Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3 and 2.4 Application

Application Number: 2016-2286
Application: New end-use product chemistry – Identity and proportion of formulants
Product: MPower Dicamba Herbicide
Registration Number: #####
Active ingredients (a.i.): Dicamba
PMRA Document Number: 2663708

Purpose of Application

The purpose of this application was to register a new commercial end use product, MPower Dicamba Herbicide (guarantee 480 g a.e./L dicamba present as dimethylamine salt), for control of certain annual broadleaved weeds in small grain cereals, field corn, reduced tillage (prior to seeding and reduced tillage fallow), pasture and rangeland grasses, crop-free land (summer fallow and stubble), red fescue, canary seed, seedling grasses grown for seed and forage and low bush blueberries.

Chemistry Assessment

MPower Dicamba Herbicide is formulated as a solution containing dicamba, present as dimethylamine salt, at a nominal concentration of 480 g/L. This end-use product has a density of 1.15 g/mL and pH of 7.8. The required chemistry data for MPower Dicamba Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

The end use product, MPower Dicamba Herbicide, is toxicologically equivalent to the precedent product. Subsequently, no toxicological data were reviewed or are required.

The use of the new end-use product MPower Dicamba Herbicide is not expected to result in potential occupational or bystander exposure over the registered uses of the active ingredient dicamba. Therefore, no health risks of concern are expected when workers follow label directions and wear the personal protective equipment as stated on the label.

No new residue data for dicamba were submitted to support the registration of MPower Dicamba Herbicide. The supported use pattern on the MPower Dicamba Herbicide label, including the target crops, application rates, timing and number of applications, spray volumes, preharvest intervals, and tank-mix partners, is the same as the registered use pattern on the label of a precedent product.

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The slight changes in the formulation ingredients of MPower Dicamba Herbicide are not expected to significantly impact the residues in/on treated commodities. Therefore, residues of dicamba in/on treated commodities are not expected to increase and will be covered under the maximum residue limits (MRLs) established for dicamba. Consequently, the dietary exposure to residues of dicamba is not expected to increase with the registration of the new 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

Given that the proposed use-pattern, application rates and environmental precautions (including spray buffer zones) are the same as the precedent product, Banvel Herbicide, the PMRA has no additional environmental concerns with the use of MPower Dicamba Herbicide.

Value Assessment

The availability of MPower Dicamba Herbicide would provide users with an alternative option to manage broadleaf weeds in an array of crops and use sites. Registration of a generic product may increase product competition in the marketplace, thereby potentially reducing purchasing costs of similar products.

The formulation of MPower Dicamba Herbicide was compared to the formulation of the cited precedent product. It was concluded that differences in the formulations were unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance. Therefore, all claims and uses registered on the cited precedent product label are supported for inclusion on the MPower Dicamba Herbicide 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 MPower Dicamba Herbicide for control of annual broadleaved weeds in listed crops.

References

PMRA Document Number	Reference
2652880	2015, Determination of Active Ingredient Content, Physical and Chemical Characteristics of DICAMBA SMA Salt 48% SL, DACO: 3.3.1,3.4.1,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2706783	2016, Container Material and Description Confirmation, DACO: 3.5.5 CBI
2706780	2016, DICAMBA DMA SALT 48% SL, DACO: 3.2.1 CBI
2652879	2016, MANUFACTURING PROCESS FLOW CHART, DACO: 3.2.1,3.2.2 CBI
2652878	2016, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2706779	2016, Starting material Response, DACO: 3.2.1 CBI

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