

Evaluation Report for Category B, Subcategories 1.1, 1.3 Application

Application Number: 2023-1297
Application: Changes to Technical Grade Active Ingredient Product Chemistry – New Source (site) and specifications
Product: Dinotefuran Technical
Registration Number: 33418
Active ingredient (a.i.): Dinotefuran
PMRA Document Number: 3603089

Purpose of Application

The purpose of this application was to amend the manufacturing process, add new manufacturing sites, and add alternate sources of starting materials for Dinotefuran Technical.

Chemistry Assessment

Common Name: Dinotefuran
 IUPAC* Chemical Name: (EZ)-(RS)-1-methyl-2-nitro-3-[(tetrahydro-3-furyl)methyl]guanidine
 CAS† Chemical Name: N-methyl-N'-nitro-N''-[(tetrahydro-3-furanyl)methyl]guanidine

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Dinotefuran Technical has the following properties:

Property	Result
Colour and physical state	White crystalline solid
Nominal concentration	99.6%
Odour	Odourless
Density	1.40 g/mL at 20°C
Vapour pressure	$<1.7 \times 10^{-6}$ Pa at 30°C
pH	5.6
Solubility in water	39.83×10^3 mg/L (pH = 6.98 at 20°C)
n-Octanol/water partition coefficient	$\log K_{ow} = -0.549$

The required chemistry data for Dinotefuran 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 manufacturing process, add new manufacturing sites, and add alternate sources of starting materials for Dinotefuran Technical.

Additional Information Being Requested

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

References

PMRA

Document

Number	Reference
3449958	2021, Dinotefuran Technical: Product Identity and Disclosure of Ingredients, Description of Materials Used To Produce the Product, Description of Production Process, Certified Limits, and Submittal of Samples, DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.3,2.13.4,2.15,2.2,2.4,2.5,2.6,2.7,2.8,2.9 CBI
3449959	2021, Content Analysis of Dinotefuran Technical, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3449960	2021, Validation of analytical methods for Dinotefuran Technical, DACO: 2.13.1 CBI
3449961	2020, Qualitative and Quantitative Profile of Dinotefuran Technical (Five Batch Analysis), DACO: 2.13.3 CBI
3449962	2018, Content Analysis of Dinotefuran Technical, DACO: 2.13.3 CBI
3591195	2024, Product Clarification Response, DACO: 2.12,2.13.3 CBI

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