

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2014-3550

Application: New end-use product, new guarantee and formulation.

Product: Mettle 210 ME Fungicide

Registration Number: 32042

Active ingredients (a.i.): Tetraconazole PMRA Document Number: 2566792

Purpose of Application

The purpose of this application was to register a new product Mettle 210 ME Fungicide, based on precedent product Mettle 125 ME Fungicide (registration number 30673) for use on gooseberries, grapes, sugar beets and strawberries.

Chemistry Assessment

Mettle 210 ME Fungicide is formulated as an emulsifiable concentrate containing tetraconazole at a nominal concentration of 210 g/L. This end-use product has a density of 1.12 g/mL and a pH of 7.1. The chemistry requirements for Mettle 210 ME Fungicide have been fulfilled.

Health Assessments

Mettle 210 ME Fungicide is of low acute oral, dermal and inhalation toxicity in rats. It is minimally irritating to the eye and skin of the rabbit. It is not a skin sensitizer in the guinea pig.

The use of Mettle 210 ME Fungicide on gooseberries, grapes, sugar beets and strawberries is not expected to result in potential occupational or bystander exposures over the exposures from the registered uses of tetraconazole. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Previously reviewed residue data from field trials conducted in/on grapes, sugar beets and strawberries were reassessed. The residue levels on grapes, gooseberries, sugar beets and strawberries, from use of Mettle 210 ME Fungicide, are not expected to exceed the currently established MRLs and, therefore, will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.



Environmental Assessment

As the uses for Mettle 210 ME Fungicide are the same as the precedent, the use of Mettle 210 ME Fungicide is not expected to pose an unacceptable risk to the environment when used according to the label directions.

Value Assessment

Based on the similarity of the precedent product, the uses on the Mettle 210 ME Fungicide are supported from a value perspective.

Conclusion

Following review of the application, the PMRA approved the use of Mettle 210 ME Fungicide on gooseberries, grapes, sugar beets and strawberries.

References

PMRA Document	
Number	Reference
2452294	2014, Additional Product Chemistry for Mettle 210 ME Fungicide, DACO: 3.1.1, 3.1.2, 3.1.3,3.1.4,3.5.11,3.5.12,3.5.13,3.5.15,3.5.4,3.5.8, CBI
2452295	2014, Additional Product Chemistry for Mettle 210 ME Fungicide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.11,3.5.12,3.5.13,3.5.15,3.5.4,3.5.8 CBI
2452296	2014, Manufacturing method for the production of Tetraconazole 210 g/L ME, DACO: 3.2.1,3.2.2,3.2.3 CBI
2452297	2014, Physical-chemical characterization and accelerated storage stability of test item Tetraconazole 210 ME, DACO: 3.3.1,3.4.1,3.5.1, 3.5.10,3.5.2, 3.5.3,3.5.5,3.5.6,3.5.7,3.5.9, CBGI
2463008	2004, Tetraconazole 230 g/L microemulsion: Acute Oral Toxicity Study in Rats (Ip and Down procedure) DACO: 4.6.1
2452301	2004, Tetraconazole 230 g/L microemulsion: Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2452302	2004, Tetraconazole 230 g/L microemulsion: 4-HOUR ACUTE INHALATION TOXICITY STUDY IN RATS, DACO: 4.6.3
2452303	2004, Tetraconazole 230 g/L microemulsion: Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2463008	2004, Tetraconazole 230 g/L microemulsion: Acute Oral Toxicity Study in the Rat (Up and Down Procedure), DACO: 4.6.1
2463011	2004, Tetraconazole 230 g/L microemulsion: Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application), DACO: 4.6.5
2463012	2004, Tetraconazole 230 g/L microemulsion: Contact Hypersensitivity in Albino Guinea Pigs, Maximization-Test, DACO: 4.6.6

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