

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2019-1558
Application: Changes to TGAI Product Chemistry-New Source (site) Same Registrant
Product: Famoxadone Technical
Registration Number: 27436
Active ingredient (a.i.): Famoxadone
PMRA Document Number: 3096070

Purpose of Application

The purpose of this submission was to add a new manufacturing site for Famoxadone Technical by the same registrant.

Chemistry Assessment

Common Name: famoxadone
IUPAC* Chemical Name: (RS)-3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione
CAS† Chemical Name: 5-methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Famoxadone Technical has the following properties:

Property	Result
Colour and physical state	Pale cream powder
Nominal concentration	97.8 %
Odour	Characteristic of burnt plastic and similar to vanilla
Density	1.31 g/cm ³ at 25°C
Vapour pressure	6.4 x 10 ⁻⁷ Pa at 20°C
pH	6.56

Property	Result	
Solubility in water	<u>pH</u>	<u>µg/L</u>
	unbuffered	52
	2	143
	3	191
	5	243
	7	111
	9	38
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K_{ow}</u>
	5.0	4.80
	7.0	4.65
	9.0	5.55

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

Health, Environmental and Value Assessments

Health, 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 found it sufficient to support the registration of the new manufacturing site for Famoxadone Technical.

References

PMRA

Document Number

Reference

2982403	2012, Description And Validation Of The Analytical Methods For Determination Of Impurities In Technical Grade Famoxadone - Confidential, DACO: 2.13.1 CBI
2982404	2012, Description And Validation Of The Analytical Methods For Determination Of Impurities In Technical Grade Famoxadone - Non-confidential, DACO: 2.13.1
2982405	2011, Description And Validation Of The Analytical Method For Determination Of Residual Solvent In Technical Grade Famoxadone- Confidential, DACO: 2.13.1 CBI
2982407	2011, Description And Validation Of The Analytical Method For Determination Of Residual Solvent In Technical Grade Famoxadone- Non-Confidential, DACO: 2.13.1
2982410	2011, Determination Of Famoxadone (Dpx-Je874) In Technical Grade Famoxadone, DACO: 2.13.1,2.13.2
2982411	2016, Technical Grade Famoxadone (DPX-JE874) Manufacturing Description And Formation Of Impurities; Confidential, DACO: 2.11 CBI
2982412	2016, Technical Grade Famoxadone (DPX-JE874) Manufacturing Description And Formation Of Impurities - Non-confidential, DACO: 2.11
2982413	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical - Confidential, DACO: 2.13.3 CBI
2982414	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical - non confid, DACO: 2.13.3
2982415	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical; Batch Chromatograms From The Analysis Of Famoxadone - Confidential, DACO: 2.13.3 CBI
2982416	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical; Batch Chromatograms From The Analysis Of Famoxadone - Non-Confidential, DACO: 2.13.3
2982417	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical; Spectral Confirmation For The Analysis Of Famoxadone - Confidential, DACO: 2.13.3 CBI
2982418	2018, Batch Analysis Of Famoxadone (DPX-JE874) Technical; Spectral Confirmation For The Analysis Of Famoxadone - Non-Confidential, DACO: 2.13.3

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