

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-7146
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy (PPIP) – Equivalency/Data compensation Assessment
Product: Nufarm Clopyralid Technical
Registration Number: 34417
Active ingredient (a.i.): Clopyralid present as acid, or as salts
PMRA Document Number : 3215914

Purpose of Application

The purpose of this application was to register Nufarm Clopyralid Technical, based on a precedent.

Chemistry Assessment

Common Name: Clopyralid
 IUPAC* Chemical Name: 3,6-dichloropyridine-2-carboxylic acid
 CAS† Chemical Name: 3,6-dichloro-2-pyridinecarboxylic acid

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Nufarm Clopyralid Technical has the following properties:

Property	Result										
Colour and physical state	White powder										
Nominal concentration	98.0%										
Odour	Odorless										
Density	1.7334 g/mL										
Vapour pressure	1.36 mPa (25 °C)										
pH	1.61										
Solubility in water	<table border="0"> <thead> <tr> <th>pH</th> <th>solubility (g/L)</th> </tr> </thead> <tbody> <tr> <td>Distilled</td> <td>7.850</td> </tr> <tr> <td>5</td> <td>1180</td> </tr> <tr> <td>7</td> <td>1430</td> </tr> <tr> <td>9</td> <td>1570</td> </tr> </tbody> </table>	pH	solubility (g/L)	Distilled	7.850	5	1180	7	1430	9	1570
pH	solubility (g/L)										
Distilled	7.850										
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7	1430										
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Property	Result	
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K_{ow}</u>
	5	-1.81
	7	-2.63
	9	-2.55
	Un-ionized water	1.07

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

Health Assessments

Nufarm Clopyralid Technical was of low toxicity by the oral, dermal, and inhalation routes. It was considered to be severely irritating to the eye, non-irritating to the skin, and is not considered to be a dermal sensitizer.

Occupational and dietary exposure 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 it sufficient to support the registration of Nufarm Clopyralid Technical.

References

PMRA Document Number	References
3072128	2019, Manufacturing Process and Synthesis Pathway Clopyralid Technical, DACO: 2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.2,2.4,2.5,2.6,2.7,2.8,2.9 CBI
3072129	2019, Determination of Physical-chemical Properties of Clopyralid, DACO: 2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9,830.7000 CBI
3072130	2019, Preliminary Analyses of Five Representative Production Batches of Clopyralid Technical Grade Active Ingredient (TGAI) to Determine Percent Clopyralid and to Quantify Its Associated Impurities, DACO: 2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
3092227	2020, Nufarm Clopyralid Technical, DACO 2.0, Chemistry Requirements for the Registration of a Technical Grade Active Ingredient (TGAI), DACO: 2.0,2.1,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI

- 3188792 2019, Letter for [CBI Removed] - Determination of [CBI Removed] in Clopyralid, DACO: 2.13.1 CBI
- 3188793 2017, Determination of [CBI Removed] in Clopyralid, DACO: 2.13.1,2.13.4 CBI
- 3072131 2019, Acute Oral Toxicity Study of Clopyralid 97% TC in Rat, DACO: 4.2,4.2.1
- 3072132 2019, Acute Dermal Toxicity Study of Clopyralid 97% TC in Rat, DACO: 4.2.2
- 3072133 2019, Acute Inhalation Toxicity Study of Clopyralid 97% TC in Rat, DACO: 4.2.3
- 3072134 2019, Skin Sensitisation Study (Buehler Test) of Clopyralid 97% TC in Guinea Pig, DACO: 4.2.6

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