

## Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

**Application Number:** 2016-4565  
**Application:** B.1.1: New Source (Site) Same Registrant  
 B.1.3: New Chemistry Specifications  
**Product:** Pyrimethanil Technical Fungicide  
**Registration Number:** 28010  
**Active ingredients (a.i.):** Pyrimethanil  
**PMRA Document Number:** 2727918

### Purpose of Application

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

### Chemistry Assessment

Common Name: pyrimethanil  
 IUPAC\* Chemical Name: 4,6-dimethyl-*N*-phenylpyrimidin-2-amine  
 CAS† Chemical Name: 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Pyrimethanil Technical Fungicide has the following properties:

Property	Result	
Colour and physical state	Off-white to light beige or light yellow crystalline powder	
Nominal concentration	99.6%	
Odour	Odourless	
Density	1.15 g/mL	
Vapour pressure	<u>Temperature (°C)</u> <u>V.P. (mPa)</u>	
	20	1.1
	25	2.2
	30	4.1
pH	7.8 (1% w/w acetone/water)	

Property	Result
Solubility in water	<u>pH</u>
	4.2
	6.1
	9.9
<u>solubility (g/L)</u>	0.160 (20°C)
	0.121 (25°C)
	0.099 (20°C)
n-Octanol/water partition coefficient	Log K <sub>ow</sub> = 2.84

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

### Health Assessment

The health risk is acceptable for the new manufacturing site.

### Environmental and Value Assessments

Environmental and value assessments were not required for this application.

### Conclusion

PMRA has conducted a critical review of the information provided in support of the new manufacturing site. Based on the results of this review, the new manufacturing site is acceptable for full registration.

## References

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- 2667883 2016, Pyrimethanil technical active substance - Discussion of formation of impurities, DACO: 2.11.4 CBI
- 2667884 2016, Pyrimethanil technical grade active substance justification of certified limits, DACO: 2.12.1 CBI
- 2667885 2014, Amendment no.1 to validation of [CBI removed] - method AM040614FP1 - Determination of [CBI removed] in pyrimethanil (AE B100309) technical material by [CBI removed], DACO: 2.13,2.13.1
- 2667886 2013, Validation of the GC - method AM033412FP1 - Determination of the by-products in technical grade pyrimethanil (AE B100309) by gas chromatography (GC), DACO: 2.13,2.13.1 CBI
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- 2667892 2014, Determination of AE B100309 (Pyrimethanil) in the technical material by high performance liquid chromatography (HPLC), DACO: 2.13,2.13.1 CBI
- 2667893 2015, Material accountability of pyrimethanil (AE B100309), DACO: 2.13.2, 2.13.3 CBI

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