

Evaluation Report for Category B Subcategory 1.1 Application

Application Number: 2008-1112

Application: B.1.1 – New Source by Same Registrant **Product:** BAY NTN 33893 Technical Insecticide

Registration Number: 24468

Active ingredients (a.i.): Imidacloprid (IMI)

PMRA Document Number: 2455154

Purpose of Application

The purpose of this application was to register an alternate manufacturing site of this registered active ingredient, imidacloprid, by the same registrant.

Chemistry Assessment

Common name: Imidacloprid

IUPAC Chemical Name: (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylidenamine CAS Chemical Name: (2E)-1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine

BAY NTN 33893 Technical Insecticide has the following properties:

Property	Results
Colour and physical state	Colourless to light yellow
Nominal concentration	98.0 %
Odour	Weak characteristic odour
Density	1.54 g/cm^3
Vapour pressure	4×10^{-7} mPa at 20° C
рН	7.8 (2 % suspension)
Solubility in water	510 – 610 mg/L
n-Octanol/water partition coefficient	$\log \text{Kow} = 0.57$

The chemistry requirements for BAY NTN 33893 Technical Insecticide have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has evaluated the available information and has determined the new manufacturing site to be acceptable.



References

1572220	2008, BAY NTN 33893 Technical Insecticide PART 2 Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product (ISP)., DACO: 2.0,2.1,2.10,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13
1572222	2007, Product Chemistry of Imidacloprid Technical Insecticide, DACO: 2.0,2.1,2.10,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.1 3.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2. 14.6,2.14.7,2
1695282	Bay NTN 33893 Technical Insecticide, Certificates of Analysis, DACO: 2.13.2 CBI
1909539	2010, Determination Of [CBI REMOVED] In 5 Batches Of Imidacloprid, DACO: 2.13.4 CBI
1909540	2010, Statement answering PMRA questions on Imidacloprid Technical Grade Active Substance, DACO: 2.13.4 CBI
1909541	2003, Determination of [CBI REMOVED], DACO: 2.13.4 CBI
1940326	2010, Determination of WAK 3839 (AE 1873886) in 5 batches of Imidacloprid (NTN 33893 / AE F106464), DACO: 2.13.4 CBI
1948764	2006, Determination of AE 1873886 (NTN33893-WAK 3839) in Technical Grade and Pure Imidacloprid (NTN33893 / AE F106464) by High Performance Liquid Chromatography (external Standard), DACO: 2.13.1 CBI
1948765	2006, Validation of HPLC - method AM010705FP1 for the Determination of AE 1873886 (NTN33893-WAK 3839) in Imidacloprid, DACO: 2.13.1 CBI

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