Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1553
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy-Equivalency/Data Compensation Assessment
Product: KQ Pyraclostrobin 250 EC
Registration Number: 34601
Active ingredient (a.i.): Pyraclostrobin
PMRA Document Number : 3245497

Purpose of Application

The purpose of this application was to register a new fungicide, KQ Pyraclostrobin 250 EC, based on registered precedent products.

Chemistry Assessment

KQ 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 1.0591-1.0672 g/mL and pH of 6.08. The required chemistry data for KQ Pyraclostrobin 250 EC have been provided, reviewed and found to be acceptable.

Health Assessments

KQ Pyraclostrobin 250 EC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. KQ Pyraclostrobin 250 EC is considered to be of high acute toxicity by the oral route. It is considered to be of low acute toxicity by the dermal and inhalation routes. It is considered severely irritating to the eyes and skin. It is not considered to be a potential skin sensitizer.

The use pattern of KQ 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 are required to support the registration of KQ Pyraclostrobin 250 EC. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the KQ Pyraclostrobin 250 EC label, including the target crops, method, rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable 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

maximum residue limits (MRLs). Consequently, dietary exposure to residues of pyraclostrobin is not expected to increase with the registration of KQ 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 KQ Pyraclostrobin 250 EC is within those currently registered for the precedent products. The registration of KQ Pyraclostrobin 250 EC to control fungal diseases in listed crops is not expected to pose any additional environmental risks when used in accordance with label directions, and environmental risk is acceptable.

Value Assessment

A formulation comparison of the fungicide product KQ Pyraclostrobin 250 EC to a precedent product was conducted to support claims to control or suppress diseases on several field crop species. The claims on the precedent product label were extrapolated to the KQ Pyraclostrobin 250 EC label based on the similarity in formulation. Registration of KQ Pyraclostrobin 250 EC will provide growers with an additional product to manage a spectrum of true fungal diseases on economically important field crops in Canada.

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 KQ Pyraclostrobin 250 EC.

References

PMRA Document Number	Reference
3114568	2020, Manufacturing process for KQ Pyraclostrobin 250 EC, DACO: 3.2.2 CBI
3114569	2020, Discussion of Impurity concern for KQ Pyraclostrobin 250 EC, DACO: 3.2.3
3114570	2019, Enforcement analytical method for KQ Pyraclostrobin 250 EC, DACO: 3.4.1
3114572	2019, Appearance of KQ Pyraclostrobin 250 EC, DACO: 3.5.1,3.5.2,3.5.3
3114573	2020, Formulation type for KQ Pyraclostrobin 250 EC, DACO: 3.5.4
3114574	2020, Container material for KQ Pyraclostrobin 250 EC, DACO: 3.5.5
3114575	2019, Density for KQ Pyraclostrobin 250 EC, DACO: 3.5.6
3114576	2019, pH for KQ Pyraclostrobin 250 EC, DACO: 3.5.7
3114577	2019, Oxidizing or reducing action for KQ pyraclostrobin 250 EC, DACO: 3.5.8
3114578	2019, Viscosity of KQ Pyraclostrobin 250 EC, DACO: 3.5.9
3114579	2019, Storage stability for KQ Pyraclostrobin 250 EC, DACO: 3.5.10
3114580	2019, Flammability for KQ pyraclostrobin 250 EC, DACO: 3.5.11
3114581	2019, Explodability for KQ pyraclostrobin 250 EC, DACO: 3.5.12

3114582 2019, Miscibility for KQ Pyraclostrobin 250 EC, DACO: 3.5.13
3114585 2020, Nano-material characteristics, DACO: 3.5.16
3223651 2021, Detailed sample preparation of KQ Pyraclostrobin 250 EC, DACO: 3.4.1