



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-1022  
**Application:** Submission Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy - Equivalency/Data Compensation Assessment  
**Product:** Wynca Pyraclostrobin 250 EC  
**Registration Number:** 35345  
**Active ingredient (a.i.):** Pyraclostrobin  
**PMRA Document Number:** 3581939

### Purpose of Application

The purpose of this application was to register the new commercial end-use product, Wynca Pyraclostrobin 250 EC, based on a registered precedent product.

### Chemistry Assessment

Wynca Pyraclostrobin 250 EC is formulated as an emulsifiable concentrate containing pyraclostrobin at a concentration of 250 g/L. This end-use product has a density of 1.05 g/mL and a pH of 6.07. The required chemistry data for Wynca Pyraclostrobin 250 EC have been provided, reviewed and found to be acceptable.

### Health Assessments

Wynca Pyraclostrobin 250 EC was considered toxicologically equivalent to the precedent product. Wynca Pyraclostrobin 250 EC was considered to be of high acute toxicity by the oral route, low acute toxicity by the dermal and inhalation routes, severely irritating to the eyes, moderately irritating to the skin, and was not considered to be a dermal sensitizer.

The use pattern of Wynca Pyraclostrobin 250 EC 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 were required to support the registration of Wynca Pyraclostrobin 250 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Wynca Pyraclostrobin 250 EC label, including the target crops, methods (ground and aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of pyraclostrobin is not expected to increase with the registration of Wynca Pyraclostrobin 250 EC and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use pattern for Wynca Pyraclostrobin 250 EC is identical to the registered use pattern of the precedent product, therefore, no additional risk is expected from the use of Wynca Pyraclostrobin 250 EC.

The label includes all the required environmental precautions, directions for use and spray buffer zones information, which adequately mitigate risks to the environment.

Risk from use of Wynca Pyraclostrobin 250 EC is acceptable from the environmental perspective when used according to label directions.

### **Value Assessment**

Based on a formulation comparison between Wynca Pyraclostrobin 250 EC and a registered precedent product, 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 therefore acceptable for Wynca Pyraclostrobin 250 EC.

The availability of Wynca Pyraclostrobin 250 EC will provide Canadian growers with an additional product option 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 acceptable to support the registration of Wynca Pyraclostrobin 250 EC.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3446491	2022, Manufacturing process, DACO: 3.2.2 CBI
3446493	2023, Discussion of the impurities, DACO: 3.2.3
3446496	2023, Impurities of toxicological concern, DACO: 3.4.2
3446497	2017, Chemical and physical characterization, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9
3446498	2023, Dielectric breakdown voltage, DACO: 3.5.15
3446499	2023, Nano-material characteristics, DACO: 3.5.16
3446502	2023, Oxidizing or reducing action, DACO: 3.5.8
3463045	2017, Enforcement analytical method of Wynca Pyraclostrobin 250 EC, DACO: 3.4.1

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

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.