



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2018-0494
Application: Applications Subject to PPIP Policy – Equivalency/Data Compensation Assessment
Product: Peshui Herbicide
Registration Number: 33837
Active ingredients (a.i.): Pendimethalin
PMRA Document Number : 3024551

Purpose of Application

The purpose of this application was to register Peshui Herbicide based on a precedent under the Protection of Proprietary Interest in Pesticide Data Policy (PPIP).

Chemistry Assessment

Peshui Herbicide is formulated as a microcapsule suspension containing pendimethalin at a concentration of 455 g/L. This end-use product has a density of 1.1733 g/mL and pH of 9.53 (1% dilution). The required chemistry data for Peshui Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Peshui Herbicide is considered toxicologically equivalent to the precedent product. Consequently, no toxicological data were reviewed or are required.

The use of Peshui Herbicide on various crops is not expected to result in potential occupational or bystander exposure over the registered use of pendimethalin. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for pendimethalin were submitted to support the registration of Peshui Herbicide under the Protection of Proprietary Interests in Pesticide Data (PPIP) program. The use pattern on the Peshui Herbicide label (including the target crops, application rates, timing and number of applications, application methods, spray volumes, pre-harvest intervals, grazing and feeding restrictions, recropping intervals and proposed tank-mix partners) are the same or within the currently registered use pattern for pendimethalin. Therefore, residues in/on treated crops are not expected to increase and will be covered under the maximum residue limits (MRLs) established for pendimethalin. Consequently, the dietary exposure to residues of pendimethalin is not expected to increase with the registration of the end-use product and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The applications sites and rates for Peshui Herbicide are similar to those of the precedent product. Therefore, the registration of Peshui Herbicide does not present any concern from an environmental protection perspective.

Value Assessment

The availability of Peshui Herbicide would provide farmers with another option to manage annual grasses and broadleaf weeds early in the season in field corn, soybean, and several minor crops. Registration of generic products may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information consisting of data from field research trials was submitted. In the field trials, the pre-emergent application of Peshui Herbicide was directly compared to a precedent product. The trial data demonstrated that the performance, in terms of efficacy and crop tolerance, of Peshui Herbicide was agronomically equivalent to the precedent product. Therefore, all labeled uses and claims found on the precedent product label are supported for inclusion on the Peshui Herbicide label.

Conclusion

The PMRA has reviewed the information provided in support of Peshui Herbicide. Based on the results of this review, Peshui Herbicide is acceptable for registration.

References

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- 2846200 2017, Viscosity of Pendimethalin 455g/L CS, DACO: 3.5.9
- 2846201 2017, Flash Point of Pendimethalin 455g/L CS, DACO: 3.5.11,3.7
- 2846207 2017, Validation of Analytical Method for Determination of Active Content of Pendimethalin 455g/L CS, DACO: 3.4.1
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- 2846209 2017, Accelerated Storage Stability and Corrosion Characteristics of Pendimethalin 455g/L CS, DACO: 3.5.10,3.5.14
- 2846212 2017, Oxidation of Pendimethalin 455g/L CS, DACO: 3.5.8
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- 2846222 2017, Determination of Explosive Properties of Pendimethalin 455g/L CS, DACO: 3.5.12
- 2846224 2017, Process_Formulation_Pendimethalin_455_CS PM modified, DACO: 3.2.1,3.2.2,3.3.1 CBI
- 2991836 2019, Description of the process to manufacture Pendimethalin 455 g/L CS, DACO: 3.2.1,3.2.2
- 2846219 2016, Weed management in corn with Sharda herbicides applied pre-emergence I

- (Confidential), DACO: 10.2.3.3.
- 2846220 2016, Weed management in corn with Sharda herbicides applied pre-emergence II, DACO: 10.2.3.3.
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