



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 11, 2016

Teresa Cox
Regulatory Product Manager
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300

**Subject: Product Name: Cyprodinil Technical
EPA Reg Number 100-811; Decision 503340; Application Dated 03/31/2015
Request to Establish New 10-Year Period of Exclusive Use for Field Trial Data on
Tuberous and Corm Vegetable Subgroup 1C (MRID 49557301) until 03/31/2025**

Dear Ms. Cox:

This letter responds to your request referenced above for exclusive use protection of minor use crop data.

You 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 providing a 10-year period of exclusive-use protection for minor use data when the exclusive use period has expired. The data pertaining solely to new minor uses can be given a 10-year exclusive use period from the date these data were submitted providing the data supports minor uses which were actually approved on the label; the data is not publically owned (e.g., can't be IR-4, public literature, etc.); and the 10-year base period of exclusivity on the chemical has ended. Furthermore, the data must relate solely to a minor use. The minor use definition pertinent here is a crop grown on less than 300,000 acres in the United States. Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)).

In your application dated 03/31/2015, exclusive use data protection was requested for the following members of the tuberous and corm vegetable subgroup 1C: arracacha, arrowroot, artichoke (Chinese and Jerusalem), canna, cassava (bitter and sweet), chayote (root), chufa, dasheen (Taro), ginger, leren, sweet potato, tanier, turmeric, and yam (bean and true). Exclusive use data protection was also requested on the residue data (MRID 49557301) for cyprodinil on potato, the representative commodity of tuberous and corm vegetable subgroup 1C.

DETERMINATION

The Agency used the most recent USDA Census of Agriculture publication¹ to determine the crop acreage. Information from USDA's Census of Agriculture indicates that potato is not considered a "minor crop" in the context of FIFRA. The study (MRID 49557301) cited in your application for 3(c)(1)(F)(vi) protection, submitted in connection with the proposed new uses and exclusive use request, contains data supporting major uses (potato). Therefore, the study does not qualify for protection under 3(c)(1)(F)(vi) because the data do not pertain solely to the minor uses requested, instead it was performed on potato. Therefore, your request for protection of data associated with these commodities does not satisfy the exclusive use criteria² in Condition 1 of the Statute. The Agency therefore concludes that your request for exclusive use data protection to be applied to MRID 49557301 and include any and all members of the tuberous and corm vegetable subgroup 1C is **DENIED**.

If you have any questions please contact Marcel Howard at 703-305-6784 or at howard.marcel@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Susan Lewis", with a small "(For)" written in the upper right corner of the signature.

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs

¹ The tuberous and corm vegetables are available at http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/st99_1_038_038.pdf

² *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 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 Federal Register 79, 6825.