

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2016-8037
Application: Changes to TGAI Product Chemistry – New Source (site) Same Registrant
Product: Technical Fluazinam Fungicide
Registration Number: 27516
Active ingredient (a.i.): Fluazinam
PMRA Document Number : 2815753

Purpose of Application

The purpose of this application was to add a manufacturing site to Technical Fluazinam Fungicide.

Chemistry Assessment

Common Name: Fluazinam
IUPAC* Chemical Name: 3-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)- α,α,α -trifluoro-2,6-dinitro-*p*-toluidine
CAS† Chemical Name: 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Technical Fluazinam Fungicide has the following properties:

| Property | Result | | | | | | | | |
|---------------------------------------|--|-----------|--------------------------|---|-------|---|-------|---|-------|
| Colour and physical state | Yellow granular powder | | | | | | | | |
| Nominal concentration | 97.47% | | | | | | | | |
| Odour | Strong musty | | | | | | | | |
| Density at 20°C | 1.74 g/mL | | | | | | | | |
| Vapour pressure at 25°C | 2.3×10^{-5} Pa | | | | | | | | |
| pH | 6.1 – 6.2 for a 1% dispersion | | | | | | | | |
| Solubility in water | <table border="0"> <tr> <td><u>pH</u></td> <td><u>Solubility (mg/L)</u></td> </tr> <tr> <td>5</td> <td>0.131</td> </tr> <tr> <td>7</td> <td>0.157</td> </tr> <tr> <td>9</td> <td>3.384</td> </tr> </table> | <u>pH</u> | <u>Solubility (mg/L)</u> | 5 | 0.131 | 7 | 0.157 | 9 | 3.384 |
| <u>pH</u> | <u>Solubility (mg/L)</u> | | | | | | | | |
| 5 | 0.131 | | | | | | | | |
| 7 | 0.157 | | | | | | | | |
| 9 | 3.384 | | | | | | | | |
| n-Octanol/water partition coefficient | $\log K_{ow} = 4.03$ | | | | | | | | |

The chemistry requirements for Technical Fluazinam Fungicide 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 determined that the addition of a manufacturing site to Technical Fluazinam Fungicide can be supported.

References

| PMRA Document Number | References |
|-----------------------------|---|
| 1243576 | 1998, Description of Beginning Materials and Manufacturing Process Technical Fluazinam (IKF-1216), DACO: 2.11.1,2.11.2,2.11.3 CBI |
| 1243577 | 1998, Discussion of the Formation of Impurities Technical Fluazinam (IKF-1216), DACO: 2.11.4 CBI |
| 1243578 | 1998, Certified Limits Technical Fluazinam (IKF-1216), DACO: 2.12.1 CBI |
| 1243579 | 1999, Fluazinam (IKF - 1216) - Method Validation [Determination of AI and Related Impurities in Fluazinam (IKF-1216), TGAI by HPLC, DACO: 2.13.1 CBI |
| 2710657 | 2016, IKF-1216 TGAI: Five-Batch Analysis, A, DACO: 2.13.3 CBI |
| 2710658 | 2016, Spectra: IKF-1216 and the impurities, DACO: 2.13.2,2.13.3 CBI |
| 2710659 | 2016, Technical Fluazinam PART 2. 2.1-2.10 Dec 19 2016, DACO: 2.1,2.2 CBI |

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