

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2022-5270  
**Application:** Changes to Technical Grade Active Ingredient (Product Chemistry) – New Source (Site) Same Registrant  
**Product:** Nufarm Imazamox Technical  
**Registration Number:** 34189  
**Active ingredient (a.i.):** Imazamox  
**PMRA Document Number:** 3532466

### Purpose of Application

The purpose of this application was to add an alternate manufacturing site for Nufarm Imazamox Technical.

### Chemistry Assessment

Common Name: Imazamox  
 IUPAC\* Chemical Name: 2-[(4*RS*)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-(methoxymethyl)pyridine-3-carboxylic acid  
 CAS† Chemical Name: 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Nufarm Imazamox Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.6%
Odour	Mild characteristic odour
Density	1.33 g/mL at 20°C
Vapour pressure	6.3 × 10 <sup>-8</sup> mPa at 20°C 2.1 × 10 <sup>-7</sup> mPa at 25°C
pH	2.85 (1% w/v in water)

Property	Result
Solubility in water	4160 mg/L (deionized) $1.16 \times 10^5$ mg/L at pH 5 $>6.26 \times 10^5$ mg/L at pH 7 $>6.28 \times 10^5$ mg/L at pH 9
n-Octanol/water partition coefficient	$\log K_{ow} = -2.9$ at pH 7 $\log K_{ow} = -0.3$ at pH 4

The required chemistry data for Nufarm Imazamox 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 support the addition of the manufacturing site to Nufarm Imazamox Technical.

## References

### PMRA

#### Document

Number	Reference
3394833	2021, Manufacturing Process of Imazamox Technical, DACO: 2.11.1,2.11.2, 2.11.3,2.5,2.6,2.7,2.8,2.9 CBI
3394835	2021, Justification of Impurities of Imazamox Technical, DACO: 2.11.4 CBI
3394836	2021, Analysis of Five Representative Production Batches of Imazamox Technical Grade Active Ingredient (TGAI) to Identify and Quantify Imazamox and Its Associate Impurities Pt. 1, DACO: 2.13,2.13.1,2.13.2, 2.13.3 CBI
3394837	2021, Analysis of Five Representative Production Batches of Imazamox Technical Grade Active Ingredient (TGAI) to Identify and Quantify Imazamox and Its Associate Impurities Pt. 2, DACO: 2.13,2.13.1,2.13.2, 2.13.3 CBI
3394838	2021, Determination of Solvent Impurities in Five Representative Production Batches of Imazamox Technical, DACO: 2.13,2.13.1,2.13.3,2.13.4 CBI
3394839	2021, Determination of [CBI removed] in Five Representative Production Batches of Imazamox Technical, DACO: 2.13,2.13.1,2.13.3,2.13.4 CBI
3394840	2021, Study on the Physico Chemical Properties of Imazamox Technical Pt. 1, DACO: 2.14,2.14.1,2.14.10,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3, 2.14.6,2.14.8,830.7000 CBI
3394841	2021, Study on the Physico Chemical Properties of Imazamox Technical Pt. 2, DACO: 2.14,2.14.1,2.14.10,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3, 2.14.6,2.14.8,830.7000 CBI
3394842	2021, Study on the Physico Chemical Properties of Imazamox Technical Pt. 1, DACO: 2.14.11,2.14.4,2.14.7,2.14.9 CBI
3394843	2021, Study on the Physico Chemical Properties of Imazamox Technical Pt. 2, DACO: 2.14.11,2.14.4,2.14.7,2.14.9 CBI
3517217	2023, Declaration Letter of Batch Scale, DACO: 2.13.3 CBI
3517218	2021, Preliminary Analysis and EAM of One Impurity in Imazamox Technical, DACO: 2.13.4 CBI

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