

Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

Application Number: 2015-2789

Application: Changes to Technical Grade Active Ingredient Product Chemistry

- New source (site), for the same registrant, and specifications

Product: Cloquintocet-mexyl Technical

Registration Number: 30527

Active ingredients (a.i.): Cloquintocet-mexyl

PMRA Document Number: 2638989

Purpose of Application

The purpose of this application was to register a new manufacturing site for the active, Cloquintocet-mexyl Technical, by the same registrant.

Chemistry Assessment

Common Name: Clethodim

IUPAC* Chemical Name: rac-(2R)-heptan-2-yl [(5-chloroquinolin-8-yl)oxy]acetate CAS† Chemical Name: 1-methylhexyl 2-[(5-chloro-8-quinolinyl)oxy]acetate

Cloquintocet-mexyl Technical has the following properties:

Property	Result
Colour and physical state	Light brown powder
Nominal concentration	96.7%
Odour	Odourless
Density	1.05 g/cm ³
Vapour pressure	5.31 x 10 ⁻⁶ Pa (25°C)
рН	5.4
Solubility in water	0.590 mg/L (25°C)
n-Octanol/water partition coefficient	$\log K_{ow} = 5.03 (25^{\circ}C)$



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

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

Health Assessments

The new manufacturing site for Cloquintocet-mexyl Technical results in a product that is chemically equivalent to the currently registered source. Subsequently, no toxicological data were reviewed or are required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application

Conclusion

The PMRA has completed a review of all available information and found it sufficient to support the registration of the new manufacturing site for the active, Cloquintocet-mexyl Technical.

References

PMRA	Reference
Document	
Number	
1526974	1988, Technical Chemistry File CFP-NVTM-M. Physico-Chemical Properties (safener),
	DACO: 2.14.1, 2.14.11, 2.14.2, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.16 CBI
1993948	2009, Formation of By-Products CGA185072 - Cloquintocet-mexyl, DACO: 2.11.4 CBI
2547232	2014, SA-94/1 - Analytical Method/Validation, DACO: 2.13.1 CBI
2547234	2015, Analytical Method Impurities SB-94/1/Validation, DACO: 2.13.1 CBI
2566512	2015, COAs_Chemical Characterization_[CBI removed]_Ref Stds Sub 2015-2789,
	DACO: 2.13.2 CBI
2547238	2015, Certificate of Analysis, DACO: 2.13.3 CBI
2557982	2015, Chemical Characterization Ref. Studies, DACO: 2.13.2 CBI
2547237	2015, Cloquintocet-mexyl - Analysis of Five Representative Batches, DACO: 2.13.3
	CBI
2547225	2015, Manufacturing Process, DACO: 2.11.1, 2.11.3 CBI
2547226	2015, Starting Materials, DACO: 2.11.2 CBI
2635121	2016, Response to Clarification, DACO: 2.11.1, 2.12, 2.13.3 CBI
2635122	2016, Technical Assessment , DACO: 2.13.3 CBI

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