



## Evaluation Report for Category B, Subcategory 5.0 Application

**Application Number:** 2020-0304  
**Application:** New Maximum Residue Limits for previous assessed Technical Grade Active Ingredient  
**Product:** Fluopyram Technical Fungicide  
**Registration Number:** 30508  
**Active ingredient (a.i.):** Fluopyram  
**PMRA Document Number:** 3204133

### Purpose of Application

The purpose of this application was to establish a maximum residue limit (MRL) to cover residues of fluopyram in/on imported green coffee beans and to amend the currently established MRL for residues of fluopyram in/on rapeseeds (crop subgroup 20A) (revised).

### Health Assessment

Residue data for fluopyram in/on canola were submitted to support the amendment of the currently established maximum residue limit (MRL) on rapeseeds (crop subgroup 20A) (revised). Residue data were also submitted for fluopyram in/on coffee to establish a MRL on imported green coffee beans. In addition, a processing study in treated coffee was reviewed to determine the potential for concentration of residues of fluopyram into processed commodities.

### Maximum Residue Limits

The recommendation for MRLs for fluopyram was based upon the submitted field trial data and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of fluopyram in/on crops are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs). Table 2 summarizes the residue data used to calculate the proposed MRLs.

**Table 1 Proposed Maximum Residue Limits for Fluopyram**

MRL (ppm) <sup>1</sup>	Food Commodity
0.3	Rapeseeds (crop subgroup 20A) (revised) <sup>2</sup>
0.03	Green coffee beans

<sup>1</sup> ppm = parts per million

<sup>2</sup> The MRL is proposed to replace the currently established MRL of 1.8 ppm for rapeseeds (crop subgroup 20A) (revised).

**Table 2            Summary of Field Trial and Processing Data Used to Support the MRLs**

<b>Commodity</b>	<b>Application Method/ Total Application Rate (g a.i./ha)<sup>1</sup></b>	<b>Preharvest Interval (days)</b>	<b>Lowest Average Field Trial Residues (ppm)</b>	<b>Highest Average Field Trial Residues (ppm)</b>	<b>Experimental Processing Factor</b>
Canola seed	Foliar application/ 293-306	27-29	0.022	0.185	No concentration in processed fractions
Coffee green beans	Drench application/ 491-516	88-90	<0.010	0.012	No quantifiable residues observed at exaggerated rates

<sup>1</sup> g a.i./ha = grams of active ingredient per hectare.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fluopyram. Risks from exposure to residues of fluopyram in these crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

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

#### **Chemistry, Environmental and Value Assessments**

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

#### **Conclusion**

The Pest Management Regulatory Agency has completed the assessment of the available information and found it acceptable to recommend MRLs as proposed in Table 1 to cover residues of fluopyram in/on imported green coffee beans and rapeseeds (crop subgroup 20A) (revised).

## References

### List of Studies/Information Submitted by Registrant

<b>PMRA Document Number</b>	<b>Reference</b>
3082506	2016, Addendum no. 01 to the final report - Determination of residues of fluopyram and its metabolite in the coffee crop (grains) following the application of fluopyram in trials in Brazil, DACO: 7.4.1,7.4.2
3082507	2017, Fluopyram 500 SC - Magnitude of residues in/on coffee; import tolerances, DACO: 7.4.1,7.4.2
3082508	2019, Amendment no. 01: Magnitude of fluopyram and prothioconazole residues in canola after seed treatment application with fluopyram FS 600 (600 g/L) followed by 2 foliar applications of fluopyram + prothioconazole (200 + 200 g/L) in North America, DACO: 7.4.1,7.4.2
3082509	2017, Amendment 1 to final report - Fluopyram 500 SC - Magnitude of residues in/on coffee processed commodities; import tolerances, DACO: 7.4.5

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.