

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2021-1710  
**Application:** Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy – Equivalency/Data Compensation  
**Product:** Raclos Fungicide  
**Registration Number:** 34615  
**Active ingredient (a.i.):** Pyraclostrobin  
**PMRA Document Number :** 3347748

### Purpose of Application

The purpose of this application was to register a new end-use product, Raclos Fungicide, based on a precedent.

### Chemistry Assessment

Raclos Fungicide is formulated as an emulsifiable concentrate containing pyraclostrobin at a concentration of 250 g/L. This end-use product has a density of 1.059-1.067 g/mL and pH of 6.08. The required chemistry data for Raclos Fungicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Raclos Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Raclos Fungicide is considered to be highly acutely toxic by the oral route, and of low acute toxicity by the dermal and inhalation routes. It is considered to be moderately irritating to the eyes and skin, and is not considered to be a dermal sensitizer.

The use pattern of Raclos Fungicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for pyraclostrobin were submitted or are required to support the registration of Raclos Fungicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Raclos Fungicide label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are similar to the precedent end-use product. Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of pyraclostrobin is not expected to increase with the registration of Raclos Fungicide, and will not pose health risks of concern to any segment of the population, including

infants, children, adults and seniors.

### **Environmental Assessment**

The uses on the Raclos Fungicide label are within the currently registered use pattern of the active ingredient pyraclostrobin. Therefore, no additional risk is expected when Raclos Fungicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

### **Value Assessment**

The formulation of Raclos Fungicide was compared to that of the cited precedent product. Based on this comparison, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. All uses and claims included in the registration of the precedent product are acceptable for Raclos Fungicide.

The availability of Raclos Fungicide will provide Canadian growers with an additional product to manage common and economically important diseases on labelled crops.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Raclos Fungicide.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
3225850	2019, Validation of Analytical Method for the Determination of Active Ingredient Content of Pyraclostrobin 250 g/L EC by HPLC-UV Method, DACO: 3.4.1
3225851	2019, Determination of Physical State, Color and Odor of Pyraclostrobin 250 g/L EC, DACO: 3.5.1, 3.5.2, 3.5.3
3225852	2019, Determination of Density of Pyraclostrobin 250 g/L EC, DACO: 3.5.6
3225853	2019, Determination of pH of Pyraclostrobin 250 g/L EC, DACO: 3.5.7
3225854	2019, Determination of Accelerated Storage Stability of Pyraclostrobin 250 g/L EC, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3
3225855	2019, Determination of explosive properties of Pyraclostrobin 250 g/L EC, DACO: 3.5.12
3225856	2019, Determination of Flash Point of Pyraclostrobin 250 g/L EC, DACO: 3.5.11
3225857	2019, Determination of Oxidation / Reduction (Chemical Incompatibility) of Pyraclostrobin 250 g/L EC, DACO: 3.5.8

<b>PMRA Document Number</b>	<b>Reference</b>
3225858	2019, Determination of Viscosity of Pyraclostrobin 250 g/L EC, DACO: 3.5.9
3225859	2019, Determination of Miscibility of Pyraclostrobin 250 g/L EC, DACO: 3.5.13
3225860	2021, Manufacturing Process of Pyraclostrobin 250g/l EC, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2022

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.