



Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2004-3553
Application: B.4.1 – Conversion to Full Registration without Consultation
Product: Famoxadone Technical
Registration Number: 27436
Active ingredients (a.i.): famoxadone
PMRA Document Number : 2313468

Purpose of Application

E.I. Du Pont Canada has submitted an application to convert the conditional registration of Famoxadone Technical to Full Registration.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Toxicology and occupational exposure assessments were not required for this application.

Confirmation was provided that analytical method DuPont-1452 is the enforcement method for animal matrices. Exposure to residues of famoxadone in food and water is acceptable and below the level of concern for all population subgroups.

Environmental Assessment

Refer to Regulatory document REG2003-10, *Famoxadone/Tanos 50DF* for a detailed assessment of the fate and behaviour of Famoxadone in the environment. The previously outstanding information on the octanol-water partition coefficients for major transformation products has been submitted to the PMRA and has been found to be satisfactory.

The major transformation products identified in the fate studies included IN-JS940, IN-H3310, IN-JL856, IN-MN968, IN-MN467, IN-MN468, IN-KF015 and IN-KZ007. The octanol-water partition coefficients ($\log K_{ow}$) of the transformation products IN-H3310, IN-JL856, IN-MN467 and IN-MN468 are 3.4, 2.4, 4.8 and 4.3, respectively. A waiver request for an octanol-water partition coefficient of IN-MN968 was approved due to the instability of this metabolite. Aerobic biotransformation studies with IN-KZ007 ($DT_{50} = 1.5-10.3$ days), IN-KF015 ($DT_{50} = 1.2$ days) and IN-JS940 ($DT_{50} = 6-23$ hours) indicated that these transformation products are not persistent in soil. Transformation products were not identified or quantified in the bioconcentration study in fish; however, depuration of the radiolabelled parent compounds was rapid with > 90% of the

accumulated residues eliminated by day 7. It is unlikely that these transformation products bioaccumulate.

During the review process, Famoxadone and the end-use product Tanos 50 DF Fungicide were assessed in accordance with the PMRA Regulatory Directive [DIR99-03](#), *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of Famoxadone were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use product, Tanos 50 DF Fungicide. The PMRA has reached the conclusion that these products do not meet TSMP Tack 1 criteria. Refer to Regulatory document REG2003-10, *Famoxadone/Tanos 50DF* for more details.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has completed its review of the available data and has no objection to the conversion of the conditional registration of Famoxadone Technical to Full registration.

List of Abbreviations

K_{ow}	Octanol–water partition coefficient
$\log K_{ow}$	Log value of the octanol–water partition coefficient
TSMP	Toxic Substances Management Policy

References

List of Studies/ Information Submitted by Registrant

PMRA Document Number: 922464

Reference: 2004, IN-H3310, IN-JL856, IN-MN467, and IN-MN468 (Famoxadone Metabolites): Partition Coefficient (n-Octanol/Water), High Performance Liquid Chromatography (HPLC) Method, ABC-48998

PMRA Document Number: 922465

Reference: 2003, DuPont Response to PMRA Request for Octanol-Water Partition Coefficients for the Famoxadone Metabolites IN-JL856, IN-H3310, IN-MN467, IN-MN468, IN-MN968, Dupont-13969

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