

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2021-3560
Application: Changes to Technical Grade Active Ingredient Product Chemistry
 – New Source (site) same registrant
Product: Flumioxazin Technical
Registration Number: 29233
Active ingredient (a.i.): Flumioxazin
PMRA Document Number: 3413117

Purpose of Application

The purpose of this application was to register a new source of flumioxazin for Flumioxazin Technical.

Chemistry Assessment

Common Name: Flumioxazin
IUPAC* Chemical Name: *N*-[7-fluoro-3,4-dihydro-3-oxo-4-(prop-2-ynyl)-2H-1,4-benzoxazin-6-yl]cyclohex-1-ene-1,2-dicarboximide
CAS† Chemical Name: 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propyn-1-yl)-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Flumioxazin Technical has the following properties:

Property	Result
Colour and physical state	Yellow-brown solid
Nominal concentration	97.9%
Odour	Odourless
Density	1.51 g/mL
Vapour pressure	0.32 mPa at 22°C
pH	7.25
Solubility in water	1.79 mg/L

Property	Result
n-Octanol/water partition coefficient	$\log K_{ow} = 2.55$

The required chemistry data for Flumioxazin 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 a new source of Flumioxazin Technical.

Additional Information Being Requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production will be required as post-market information after registration.

References

PMRA Document Number	References
3255148	2021, Manufacturing Process of Flumioxazin Technical Grade and Discussion of Impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
3255149	2021, Certified Limits of Flumioxazin Technical, DACO: 2.12.1
3255151	2021, Validation of Analytical Methods for Flumioxazin Technical Grade, DACO: 2.13.1
3255152	2021, Validation of Analytical Methods for Flumioxazin Technical Grade, DACO: 2.13.1 CBI
3255153	2021, Confirmation of Identities of Ingredients in Flumioxazin Technical Grade, DACO: 2.13.2
3255154	2021, Confirmation of Identities of Ingredients in Flumioxazin Technical Grade, DACO: 2.13.2 CBI
3255155	2021, 5-Batch Analysis for Flumioxazin Technical Grade, DACO: 2.13.3
3255156	2021, 5-Batch Analysis for Flumioxazin Technical Grade, DACO: 2.13.3 CBI
3255158	2020, Certification of Impurity Reference Standards for Flumioxazin Technical Grade, DACO: 2.16 CBI
3270611	2021, Re: Deficiency Response for Category B Submission - Additional Source of Technical for Flumioxazin Technical (Sub. No. 2021-3560; Reg. No. 29233), DACO: 2.1,2.13.3,2.2 CBI
3327881	2022, Amended Manufacturing process of Flumioxazin Technical grade and Discussion of Impurities, DACO: 2.11 CBI
3327882	2022, Enforcement Analytical Method of Residual Solvents in Flumioxazin Technical Grade. DACO: 2.13.1
3327883	2022, Enforcement Analytical Method of Residual Solvents in Flumioxazin Technical Grade, DACO: 2.13.1 CBI
3327884	2022, 5-Batch Analysis of Flumioxazin Technical Grade for Residual Solvents, DACO: 2.13.3
3327885	2022, 5-Batch Analysis of Flumioxazin Technical Grade for Residual Solvents, DACO: 2.13.3 CBI
3409715	2022, Re: Clarification Response for Category B Submission - Additional Source of Technical for Flumioxazin Technical (Sub. No. 2021-3560; Reg. No. 29233), DACO 0.8, 2.12, 2.13.1 2.13.3 CBI

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