



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

**Petition for Tetraconazole**

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**VIA COURIER DELIVERY**

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**SUBJECT: PRIA M007: Petition to Extend the Exclusive Use Period for Tetraconazole Data**

Isagro Agro USA, Inc. (Isagro) is submitting this petition to extend the exclusive use period for tetraconazole data based in Isagro's registration of minor uses for its end use products containing tetraconazole. Appendix 4 contains an Application for Registration form 8570-1 and copies of the PRIA payment letter and check sent to EPA.

**Background**

The Food Quality Protection Act of 1996 (FQPA) amended section 3(c)(1)(F) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to add a new section 3(c)(1)(F)(ii). Section 3(c)(1)(F)(ii) sets forth the criteria for extending the period of exclusive use protection. This section states that 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 for which data retain exclusive use protection up to a total of three additional years. In order for EPA to extend the period of data exclusivity the Agency must determine that at least one of four criteria is satisfied. These criteria are:

- There are insufficient efficacious alternative registered pesticides for the use;
- The alternatives to the minor use pesticide pose greater risk to the environment or human health;
- The minor use pesticide plays or will play a significant part in managing pest resistance; or
- The minor use pesticide plays or will play a significant part in an integrated pest management program.

Isagro believes that its registered minor uses meet the first and third criteria; namely, that there are insufficient efficacious alternatives registered for these uses and Isagro's tetraconazole-containing METTLE® fungicide plays a significant role in resistance management.

## Isagro Products and Exclusive Use Data

EPA registered Isagro's technical tetraconazole product on August 1, 2005 (EPA Registration No. 80289-1). The Agency registered a Sipcam Agro USA, Inc. (Sipcam) technical tetraconazole product on April 14, 2005 (EPA Registration No. 60063-11). The Sipcam registration was the first registration for tetraconazole.

Isagro and Sipcam Agro USA, Inc. (Sipcam) entered into a Post-Termination Data Transfer and Access Agreement whereby Sipcam transferred data compensation and exclusive use rights for tetraconazole to Isagro. Appendix 1 provides a copy of the document Sipcam submitted to EPA on December 20, 2013 covering the transfer between the two companies.

The Isagro product that is the subject of this petition is Isagro's METTLE® Fungicide containing 11.6% tetraconazole (EPA Registration No. 80289-8). Appendix 2 provides the most recent EPA stamped approved label and the commercial labels for the 1 gallon and 30 fluid ounce METTLE® products. These labels include the use of these products on EPA Crop Group 13-07F (small fruit vine climbing subgroup except fuzzy kiwifruit) and Crop Group 13-07G (low growing berry subgroup). Note that cranberries are not included among the Crop Group 13-07G crops on the METTLE® label. EPA registered the use of tetraconazole on these Crop Groups on August 30, 2011. Thus the minor crop uses covered by these two Crop Groups were all registered within the first seven years of the first tetraconazole registration.

In summary, EPA granted the first tetraconazole registration on April 14, 2005. The 10 year exclusive use period is still in effect. Exclusive use rights for tetraconazole data belong to Isagro. The Agency registered minor crop uses for Isagro's METTLE® tetraconazole product within seven years of the initial tetraconazole registration.

### Rationale for Extension of Exclusive Use Period

The basis for Isagro's petition to extend the exclusive use period for tetraconazole data is: (1) there are insufficient efficacious alternative pesticides registered and sold for use on the minor crops that are in EPA Crop Groups 13-07F, and (2) Isagro's METTLE® product plays a significant role in resistance management of fungal diseases that affect the minor use crops in Crop Groups 13-07F and 13-07G.

#### Crop Group 13-07F

Crop Group 13-07F includes six minor crops; namely, amur river grape, gooseberry, hardy kiwifruit, maypop, schisandra berry, and cultivars, varieties and hybrids of the named crops. Based on the discussion below, Isagro believes that its sale of tetraconazole for these six minor crop uses supports two additional years of exclusive use data rights.

