Health Canada Santé Canada

# Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-5292
**Application:** Application Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
**Applicant:** UPL AgroSolutions Canada Inc.
**Product:** Telaron DC
**Registration Number:** 35763
**Active ingredient (a.i.):** Prothioconazole
**PMRA Document Number: 3694989**

## Purpose of Application

The purpose of this application was to register the new end-use product Telaron DC, to control fungal diseases on the label's listed crops.

## Chemistry Assessment

Telaron DC is formulated as an emulsifiable concentrate containing prothioconazole at a concentration of 250 g/L. This end-use product has a density of 1.07 – 1.09 g/mL and pH of 4 - 5. The required chemistry data for Telaron DC have been provided, reviewed and found to be acceptable.

## Health Assessments

Telaron DC is of low acute toxicity via the oral, dermal, and inhalation routes. It is minimally irritating to the eyes, non-irritating to the skin, and is not a dermal sensitizer.

The use pattern of Telaron DC is comparable to the registered use pattern of the precedent products.

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 prothioconazole were submitted or are required to support the registration of Telaron DC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Telaron DC label, including the target crops, methods (ground and/or aerial), rates and timing of application, preharvest intervals,

feeding restrictions, and crop rotation restrictions are comparable to those on the labels of the precedent end-use products.

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 MRLs. Consequently, dietary exposure to residues of prothioconazole is not expected to increase with the registration of Telaron DC 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 and application rate on the label of Telaron DC is within the currently registered use pattern and rates for prothioconazole. Therefore, no additional risk is expected when Telaron DC is used in accordance with the label, which includes statements to mitigate risks to the environment.

**Value Assessment**

The formulation of the fungicide Telaron DC was compared to one of the cited precedent products. Based on this comparison, it was concluded that these two products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the evidence of value for use claims included in the registration of that precedent product is acceptable for extrapolation to support comparable claims on the Telaron DC label. In addition, the use against certain diseases in cucurbit vegetables and certain pulse crops can be also supported based on another precedent product.

The registration of Telaron DC will provide Canadian growers with an additional end-use product option to manage disease 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 Telaron DC.

## References


| PMRA Document Number | Reference |
|---|---|
| 3506851 | 2022, Physical & Chemical Properties in one batch of Prothioconazole 250 DC, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.9 CBI |
| 3506852 | 2022, Method validation report for Prothioconazole 250 DC, DACO: 3.4.1 CBI |
| 3506853 | 2022, Physical & Chemical Properties in one batch of Prothioconazole 250 DC, DACO: 3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.5,3.5.7,3.5.8,3.5.9 CBI |
| 3506854 | 2020, Formulation process for Prothioconazole 250 DC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI |
| 3515319 | 2023, Additional Product Chemistry for UPL Prothioconazole 250, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.4,3.5.5 |
| 3674246 | 2024, Acute oral toxicity study of Prothioconazole 250 DC in rats, DACO 4.6.1 |
| 3674245 | 2024, Acute dermal toxicity study of Prothioconazole 250 DC in rats, 4.6.2 |
| 3674247 | 2024, Acute inhalation toxicity study of Prothioconazole 250 DC in rats, 4.6.3 |
| 3674248 | 2024, Acute eye irritation study of Prothioconazole 250 DC in rabbits, 4.6.4 |
| 3674249 | 2024, Acute dermal irritation study of Prothioconazole 250 DC in rabbits, 4.6.5 |
| 3674250 | 2024, Skin sensitization study of Prothioconazole 250 DC by local lymph node assay in mice, DACO 4.6.6 |