



## Evaluation Report for Category B, Subcategory 1.2 Application

**Application Number:** 2010-4505  
**Application:** New Source of Technical Grade Active Ingredient by a New Registrant  
**Product:** Nufarm Azoxystrobin Technical  
**Registration Number:** 31378  
**Active ingredients (a.i.):** Azoxystrobin  
**PMRA Document Number :** 2414826

### Background

The source of azoxystrobin used to determine chemical equivalence was Registration Number 26152.

### Purpose of Application

The purpose of this application was to register a new source of the active ingredient, azoxystrobin, by a different Registrant.

### Chemistry Assessment

Common Name: Azoxystrobin

Chemical Name: methyl (2E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate

Nufarm Azoxystrobin Technical has the following properties:

| Property                    | Result  |    |                   |      |               |      |               |      |               |
|-----------------------------|---|----|-------------------|------|---------------|------|---------------|------|---------------|
| Colour and physical state   | Off white solid   |    |                   |      |               |      |               |      |               |
| Nominal Concentration       | 98.5%   |    |                   |      |               |      |               |      |               |
| Odour                       | Bitter  |    |                   |      |               |      |               |      |               |
| Density at 20°C             | 1.30-1.34 g/cm <sup>3</sup>   |    |                   |      |               |      |               |      |               |
| Solubility in water at 20°C | <table><thead><tr><th>pH</th><th>Solubility (mg/L)</th></tr></thead><tbody><tr><td>5.08</td><td>5.982 ± 0.102</td></tr><tr><td>7.08</td><td>6.310 ± 0.048</td></tr><tr><td>9.05</td><td>6.451 ± 0.029</td></tr></tbody></table> | pH | Solubility (mg/L) | 5.08 | 5.982 ± 0.102 | 7.08 | 6.310 ± 0.048 | 9.05 | 6.451 ± 0.029 |
| pH                          | Solubility (mg/L)   |    |                   |      |               |      |               |      |               |
| 5.08                        | 5.982 ± 0.102   |    |                   |      |               |      |               |      |               |
| 7.08                        | 6.310 ± 0.048   |    |                   |      |               |      |               |      |               |
| 9.05                        | 6.451 ± 0.029   |    |                   |      |               |      |               |      |               |
| Vapour pressure at 20°C     | 1.1 × 10 <sup>-7</sup> mPa  |    |                   |      |               |      |               |      |               |

| Property   | Result                      |
|--|-----------------------------|
| pH   | 7 (1% w/v susp)             |
| Octanol/water partition coefficient ( $K_{ow}$ ) | $\log K_{ow} = 2.5$ at 20°C |

The chemistry requirements for Nufarm Azoxystrobin Technical have been completed.

### **Health and Environmental Assessments**

As the new source of azoxystrobin is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

### **Value Assessment**

A value assessment is not required for technical grade active ingredient products.

### **Conclusion**

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Nufarm Azoxystrobin Technical

## References

### Studies/Information Provided by the Applicant

| PMRA No. | Title  |
|----------|--|
| 1958869  | 2010, TGAI Chemistry Summary Information, DACO: 2.1,2.2,2.3,2.3.1 CBI  |
| 1958878  | 2009, Preliminary Analysis - 5BA - Volume I, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI                          |
| 1958879  | 2010, Enforcement of Analytical Method, DACO: 2.13.1, 2.13.2 CBI   |
| 1958884  | 2008, Accelerated Storage Stability of NUP 08088, DACO: 2.14.14 CBI  |
| 1958886  | 2008, Colour, Physical State, odor, DACO: 2.14.1,2.14.2,2.14.3 CBI   |
| 1958887  | 2008, Dissociation constants in water, DACO: 2.14.10 CBI   |
| 1958888  | 2008, Infrared Spectral Analyses of NUP 08088, DACO: 2.13.2 CBI  |
| 1958889  | 2008, Melting Point, DACO: 2.14.4 CBI  |
| 1958891  | 2010, Determination of Specificity Method Validation of Study 8737, DACO: 2.13.1, 2.13.2 CBI                   |
| 1958893  | 2008, Methodology Validation, DACO: 2.13.1,2.13.2 CBI  |
| 1958895  | 2009, Method Development, Validation and Determination by HPLC, DACO: 2.13.1, 2.13.2 CBI                       |
| 1958898  | 2008, Partition coefficient, DACO: 2.14.11 CBI   |
| 1958899  | 2010, Identity of the Active Substance, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI |
| 1958901  | 2008, Solubility in organic solvents, DACO: 2.14.8 CBI   |
| 1958902  | 2008, Specific Gravity, DACO: 2.14.6 CBI   |
| 1958903  | 2008, Determination of Stability, DACO: 2.14.13 CBI  |
| 1958904  | 2008, Vapour Pressure, DACO: 2.14.9 CBI  |
| 1958905  | 2008, Water Solubility, DACO: 2.14.7 CBI   |
| 2036991  | 2009, Production Chemistry of AZOXYSTROBIN [CBI removed] 30Nov2009, DACO: 2.11.3 CBI                           |

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