

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2014-2553

Application: New Source of Technical Grade Active Ingredient by a New

Registrant

Product: Sharda Azoxystrobin Technical

Registration Number: 31723

Active ingredients (a.i.): azoxystrobin PMRA Document Number: 2499515

Background

The source of azoxystrobin used to determine chemical equivalence was Registration Number 26152.

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, azoxystrobin, by a different Registrant.

Chemistry Assessment

Common Name: Azoxystrobin

IUPAC* Chemical Name: Methyl (2*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-

yloxy]phenyl}-3-methoxyacrylate

CAS† Chemical Name: Methyl (αE)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- α -

(methoxymethylene)benzeneacetate

Sharda Azoxystrobin Technical has the following properties:

Property	Result
Colour and physical state	Ochre Brown solid
Nominal concentration	98.40%
Odour	No characteristic odour
Density	1.326
Vapour pressure	< 5 E -06 Pa
рН	6-7



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

Solubility in water	1.66 mg/L in water at 25 °C (average solubility). 2.01 mg/L in deionized water at 25 °C 1.65 mg/L at pH 4 at 25 °C 1.10 mg/L at pH 7 at 25 °C 1.87 mg/L at pH 9 at 25 °C
n-Octanol/water partition coefficient	At pH 5.3, $K_{ow} = 90.99 \pm 2.98$ At pH 5.3, $Log(K_{ow}) = 1.96 \pm 0.01$

The chemistry requirements for Sharda Azoxystrobin Technical have been fulfilled.

Health and Environmental Assessment

As the new source of azoxystrobin is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Sharda Azoxystrobin Technical.

References

PMRA No.	Title
2441248	2014, Azoxystrobin manufacturing process, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2441249	2013, Analysis and Method Validation for 5 Batches of Azoxystrobin Technical
	Material to Determine the Content of DMF, DACO: 2.13.4 CBI
2441251	2013, Analysis and Method Validation for 5 Batches of Azoxystrobin Technical
	Materialto Determine the Content of DMF, DACO: 2.13.4 CBI
2441252	2013, Analysis and Method Validation for 5 Batches of Azoxystrobin Technical
	Material to Determine the Content of DMF, DACO: 2.13.4 CBI
2441254	2006, Determination of the Physical and Chemical Properties of Azoxystrobin
	Technical, DACO: 2.14.1,2.14.10,2.14.11,2.14.13,2.14.15,2.14.2,2.14.3,2.14.4,
	2.14.6,2.14.7,2.14.8, 2.14.9,830.7000 CBI
2441255	2008, Reactivity with Packing Material of Azoxystrobin Technical, DACO: 2.14.13
2441256	2013, Purity Profile of 5 Batches of Azoxystrobin Technical, DACO: 2.13.1,2.13.2,
	2.13.3, 2.14.12,2.4,2.5,2.6,2.7,2.8,2.9 CBI

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