Table 1 in Appendix 3 summarizes product use information, and Table 2 in the same Appendix provides application rate information. The product use and rate information provided in these tables is discussed below. Note that in Table 2 the application rates for propiconazole in Quilt Xcel® are the same propiconazole application rates in Tilt®, and the application rates for myclobutanil in Rally® are the same myclobutanil application rates in two of Albaugh's Sonoma® products. Each of these

products is discussed below, but the rate information in Table 2 is only provided for Quilt Xcel® and Rally®.

Based on data and information available from CDMS, Inc., an industry supported information database, Isagro believes that only its METTLE® product and Syngenta's Abound® (EPA Registration No. 100-1098) are commercially labeled for use on five of the six minor crops in Crop Group 13-07F against the fungal diseases, *Sphaerotheca spp.*, and *Erysiphe spp.* Gooseberries are discussed separately below.

For the five minor crops in Crop Group 13-07F, not including gooseberries, Isagro believes having only two products commercially labeled for use on these crops against *Sphaerotheca spp.* and *Erysiphe spp.* demonstrates that there are insufficient registered alternatives. In addition, both products have limitations concerning the number of applications allowed. If an application limit is reached for either product, there needs to be another product available to meet grower requirements. Again, the insufficient alternative criterion is met. Furthermore, since METTLE® (containing a Group 3 triazole fungicide) and Abound® (containing azoxystrobin which is a Group 11 fungicide) are different classes of chemistry, they provide an important resistance management tool since the two products can be rotated with each other or tank mixed. Thus, Isagro believes that METTLE® meets both the insufficient alternatives and importance as a resistance management tool criteria for the five minor crops.

For the sixth minor crop, gooseberries, both METTLE® and Abound® are commercially labeled for use on gooseberries against two fungal diseases, *Sphaerotheca spp.*, and *Drepanopeziza spp.* In addition, there are additional products that are also commercially labelled for use on gooseberries. Dow Agrosiences' Rally® (EPA Registration No. 62719-410), Albaugh's Sonoma® 20EW AG (EPA Registration No. 42750-165), Albaugh's Sonoma® 40WSP (EPA Registration No. 42750-141), and Syngenta's Tilt® (EPA Registration No. 100-617) are also commercially labeled for use against the same two diseases. In addition, Syngenta's Quilt Xcel® (EPA Registration No. 100-1324) is commercially labeled for use against *Sphaerotheca spp.*

Rally® and the two Sonoma® products contain the triazole fungicide, myclobutanil, as an active ingredient. Tilt® contains propiconazole, another triazole fungicide. Quilt Xcel® has two active ingredients, propiconazole and azoxystrobin. Thus, three triazoles (including tetraconazole in Isagro's product) and azoxystrobin are available to meet gooseberry grower needs.

Isagro believes that with the limited number of products and with limitations on number of applications, there is an insufficient number of alternative pesticides. In addition, having two classes of chemistry facilitates resistance management programs. Finally, rotating within the triazole class of chemistry has been shown to reduce the potential for resistance problems. Isagro's METTLE® has the lowest application rates of any of the alternatives including the triazole-containing products. Thus, METTLE® contributes to resistance management while at the same time resulting in lower environmental burden.

In summary, Isagro thinks that METTLE® meets both the insufficient alternatives and the resistance management criteria for all of the minor crops in Crop Group 13-07F including gooseberries. Thus, Isagro asserts that it is entitled to two additional years of exclusive use protection for its tetraconazole data when the total of six minor crops is considered.

### Crop Group 13-07G

Because Isagro was able to identify seven commercial product labels that provide use on eight minor crops in Crop Group 13-07G, we are not asking for a time extension based on the minor crops in this Crop Group.

#### Conclusions

EPA granted the first registration for tetraconazole on April 14, 2005. The Agency registered the minor crop uses included in Crop Groups 13-07F and 13-07G (not including cranberries) for Isagro's METTLE® tetraconazole product on August 30, 2011, and Isagro has sold METTLE® for these uses ever since. These minor crop uses were registered within the first seven years of the initial tetraconazole registration.

Counting the named Crop Group 13-07F minor crops and cultivars, varieties and hybrids of those crops gives a total of six minor uses.

