Health Canada Santé Canada

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

Application Number: 2018-0559
Application: New End-use Product (Product Chemistry) – Guarantee; Form of Technical Grade Active Ingredient; Identity of Formulants; Proportion of Formulants
Product: M1832 Herbicide
Registration Number: 33501
Active ingredient (a.i.): Dicamba (present as monoethanolamine salt)
PMRA Document Number: 3014589

Purpose of Application

The purpose of this application was to register the end use-product M1832 Herbicide for control of broadleaf weeds in Roundup Ready 2 Xtend soybeans, cereals, corn, reduced tillage (prior to seeding and reduced tillage fallow), pastures and rangeland grasses, crop-free land (summerfallow and stubble), red fescue, canary seed (*Phalaris canariensis*), seedling grasses grown for seed and forage, and lowbush blueberries.

Chemistry Assessment

M1832 Herbicide is formulated as a solution containing dicamba, present as the monoethanolamine salt, at a concentration of 474 g ae/L. This end-use product has a density of 1.264 g/mL and pH of 5.2 (1% solution). The required chemistry data for M1832 Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

M1832 Herbicide was of low acute toxicity in rats via the oral, dermal and inhalation routes of exposure. It was mildly irritating to the eyes and minimally irritating to the skin of rabbits. It was not a skin sensitizer in guinea pigs.

The use of M1832 Herbicide on soybeans, cereals, corn, reduced tillage (prior to seeding and reduced tillage fallow), pastures and rangeland grasses, crop-free land (summerfallow and stubble), red fescue, canary seed (*Phalaris canariensis*), seedling grasses grown for seed and forage, and lowbush blueberries is not expected to result in potential occupational or bystander exposure over the registered use of dicamba. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

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No residue data were submitted to support the registration of M1832 Herbicide, which contains a new salt form of dicamba (monoethanolamine). The use directions for M1832 Herbicide were compared to those for the precedent end-use product containing dicamba, present as the diglycolamine salt. It was determined that the use directions including the crops and non-crop sites; 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 M1832 Herbicide and the precedent end-use product are solution formulations. Dicamba is formulated as a new salt form in M1832 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 in/on commodities treated according to the approved use directions for M1832 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 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 new monoethanolamine salt form of dicamba is expected to dissociate rapidly in the environment to the acid form of dicamba, as do other registered salt forms of the active ingredient. The uses for M1832 Herbicide are within the currently registered use patterns of the active ingredient dicamba. No additional risk is expected from the use of this new end-use product as directed; however, buffer zones are required to protect sensitive terrestrial and aquatic habitats. The risks associated with the use of this product are acceptable when used according to the label directions.

Value Assessment

M1832 Herbicide, which is formulated with a higher concentration of the active ingredient 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 M1832 Herbicide was agronomically equivalent to that of a currently registered product, which is formulated with the same active ingredient but at a lower concentration. Therefore, the same uses and claims are supported for inclusion on the M1832 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 M1832 Herbicide.

References

PMRA Document Number	Reference
2849075	2016, Chemical and Physical Properties, DACO: 3.1,3.2,3.3.1,3.5 CBI
2940260	2016, Enforcement Analytical Method, DACO: 3.4.1 CBI
2952861	2019, Methodology/Validation, DACO: 2.13.1 CBI
2849087	2018, Efficacy trial reports, DACO: 10.2.3 and 10.2.3.2(B)
2849091	2018, Trial reports - Field corn, DACO: 10.3.2(A)
2849092	2018, Trial reports - Soybeans, DACO: 10.3.2(A)
2849076	2016, MON 119144: Acute Oral Toxicity - Up and down procedure in rats, DACO: 4.2.1
2849077	2016, MON 119144: Acute dermal toxicity in Rats, DACO: 4.2.2
2849078	2016, MON 119144: Acute Inhalation Toxicity in Rats, DACO: 4.2.3
2849079	2016, MON 119144: Primary Eye Irritation in Rabbits, DACO: 4.2.4
2849080	2016, MON 119144; Primary skin irritation in rabbits, DACO: 4.2.5
2982017	2016, MON 119144: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.2.6

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