

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-2983
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy (PIIP)
Product: Wynca Sunphosate 5 Plus
Registration Number: 34529
Active ingredient (a.i.): Glyphosate present as potassium salt
PMRA Document Number : 3132638

Purpose of Application

The purpose of this application was to register Wynca Sunphosate 5 Plus, an end-use product containing Glyphosate present as potassium salt, for use in cropland systems and in non-cropland areas, based on a precedent.

Chemistry Assessment

Wynca Sunphosate 5 Plus is formulated as an emulsifiable concentrate containing glyphosate present as potassium salt at a concentration of 540 g/L. This end-use product has a density of 1.38 g/mL and pH of 4.88. The required chemistry data for Wynca Sunphosate 5 Plus have been provided, reviewed and found to be acceptable.

Health Assessments

Wynca Sunphosphate 5 Plus was considered toxicologically equivalent to the precedent product, therefore, no toxicology data were required. Wynca Sunphosphate 5 Plus is considered to be of low acute toxicity via the oral and dermal routes, of slight acute toxicity via the inhalation route of exposure, and moderately irritating to the eyes and skin, and is not considered to be a dermal sensitizer.

The use pattern of Wynca Sunphosate 5 Plus containing glyphosate, for applications to various cropland and non-cropland areas, fits within the registered use pattern of the precedent product as required for a PPIP submission. The potential exposure for mixers, loaders, applicators, and postapplication workers, is not expected to exceed the current exposure to the previously registered products of glyphosate. There are no health risks of concern for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for glyphosate were submitted to support the registration of Wynca Sunphosate 5 Plus, under the Protection of Proprietary Interests in Pesticides (PIIP) program (DIR2010-04).

The proposed target crops, timing and number of applications, application methods and rates, spray volumes, preharvest intervals, restricted-entry intervals, rotational crop

intervals, as well as any other use direction, restriction or limitation remained unchanged from the precedent end-use product.

In addition, the differences in formulation are not expected to impact the magnitude of glyphosate residues in/on treated crops.

Therefore, the dietary exposure to residues of glyphosate is not expected to increase over the currently registered uses. In addition, the established MRLs for residues of this active ingredient in/on food commodities are expected to adequately cover the level of residues resulting from the use of Wynca Sunphosate 5 Plus.

Environmental Assessment

The uses are within the currently registered use pattern of the active ingredient, glyphosate, and therefore, no additional risk is expected from the use of Wynca Sunphosate 5 Plus as proposed. The label was amended to include all of the required environmental precautions and hazards statements, including buffer zones, which adequately mitigates risks to the environment.

Value Assessment

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

The formulation of Wynca Sunphosate 5 Plus was compared to the formulations of the cited precedent product. The differences between the formulations were considered acceptable and unlikely to result in any significant impact on product performance, in terms of efficacy and crop tolerance. All uses and claims found on the precedent product label are supported for inclusion on the Wynca Sunphosate 5 Plus label.

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 Wynca Sunphosate 5 Plus.

References

PMRA Document Number	References
3007172	2019, Formualtion Process of Glyphosate 540 g/L SL present as its potassium salt, DACO: 3.2.2 CBI
3007173	2019, Discussion of formulation of impurities of toxicological concern, DACO: 3.2.3
3007174	2013, Enforcement Analytical Method, DACO: 3.4.1
3007176	2013, Appearance (Colour, Physical State and Odour) of Glyphosate Potassium

Salt SL, DACO: 3.5.1,3.5.2,3.5.3
3007177 2019, Formulation Type, DACO: 3.5.4
3007178 2019, Container Material and Description, DACO: 3.5.5
3007179 2013, Specific Gravity of Glyphosate Potassium Salt SL, DACO: 3.5.6
3007180 2013, pH of Glyphosate Potassium Salt SL, DACO: 3.5.7
3007181 2019, Oxidation/Reduction, DACO: 3.5.8
3007182 2013, Viscosity of Glyphosate Potassium Salt SL, DACO: 3.5.9
3007183 2013, Storage Stability of Glyphosate Potassium Salt SL, DACO: 3.5.10
3007184 2014, Flash Point of Glyphosate Potassium Salt SL, DACO: 3.5.11
3073520 2020, Updated formulation process 2019-2983, DACO: 3.2.2 CBI
3073521 2018, Corrosion characteristics of Wynca Sunphosate 5 Plus 2019-2983, DACO:
3.5.14

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