Based on that number of minor use crops supported by METTLE®, based on the importance of the low application rate METTLE® product being registered for use on crops for which there are insufficient efficacious alternatives, and based on the important role tetraconazole-containing METTLE® plays in resistance management, Isagro is entitled to two additional years of exclusive use protection for its tetraconazole data. Thus, Isagro requests that EPA grant its petition for additional exclusive use data protection.

Sincerely,



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Attachments

Table 1 - Use Information

Crop Group	Crop	Product Active Ingredient/s	METTLE Tetraconazole	BALLY Myclobutanil	SONOMA ZEBWAG Myclobutanil	SONOMA ZEBWAG Myndobutanil	SONOMA ZEBWAG Hydrobutanil	TILT Propiconazole	OBBIT Propiconazole	AROUND Azoxystrobin	RUNIT Trifloxystrobin	FONTELIS Penthiopyrad	PROCURE Triflumizole	QUADRUS TOP Azoxystrobin Difenoconazole	QUILT XCEL Azoxystrobin Propiconazole	
																Manufacturer
13-07F	Gooseberry	Sphaeroteca spp.	Y	Y	Y	Y	Y	Y	Y	Y					Y	
	Gooseberry	Drepanopeziza spp.	Y	Y	Y		Y									
	Amur river grape	Sphaeroteca / Erysiphe spp.	Y													
	Kiwifruit hardy	Sphaeroteca / Erysiphe spp.	Y													
	Maypop	Sphaeroteca / Erysiphe spp.	Y													
	Schisandra berry	Sphaeroteca / Erysiphe spp.	Y													
	cultivars, varieties, and/or hybrids	Sphaeroteca / Erysiphe spp.	Y				Y	Y								
	13-07G	Strawberry	Podosphaera aphanis, Sphaeroteca	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		Strawberry	Mycosphaerella spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y
		Strawberry	Phomopsis spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	
Blueberry lowbush		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y	Y (No CA)			Y	Y	
Bearberry		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
Bilberry		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
Cloudberry		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
Lingonberry		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
Muntries		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
Partridge berry		Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	
cultivars, varieties, and/or hybrids	Sphaeroteca, Microsphaera, Oidium spp.	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y		

Table 2. Application Information – Crop Group 13-07 F

Trade Name	Formulation	g ai/L	lb ai/gal	g ai/L	lb ai/gal	Use Rate (oz/A)	Application Interval (d)	Max Appl. #/Season	Max Use/Season (oz/A)	PHI (d)	Low Use Rate (oz/A)	lb ai/A	g ai/ha	High Use Rate (oz/A)	lb ai/A	g ai/ha
Rally	40 WSP	myclobutanol				3 - 5	<21	8 to 4	24	14	3	0.075	84	5	0.125	140
		0.40														
Mettle	125 ME	tetraconazole				3 - 5	14 - 21	3 to 2	10	14	3	0.023	26.25	5	0.039	43.75
		125	1													
Quadris Top	2.72 L	difenoconazole		azoxystrobin		12 - 14	10 - 21	5 to 4	56	14	12	0.098 + 0.157	109.76 + 175.84	14	0.197 + 0.183	220.64 + 204.96
		125.83	1.05	200.14	1.67											
		87.48	0.73	251.67	2.1											
Quilt Xcel	2.08 L	propiconazole		azoxystrobin		14	10 to 14	4	56	0	14	0.112 + 0.129	125.44 + 144.48			
		122.24	1.02	141.41	1.18											
Tilt	3.6 L	propiconazole				6	7 to 14	5	30	30	6	0.141	157.92			
		360	3.00													
Procure	480 SC	triflumizole				4 to 8	14 - 21	8 to 4	32	7	4	0.125	140	8	0.25	280
		480	4.00													
Abound	2.08 F	azoxystrobin				10 - 15.5	10 - 14	9 to 5	92.3	14	10	0.163	182	15.5	0.121	135.62
		249.27	2.08													
Flint	50 WG	trifloxystrobin				2 - 3.2	7 - 14	6	19.2	0	2	0.063	70.56	3.2	0.1	112
			0.50													