

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

**Application Number:** 2012-4133  
**Application:** Changes to technical grade active ingredient (TGAI); new manufacturing site by same registrant and new product specifications  
**Product:** Prothioconazole Technical Fungicide  
**Registration Number:** 28358  
**Active ingredients (a.i.):** Prothioconazole  
**PMRA Document Number :** 2286998

### Background

Prothioconazole Technical Fungicide is used to formulate several seed treatment products and fungicides that are applied on cereal and vegetable crops. The active ingredient, prothioconazole, is a systemic fungicide from the Group 3 Fungicides, specifically within the demethylation inhibitor class of sterol biosynthesis inhibitor fungicides.

### Purpose of Application

The purpose of this application was to register a new manufacturing site. This application was assessed as a NAFTA joint review between USEPA and the PMRA.

### Chemistry Assessment

**Common Name:** Prothioconazole  
**IUPAC\* Chemical Name:** (RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione  
**CAS† Chemical Name:** 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Prothioconazole Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Colourless to faint beige powder
Nominal concentration	98.8%
Odour	Faint uncharacteristic

Property	Result	
Density	1.36 g/mL	
Vapour pressure	<u>Temperature (°C)</u>	<u>Vapour pressure (Pa)</u>
	20	<4 x 10 <sup>-7</sup>
	25	<4 x 10 <sup>-7</sup>
pH	5.8 for a 1% solution	
Solubility in water	<u>pH</u>	<u>Solubility (g/L)</u>
	4	0.005
	8	0.3
	9	2.0
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K<sub>ow</sub></u>
	unbuffered water	4.05
	4	4.16
	7	3.82
	9	2.00

The chemistry requirements for Prothioconazole Technical Fungicide have been fulfilled.

### Health Assessments

The changes in the levels of impurities are not considered toxicologically significant. Subsequently no toxicological data were required.

### Environmental and Value Assessments

Environmental and value assessments were not required for this application.

### Conclusion

The new site of manufacture was found to be acceptable for registration under the same registration number.

### References

PMRA Document Number	Reference
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1775213	2005, Material Accountability of Prothioconazole Manufactured in [PRIVACY REMOVED], DACO: 2.13.2,2.13.3 CBI

1787997	2005, Material Accountability of Prothioconazole Manufactured in [PRIVACY REMOVED], Analytical Profile of Production Batches, DACO: 2.13.2,2.13.3 CBI
2230378	2012, Prothioconazole Technical Fungicide: Part 2 Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product (ISP), DACO 2.1 - 2.9, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2230379	2012, Prothioconazole - Description of the manufacturing process of the technical grade active substance - for USA and Canada, DACO: 2.11.1,2.11.2,2.11.3 CBI
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2230381	2012, Prothioconazole TC - Discussion of formation of impurities, DACO: 2.11.4 CBI
2230382	2012, Validation of AM018712MP1 - Prothioconazole (JAU 6476) - Impurities in technical grade active substance - HPLC - external standard, DACO: 2.13.1 CBI
2230383	2012, Validation of AM018712MP1 - Determination of [CBI REMOVED] in technical grade active substance - HPLC - external standard, DACO: 2.13.1 CBI
2230384	2012, Validation of AM018612MP1 - Prothioconazole (JAU 6476) - Determination of technical grade active substance HPLC - External standard, DACO: 2.13.1 CBI
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2230387	2012, [CBI REMOVED]- Determination of [CBI REMOVED]in prothioconazole - JAU6476, DACO: 2.13.1 CBI
2230389	2012, Material accountability of technical prothioconazole (JAU 6476) - Five batches of technical prothioconazole, DACO: 2.13.2,2.13.3 CBI
2253525	2012, Authority Request: Prothioconazole (JAU 6476) MA-study 15-920-2576, DACO: 2.13.2 CBI
2253526	2012, BCS response to questions received from the PMRA (November 19, 2012) regarding the product chemistry for Prothioconazole Technical Fungicide (Reg. No. 28358; Sub. No. 2012-4133), DACO: 2.12,2.13.2 CBI
2253527	2012, Prothioconazole (JAU 6476), List of Reference Materials, DACO: 2.13.2 CBI
2257815	2012, Clarification response to DACO: 2.13.4 CBI

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