

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2023-0581
Application: Changes to Technical Grade Active Ingredient (Product Chemistry) - New Source (site), same registrant
Product: Famoxadone Technical
Registration Number: 27436
Active ingredient (a.i.): Famoxadone
PMRA Document Number: 3597117

Purpose of Application

The purpose of this application was to amend the registration of Famoxadone Technical to add a new manufacturing site.

Chemistry Assessment

Common Name: Famoxadone
IUPAC* Chemical Name: (RS)-3-anilino-5-methyl-5-(4-phenoxyphenyl)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>solubility (µg/L)</u>
	unbuffered 52
	2 143
	3 191
	5 243
	7 111
	9 38
n-Octanol/water partition coefficient	log K _{ow} = 4.65 (pH 7.0)

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 the information acceptable to amend the registration of Famoxadone Technical to add a new manufacturing site.

Additional Information Being Requested

GLP-compliant five-batch data representing commercial-scale production at the approved manufacturing site will be required as post-market information after registration. The analysis is to include the active ingredient and solvents/impurities of concern as applicable, determined at appropriate levels of method sensitivity.

References

PMRA Document Number	Reference
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
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
3434965	2023, Famoxadone 5-Batch Analysis, DACO: 2.13.3, CBI

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