

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2013-1019
Application: New or Changes to Product Labels-Precautions
Product: Folicur Technical Fungicide
Registration Number: 25763
Active ingredients (a.i.): Tebuconazole
PMRA Document Number: 2388271

Purpose of Application

The purpose of this application was to amend the registration of Folicur Technical Fungicide by removing the q1* in the cancer risk assessment of tebuconazole.

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

The submitted data supported a threshold mode of action (MOA) for the liver tumours observed in the mouse following prolonged dosing. As a result, the linear low dose extrapolation is not required for the cancer risk assessment. Three studies were provided to assess endocrine effects. A delay in sexual maturation in juvenile male and female rats was observed at a high dose in one study. The uterotrophic assay in female rats and the in vitro estrogenic receptor transcription assay were both negative. The results of these studies did not affect the endpoints previously established for risk assessment.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product Folicur Technical Fungicide, and has found the information sufficient to use the proposed MOAs to remove the cancer risk assessment via the q1* linear low dose extrapolation.

References

<u>PMRA</u> <u>Doc No.</u>	<u>Reference</u>
2250369	2012, SUMMARY OF MODE OF ACTION STUDIES IN MICE EXPOSED TO TEBUCONAZOLE IN THE DIET, DACO: 4.8
2250370	2012, Tebuconazole - 28-day liver mechanistic study in the male and female mice by dietary administration (liver enzyme activity and gene transcript investigation), DACO: 4.8
2250374	2012, Tebuconazole - 28-day liver mechanistic study in male and female mice by dietary administration (liver histopathology and cell proliferation investigations), DACO: 4.8
2250377	2012, Assessment of pubertal development and thyroid function in juvenile/peripubertal male and female rats, DACO: 4.8
2250378	2012, Tebuconazole - Evaluation in the immature rat - Uterotrophic assay, DACO: 4.8
2250379	2011, Tebuconazole: evaluation in the in vitro (hela-9903) estrogen receptor transcriptional activation assay, DACO: 4.8

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