



Evaluation Report for Category B, Subcategories 1.1, 1.3 Application

Application Number: 2021-1296
Application: Changes TGAI Product Chemistry-New Source (site)
Product: FBN Clethodim Technical
Registration Number: 33594
Active ingredient (a.i.): Clethodim
PMRA Document Number : 3277453

Purpose of Application

The purpose of this application was to add two new manufacturing sites for FBN Clethodim Technical.

Chemistry Assessment

Common Name: clethodim
IUPAC* Chemical Name: (5*RS*)-2-[(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl]-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one
CAS† Chemical Name: 2-[1-[[[(2*E*)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

FBN Clethodim Technical has the following properties:

Property	Result
Colour and physical state	Yellow liquid
Nominal concentration	96.5 %
Density	1.1369 g/cm ³ at 20°C
Vapour pressure	13 mPa (25°C)
pH	4.15 (1% aqueous dilution)
Solubility in water	5.52 g/L (pH 7)
n-Octanol/water partition coefficient	log K _{ow} = 4.14

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

Health Assessments

The new manufacturing sites were considered toxicologically equivalent to the product manufactured at the registered site, hence no toxicological data were required.

Occupational exposure and food residue assessments were not required for this application.

Environmental and Value Assessments

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 sufficient to add the new manufacturing sites for FBN Clethodim Technical.

References

PMRA

Document

Number	Reference
3215447	2018, 5 Batch Analysis of Clethodim and Main Impurities in Clethodim TC (Amendment 2) – [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215448	2019, 5 Batch Analysis of Clethodim and Main Impurities in Clethodim TC (Amendment 3) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215449	2018, 5 Batch Analysis of Clethodim and Main Impurities in Clethodim TC (Amendment 1) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215450	2020, 5 Batch Analysis of Clethodim and Main Impurities in Clethodim TC (Amendment 4) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215470	2021, Manufacturing Process of Clethodim Technical - [Private Info Removed], DACO: 2.11,2.11.1,2.11.2,2.11.3 CBI
3215471	2021, Clethodim manufacturing process and impurities formation description - [Private Info Removed], DACO: 2.11.1,2.11.3,2.11.4 CBI
3215477	2018, Analysis of Five Representative Production Batches of Clethodim Technical Grade Active Ingredient (TGAI) to Identify and Quantify Clethodim and its Associate Impurities (Part 1) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215478	2018, Analysis of Five Representative Production Batches of Clethodim Technical Grade Active Ingredient (TGAI) to Identify and Quantify Clethodim and its Associate Impurities (Part 2) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215479	2020, Identification and Determination of the Purity of Li-Clethodim - [Private Info Removed], DACO: 2.13.2 CBI

3215480	2020, Analysis of Five Representative Production Batches of Clethodim Technical Grade Active Ingredient (TGAI) to Identify and Quantify Clethodim and its Associate Impurities (Amendment) - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3215481	2020, Justification of Impurities of Clethodim Technical - [Private Info Removed], DACO: 2.11.4 CBI
3215488	2021, Supplier List - [Private Info Removed], DACO: 2.11.2 CBI
3215489	2017, 5 Batch Analysis of Clethodim and Main Impurities in Clethodim TC - [Private Info Removed], DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI

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