Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2023-3004
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Applicant: Zhejiang Xinan Chemical Industrial Group Co., Ltd.
Product: Wynca Sun-Quiz Herbicide
Registration Number: 35341
Active ingredient(s) (a.i.): Quizalofop-p-ethyl
PMRA Document Number: 3608781

Purpose of Application

The purpose of this application was to register the end-use product, Wynca Sun-Quiz Herbicide, based on a registered precedent product.

Chemistry Assessment

Wynca Sun-Quiz Herbicide is formulated as an emulsifiable concentrate containing quizalofop-p-ethyl at a concentration of 96 g/L. This end-use product has a density of 0.9548 g/mL and pH of 5.53. The required chemistry data for Wynca Sun-Quiz Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Wynca Sun-Quiz Herbicide was not considered toxicologically equivalent to the precedent product. With the submission of an acute oral toxicity study and a skin irritation study, no additional toxicology data were required. Wynca Sun-Quiz Herbicide is of low acute toxicity via the oral route and is considered to be of low acute toxicity via the dermal and inhalation routes of exposure. It is considered extremely irritating to the eyes and is moderately irritating to the skin. It is considered to be a dermal sensitizer.

The use pattern of Wynca Sun-Quiz Herbicide 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 quizalofop-p-ethyl were submitted or are required to support the registration of Wynca Sun-Quiz Herbicide. Previously reviewed residue data were re-assessed in the framework of this submission. The use directions on the Wynca Sun-Quiz Herbicide label, including the target crops, methods (ground and/or aerial), rates and timing of

application, geographic restrictions, preharvest intervals, and feeding 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 quizalofop-p-ethyl is not expected to increase with the registration of Wynca Sun-Quiz Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of Wynca Sun-Quiz Herbicide is within the currently registered use pattern for quizalofop-p-ethyl and is within the use pattern of the cited precedent. Therefore, the risk is acceptable when Wynca Sun-Quiz Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Wynca Sun-Quiz Herbicide was compared to the formulation of the cited precedent product. The differences between the formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Wynca Sun-Quiz Herbicide label.

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 Sun-Quiz Herbicide.

References

PMRA Document Number.	Reference
3478231	2021, Color, physical state and odour, DACO: 3.5.1,3.5.2,3.5.3
3478234	2021, Density or specific gravity, DACO: 3.5.6
3478235	2021, pH, DACO: 3.5.7
3478236	2021, Oxidizing or reducing action, DACO: 3.5.8
3478237	2021, Viscosity, DACO: 3.5.9
3478238	2021, Storage stability, DACO: 3.5.10
3478239	2021, Flash point, DACO: 3.5.11
3478240	2021, Explodability, DACO: 3.5.12
3478241	2021, Miscibility, DACO: 3.5.13
3478242	2021, Corrosion characteristics, DACO: 3.5.14
3478243	2023, Dielectric breakdown voltage, DACO: 3.5.15
3478226	2023, Manufacturing process, DACO: 3.2.2 CBI
3478227	2023, COC of manufacturing process, DACO: 3.2.2 CBI
3478228	2023, Discussion of the formation of impurities of toxicological concern, DACO: 3.2.3
3497411	2021, Enforcement analytical method, DACO: 3.4.1
3603489	2021, Acute oral toxicity study of Quizalofop-P-ethyl 10% EC in rats, DACO 4.6.1
3603490	2021, Acute dermal irritation study of Quizalofop-P-ethyl 10% EC in rats, DACO 4.6.5