop, and

Schisandra berry are all listed. The Agency believes that *Mettle 125 ME Fungicide* is being marketed. Both the Sipcam Agro USA, Inc. and Isagro S.P.A., D/B/A Isagro USA, Inc. letters are available at the following link: <http://www2.epa.gov/pesticide-registration/tetraconazole-petition-and-response>.

You cited FIFRA section 3(c)(1)(F)(ii) 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). FIFRA section 3(c)(1)(F)(ii) sets forth the criteria for extending the period of exclusive-use protection. The period of exclusivity can be extended one year for every three qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive-use protection, with a maximum addition of three years to the original ten year exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive-use period is to ascertain whether there are exclusive-use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive-use protection. A study entitled to exclusive-use protection is defined in 40 C.F.R. 152.83(c), and the following requirements must be met:

- (1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;
- (2) The study was submitted in support of, or as a condition of approval of the application, resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and
- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and a study is an exclusive-use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive-use data.

First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient that was first registered after September 30, 1978.

Second, the data was submitted in support of the first registration of the new chemical.¹

¹ Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive-use protection. Additionally, data submitted in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain exclusive-use protection, but the protection is limited to data that pertain solely to the new use. Thus for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive-use protection for only two years, or the remainder of the original 10-year exclusive-use period. See 49 FR 30884, 30889.

The registration cited was granted on April 14, 2005 and was the first registration for tetraconazole with the product name Tetraconazole Technical.

Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B).

Data generated by IR-4 are not entitled to exclusive-use protection (see 40 CFR 152.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive-use protection may be extended.

Although, EPA has determined that there are exclusive-use protected data associated with this registration, the Agency has not made individual determinations on every study associated with the above referenced registration as to exclusive-use protection. If the Agency receives a me-too application for this pesticide during the extension period citing Isagro S.P.A., D/B/A Isagro USA, Inc. data, it will then address which of those data have the extension of protection. Therefore, this response is a general determination that the exclusive-use studies associated with this registration will receive the determined extension of exclusive-use protection.

After determining that there are exclusive-use data associated with this registration, EPA analyzed whether: (1) minor uses have been registered within seven years of the original registration and (2) at least one of the following required criteria were satisfied for extending the exclusive-use protection pursuant to FIFRA section 3(c)(1)(F)(ii), and if so, by how many years. FIFRA section 3(c)(1)(F)(ii) states, in pertinent part:

“The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause, and within 7 years of the commencement of the exclusive-use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that-

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.”

The Agency determined that the following minor uses were registered within seven years of the original registration of Tetraconazole Technical: (1) amur river grape, (2) hardy kiwifruit, (3) maypop, and (4) Schisandra berry. Isagro originally requested an extension of two years

based on tetraconazole use on the four previously mentioned crops as well as gooseberry and “cultivars, varieties, and/or hybrids” of crops of Crop Group 13-07F. Gooseberry and “cultivars, varieties, and/or hybrids” of crops of Crop Group 13-07F do not meet the FIFRA criteria. Therefore, the Agency has reviewed the extension request for one year only.

As to the criteria mentioned above, Isagro S.P.A., D/B/A Isagro USA, Inc. submitted information to support its claims that there are insufficient efficacious alternative registered pesticides to tetraconazole available for the uses (criterion I); and that the minor use pesticide plays or will play a significant part in managing pest resistance (criterion III).

Summary of Findings

EPA evaluated information about characteristics of tetraconazole, disease claims, and production practices for four crop sites. The Fungicide Resistance Action Committee (FRAC) has designed a group classification system based on a fungicide's mode of action (FRAC, 2011). Tetraconazole is classified as a triazole fungicide (FRAC Group 3), which acts as a demethylation inhibitor (DMI) that inhibits sterol biosynthesis in fungi. DMI fungicides are among the most widely used fungicides due to their effectiveness in managing many diseases caused by numerous fungal pathogens.

Isagro S.P.A., D/B/A Isagro USA, Inc. submitted information to support its claim for extension of the exclusive-use period based on criterion I and III. In considering these claims, and other information relative to this determination, EPA reviewed four minor crops and determined that they meet criteria I and III. The Registration Division (RD) of the Office of Pesticide Programs (OPP) has verified that the four subject commodities are included on the most recently stamped tetraconazole end-use product label. RD has also verified that tetraconazole tolerance citations for the Crop Groups encompassing the four minor uses are enumerated in 40 CFR 180.557.

Tetraconazole targets powdery mildew on amur river grape, hardy kiwifruit, maypop, and Schisandra berry. Tetraconazole is the only Group 3 (DMI) fungicide registered for powdery mildew on amur river grape, hardy kiwifruit, maypop and schisandra berry. DMI fungicides provide post-infection activity (systemic) and remain highly effective against susceptible powdery mildew pathogens. As with other newer fungicides, resistance to strobilurin pesticides has become problematic in some locations. There are three other non-DMI fungicides that are registered to manage powdery mildew on amur river grape, hardy kiwifruit, maypop, and Schisandra berry (cyprodinil, cyflufenamid, and azoxystrobin). The Agency evaluated these alternatives and determined that all three of them have a high to moderately high risk for pathogen resistance. In order to institute effective disease management and comply with resistance management recommendations, the Agency finds that the presence of a Group 3 fungicide plays a significant role in resistance management.

The Agency concludes that Criterion I and Criterion III have been met for tetraconazole on four minor uses: Amur river grape, hardy kiwifruit, maypop, and Schisandra berry.

DETERMINATION

After reviewing your petition, the Agency concludes that for at least four minor uses that there are insufficient efficacious alternative registered pesticides to tetraconazole available and that tetraconazole plays or will play a significant part in managing pest resistance . Therefore, the Agency **GRANTS** a one year extension of exclusive-use data protection for selected data under EPA Registration No. 80289-1. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on April 14, 2016.



Susan Lewis, Director
Registration Division
Office of Pesticide Programs

Enclosure: BEAD review dated April 3, 2015; DP# 425426

cc: Cynthia Giles-Parker
Hope A. Johnson
Michele Knorr
Leonard Yourman