Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.2, 2.3, 2.4 Application

Application Number: 2018-0552
Application: New End-use Product (Product Chemistry) – Guarantee; Form of Technical Grade Active Ingredient; Identity of Formulants; Proportion of Formulants
Product: M1833 Premix Herbicide
Registration Number: 33502
Active ingredients (a.i.): Dicamba (present as monoethanolamine salt) and Glyphosate (present as ethanolamine salt)
PMRA Document Number: 3014586

Purpose of Application

The purpose of this application was to register the end-use product M1833 Premix Herbicide for control of annual and perennial grasses and broadleaf weeds in Roundup Ready 2 Xtend soybeans and Roundup Ready 2 corn.

Chemistry Assessment

M1833 Premix Herbicide is formulated as a solution containing glyphosate (present as the monoethanolamine salt) at a concentration of 317 g ae/L, and dicamba (present as the monoethanolamine salt) at a concentration of 159 g ae/L. This end-use product has a density of 1.279 g/mL and pH of 5.3. The required chemistry data for M1833 Premix Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

M1833 Premix Herbicide was of low acute toxicity in rats via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes, and slightly irritating to the skin, of rabbits. It was not a skin sensitizer in guinea pigs.

The use of M1833 Premix Herbicide on Roundup Ready 2 Xtend soybeans and Roundup Ready 2 corn is not expected to result in potential occupational or bystander exposure over the registered use of glyphosate and dicamba. 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 were submitted to support the registration of M1833 Premix Herbicide, which contains a new salt form of dicamba (monoethanolamine). The use directions for M1833 Premix Herbicide were compared to those for the precedent end-use product containing dicamba, present as the diglycolamine salt, and glyphosate, present as monoethanolamine salt.

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It was determined that the use directions including the crops; methods, timing, number, and rate of application(s); pre-harvest and grazing intervals; plant-back restrictions; and tank-mixes are identical to that of the precedent product.

Both M1833 Premix Herbicide and the precedent end-use product are solution formulations. Glyphosate is formulated as the monoethanolamine salt in the formulations of both end-use products; dicamba is formulated as a new salt form in M1833 Premix Herbicide (monoethanolamine). Given that the dicamba salt will dissociate in solution, the differences in salt form from the precedent end-use product will not be an issue from a dietary exposure perspective. Based on this assessment, exposure to residues of dicamba and glyphosate in/on commodities treated according to the approved use directions for M1833 Premix Herbicide should not increase and will be covered under the respective established maximum residues limits, MRLs (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php). As such, residues of dicamba and glyphosate in/on treated commodities will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses of M1833 Premix Herbicide are within the currently registered use pattern of the active ingredients glyphosate and dicamba. The new monoethanolamine salt form of dicamba is expected to dissociate in the environment, as do other registered salt forms of the active ingredient. No additional risk is expected from the use of M1833 Premix Herbicide as directed. The label, with required revisions, includes the necessary environmental precautions and statements, which are expected to adequately mitigate risks to the environment.

Value Assessment

M1833 Premix Herbicide, which is co-formulated with higher concentrations of active ingredients than a currently registered product, provides manufacturers and users an opportunity to manage the same acreage of weeds with less product, which in turn reduces the packaging and transportation costs.

Value information submitted for review consisted of efficacy and crop tolerance data from replicated field trials. This information demonstrated that the performance of M1833 Premix Herbicide was agronomically equivalent to that of a currently registered product, which is co-formulated with the same active ingredients but at lower concentrations. Therefore, the same uses and claims are supported for inclusion on the M1833 Premix 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 M1833 Premix Herbicide.

References

PMRA Document Number	Reference
2847983	2016, Chemical and Physical Properties, DACO: 3.1, 3.2, 3.3.1, 3.5 CBI
2874047	2018, Establishing Certified Limits, DACO: 3.3.1 CBI
2940252	2018, Clarification response, DACO: 0.8
2940253	2016, Enforcement Analytical Method, DACO: 3.4.1 CBI
2952861	2019, Methodology/Validation, DACO: 2.13.1 CBI
2847995	2018, Efficacy trial reports, DACO: 10.2.3 and 10.2.3.2(B)
2847998	2018, Trial reports - Field corn, DACO: 10.3.2(A)
2847999	2018, Trial reports - Soybeans, DACO: 10.3.2(A)
2847984	2016, MON 119151: Acute Oral Toxicity - Up and down procedure in rats, DACO: 4.2.1
2847987	2016, MON 119151: Primary Eye Irritation in Rabbits, DACO: 4.2.4
2847988	2016, MON 119151; Primary skin irritation in rabbits, DACO: 4.2.5
2982011	2016, MON 119151: Acute Dermal Toxicity in Rats, DACO: 4.6.2
2982012	2016, MON 119151: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2982013	2016, MON 119151: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.6.6

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