

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2015-6487

Application: Changes to TGAI Product Chemistry – New Source (site) Same

Registrant and Specifications

Product: Fluoxastrobin Technical Fungicide

Registration Number: 30407

Active ingredient (a.i.): Fluoxastrobin PMRA Document Number: 2695101

Purpose of Application

The purpose of this application was to add a new manufacturing site to Fluoxastrobin Technical Fungicide with minor changes in the manufacturing process.

Chemistry Assessment

Common Name: Fluoxastrobin

IUPAC* Chemical Name: (1E)-1-(2-{[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-

yl]oxy}phenyl)-1-(5,6-dihydro-1,4,2-dioxazin-3-yl)-*N*-

methoxymethanimine

CAS† Chemical Name: (1*E*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]

phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone

methyloxime

Fluoxastrobin Technical Fungicide has the following properties:

Property	Result	
Colour and physical state	White crystalline solid	
Nominal concentration	95.76%	
Odour	Faint characteristic	
Density	1.4216 g/mL	
Vapour pressure	T (°C) Vapour pressure (Pa)	
	$20 5.63 \times 10^{-10}$	
	8.72×10^{-10}	



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^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

Property	Result	
рН	6.3	
Solubility in water	<u>pH</u>	Solubility (mg/L)
	un-buffered	2.559
	4	2.431
	7	2.292
	9	2.272
n-Octanol/water partition coefficient	$Log K_{ow} = 2.8$	36

The required chemistry data for Fluoxastrobin Technical Fungicide have been provided, reviewed, and found to be acceptable.

Health Assessments

Exposure assessments were not required for this application.

The new source of fluoxastrobin technical is considered toxicologically equivalent to the currently registered source. No toxicological data were submitted or are required at this time.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has determined that the addition of a new manufacturing site to Fluoxastrobin Technical Fungicide with minor changes in the manufacturing process can be supported.

References

PMRA Document Number	References
2586368	2015, Production Process of Fluoxastrobin, DACO: 2.11.2, 2.11.3, 2.11.4, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2586369	2015, Five batches of technical Fluoxastrobin, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
2654382	2010, Analytical Method Fluoxastrobin (HEC 5725) Determination of technical grade active substance HPLC – ESTD, DACO: 2.13.1 CBI
2654383	2010, Validation of AM010610MP1 Fluoxastrobin (HEC 5725) – Determination of technical grade active substance HPLC – External standard, DACO: 2.13.1 CBI
2654384	2014, Analytical Method Fluoxastrobin (HEC 5725) Impurities in technical grade active substance HPLC - external standard, DACO: 2.13.1, 2.13.4 CBI
2654385	2014, Analytical Method Fluoxastrobin Determination of 4-methyl-2-pentanon and Methanol in technical grade active substance GLC-Headspace - external standard, DACO: 2.13.1, 2.13.4 CBI
2654386	2014, Validation of AM010410MP2 Fluoxastrobin (HEC 5725) impurities in technical grade active substance HPLC - external standard, DACO: 2.13.1, 2.13.4 CBI
2654387	2014, Validation of GLC-method AM024814MP1 Fluoxastrobin - Determination of 4-methyl-2-pentanon and Methanol in technical grade active substance GLC - external standard (Headspace), DACO: 2.13.1, 2.13.4 CBI
2664607	2010, Validation of AM010410MP1 Fluoxastrobin (HEC 5725) Impurities in technical grade active substance HPLC - external standard, DACO: 2.13.1 CBI

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