Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.10 Application

Application Number: 2013-7125
Application: New end-use product chemistry-Guarantee, identity and proportion of formulants, new combination of technical grade active ingredients, tank mixes
Product: Zemax Herbicide
Registration Number: 31725
Active ingredients (a.i.): S-Metolachlor and R-Enantiomer and Mesotrione
PMRA Document Number: 2408917

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Zemax Herbicide (guarantee: 401 g/L s-metolachlor and r-enantiomer; and 40.1 g/L mesotrione) for use as a pre-mix for pre-emergent use on field corn, production seed corn and sweet corn as well as post-emergent use in field corn (up to 6-leaf stage) in Eastern Canada only.

These active ingredients are currently registered under Use Site Category 13 (Terrestrial Feed Crops) and Use Site Category #14 (Terrestrial Food Crops) for the control of various broadleaf weeds and grasses.

Chemistry Assessment

Zemax Herbicide is formulated as a suspension containing s-metolachlor and r-enantiomer at 401 g/L and mesotrione at 40.1 g/L. Zemax Herbicide also contains 1,2-benzisothiazolin-3-one as a preservative at 0.012%. This end-use product has a density of 1.095 g/mL and a pH of 4.5. The chemistry requirements for Zemax Herbicide are complete.

Health Assessments

Zemax Herbicide is of low acute oral, dermal and inhalation toxicity in rats. It was minimally irritating to the eyes and slightly irritating to the skin of rabbits. It did not cause dermal sensitization in guinea pigs.

Previously reviewed residue data were considered in the context of the current submission. As both active ingredients are currently registered for field corn, production seed corn and sweet corn at similar application rates and conditions, the registration of Zemax Herbicide will not result in an increase in dietary exposure to these active ingredients and will not pose risks of concern to any segment of the population, including infants, children, adults and seniors.

The use of the new end-use product Zemax Herbicide on field corn, seed corn and sweet corn is not expected to result in potential exposure above the current registered uses of s-metolachlor or mesotrione. No risks of concern were identified or are expected when workers follow the label directions and wear the personal protective equipment stated on the label.

Environmental Assessment

The environmental exposure resulting from the use of the new product, Zemax Herbicide, is not expected to exceed that from the currently registered uses of the two active ingredients. Thus, increased environmental risk is not expected compared to currently registered uses and products.

Value Assessment

Value information including bridging data from six combined efficacy and crop tolerance trials conducted in Ontario at five locations in 2013 were submitted for review. Efficacy and crop safety of Zemax Herbicide were directly compared to the tank mixture of Callisto 480SC + Dual II Magnum at the same a.i. rate per hectare in these trials.

The efficacy of Zemax Herbicide and the tank mixture of Callisto 480SC + Dual II Magnum at their respective labelled rates was visually assessed for control of a number of weed species. The trial results demonstrated that the level of control of these weeds with Zemax Herbicide was comparable to that with the tank mixture of Callisto 480SC + Dual II Magnum. Therefore, efficacy claims for the tank mixture of Callisto 480SC + Dual II Magnum and as well for each tank mixture component are supported for inclusion on the Zemax Herbicide label.

The crop safety (visually assessed as a percentage relative to an untreated check) following the pre-emergent application of Zemax Herbicide and the tank mixture of Callisto 480SC + Dual II Magnum at the labelled 1 x rate and the early post-emergent application of these treatments at the double rate were reported for five corn hybrids. Crop injury was not detectable for the pre-emergent application treatments. Moderate injury was observed for the early post-emergent application treatments at the early ratings, but the observed injury declined at the late ratings. Yield data confirmed that corn hybrids may exhibit a comparable degree of tolerance to Zemax Herbicide versus the tank mixture of Callisto 480SC + Dual II Magnum. Therefore, crops labelled for the tank mixture of Callisto 480SC + Dual II Magnum are supported for inclusion on the Zemax Herbicide label, including the pre-emergent application in field, seed, and sweet corn and the early post-emergent application in field corn.

The late post-emergent application of Zemax Herbicide is supported given that the requested late post-emergent application timing and rate for Zemax Herbicide is consistent with those labelled for each Callisto 480SC and Dual II Magnum.

The early season weed suppression with the pre-plant and pre-emergent applications of Zemax Herbicide at 2.5 L/ha and as well the late season weed suppression with the late post-emergent application of the same treatment are supported given that those claims are labelled or supported for Lumax EZ Herbicide (Reg. No. 30864; 298 g/L s-metolachlor + 112 g/L atrazine + 29.8 g/L mesotrione) at 3.35 L/ha. The rates of s-metolachlor and mesotrione that would be applied with Lumax EZ Herbicide for the early and late season weed suppression are the same as those which would be applied with Zemax Herbicide for similar efficacy claims.

Rotational crop tolerance claims for Lumax SE can be extrapolated to Zemax Herbicide because the maximum rates of mesotrione and s-metolachlor would be applied with Lumax SE Herbicide are the same with those which would be applied with Zemax Herbicide.

Registration of two active ingredients in a single formulation will be easily handled and applied by farmers compared to the registered tank mixture of Callisto 480SC + Dual II Magnum.

Based on the weight of evidence, the proposed registration of Zemax Herbicide for control of annual grass and broadleaf weeds in corn was supported from a value standpoint.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and determined that it is sufficient to support the registration of the new commercial end-use product, Zemax Herbicide.

References

PMRA Document Number	Reference
2377088	2011, Bridge A18263D 440ZC formulation at full rates to the Dual II Magnum 915EC + Callisto 480SC tank-mixture in addition to establishing a new foundation rate in conventional tillage corn - Pre (Efficacy) and epost (Tolerance), DACO: 10.2.3.2 and 10.3.2
2377009	2013, Identification- Zemax Herbicide- New EUP, DACO: 3.1.1, 3.1.3, 3.1.4 CBI
2377010	2013, Identification Plant- Zemax Herbicide- New EUP, DACO: 3.1.2 CBI
2377011	2013, Materials and Limits- Zemax Herbicide- New EUP, DACO: 3.2.1,3.3.1 CBI
2377012	2013, Manufacturing Process- Zemax Herbicide- New EUP, DACO: 3.2.2 CBI
2377013	2011, Analytical Method- Zemax Herbicide- New EUP, DACO: 3.4.1 CBI
2377014	2013, Characteristics- Zemax Herbicide- New EUP, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2377015	2013, Acute summary- ZEMAX Herbicide- New EUP, DACO: 4.1
2377016	2011, A18263D- Acute oral toxicity study in rats- Final report, DACO: 4.6.1
2377017	2011, A18263D- Acute dermal toxicity study in rats- Final report, DACO: 4.6.2
2377018	2011, A18263D- Acute inhalation toxicity study in rats- Final report, DACO: 4.6.3
2377019	2011, A18263D- Acute eye irritation study in rabbits- Final report, DACO: 4.6.4
2377020	2011, A18263D- Acute dermal irritation study in rabbits, DACO: 4.6.5
2377021	2011, A18263D- Skin sensitization study in guinea pigs- Final report, DACO: 4.6.6

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