

## Evaluation Report for Category B, Subcategory B.1.1 Application

**Application Number:** 2007-4396  
**Application:** Category B, Subcategory 1.1 (new source by the same registrant)  
**Product:** Fenamidone Technical Fungicide  
**Registration Number:** 27461  
**Active ingredients (a.i.):** Fenamidone at 99.0%  
**PMRA Document Number:** 1643815

### Background

The original source of fenamidone technical grade active ingredient, “Fenamidone Technical Fungicide” (Reg. No. 27461), was first registered in 2003.

### Purpose of Application

The purpose of this application is to register a new technical source of fenamidone.

### Chemistry Assessment

**Common Name:** Fenamidone  
**IUPAC Chemical Name:** (S)-1-anilino-4-methyl-2-methylthio-4-phenylimidazolin-5-one  
**CAS Chemical Name:** (5S)-3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4H-imidazol-4-one

Fenamidone Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White to cream fine powder
Nominal concentration	99.0%
Odour	No characteristic odour
Density	1.29 g/cm <sup>3</sup> (at 20°C)
Vapour pressure	3.4 x 10 <sup>-4</sup> mPa (at 25°C)
pH	5.65 (1% in water)
Solubility in water	7.8 mg/L (at 20°C)
<i>n</i> -Octanol–water partition coefficient	log K <sub>ow</sub> = 2.8 (at 20°C)

The chemistry requirements for Fenamidone Technical Fungicide have been completed.

### **Health Assessments**

A health assessment was not required for this application.

### **Environmental Assessment**

An environmental assessment was not required for this application.

### **Value Assessment**

A value assessment was not required for this application.

### **Conclusion**

The PMRA has completed an evaluation of the subject application and has determined that the new technical source of fenamidone should be added as a source of the registered product Fenamidone Technical Fungicide.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
777072	1997, Technical fenamidone HPLC determination of active ingredient chemical purity., Report No. 98-02, MRID: N/S, DACO: 2.13.1 CBI
777073	1999, Technical fenamidone HPLC determination of main impurities, Report No. 98-02, MRID: N/S, DACO: 2.13.1 CBI
1431986	2007, Fenamidone Technical Fungicide PMRA Requirement PART 2.1 and 2.2 Product Chemistry Requirements for the Registration of a TGAI, DACO: 2.1,2.2
1431987	2007, Fenamidone Technical Material Manufactured by Hikal Ltd (India) Manufacturing Process Description of Materials Used to Product the Product and Description of Production Process, PA07/007, DACO: 2.11.1,2.11.2,2.11.3 CBI
1431988	2007, Material Accountability of AE C649693 (Fenamidone) Technical Material Analytical Profile of Five Production Batches Manufactured by Kikal Limited at Maharashtra in India, PA07/007, DACO: 2.11.4,2.13.1,2.13.2,2.13.3 CBI
1431989	2007, Fenamidone Composition Statement Technical Material, DACO: 2.12.1 CBI

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