Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2011-1579
Application: B.2.6 – New / Changes EP or MA Product Chemistry – New Combination of TGAIs
Product: ARY 0548-019 Herbicide
Registration Number: 30580
Active ingredients: Fluroxypyr (present as 1-methyl heptyl ester) [FLR] and Flucarbazone (present as flucarbazone-sodium) [FLS]
PMRA Document Number: 2192415

Background

All the proposed claims and uses for ARY 0548-019 Herbicide are based on the currently registered herbicides Everest 70WDG (PCP # 26447) containing 70% flucarbazone-sodium (66% flucarbazone) formulated as a water dispersible granule and Starane Herbicide (PCP # 24815) or Starane GBX Herbicide (PCP # 29670) containing 180 g ae/L of fluroxypyr (present as fluroxypyr 1-methylheptyl ester) formulated as an emulsifiable concentrate.

Purpose of Application

The purpose of this application was to register a new end-use product, ARY 0548-019 Herbicide, a suspension concentrate herbicide for the post-emergence control of wild oat, green foxtail, tame oat, volunteer flax, cleaver, kochia, volunteer canola, redroot pigweed, wild mustard, stinkweed, green smartweed, shepherd's purse and wild buckwheat and suppression of stork's bill in spring wheat and durum wheat for use in Alberta, Manitoba, Saskatchewan and the Peace River region of British Columbia.

ARY 0548-019 Herbicide is a co-formulation of two (2) active ingredients, flucarbazone (Reg. No. 26446), a Group 2 herbicide that belongs to the sulfonylanimocarbonyl-triazolinone class of chemistry and fluroxypyr (Reg. No. 24814), a pyridine carboxylic acid belonging to the herbicide mode of action Group 4. The proposed use rate for ARY 0548-019 is 95 to 155 g ai/ha equivalent to 15 to 25 g ai/ha of flucarbazone-sodium + 80 to 130 g ae/ha of fluroxypyr.

Chemistry Assessment

ARY 0548-019 Herbicide is formulated as a suspension containing flucarbazone (present as flucarbazone-sodium) and fluroxypyr (present as 1-methylheptyl ester) at 36.3 g/L and 200 g/L nominal, respectively. This end-use product has a density of 1.0985 – 1.1004 g/mL and pH of 7.0 – 9.0. The chemistry requirements for ARY 0548-019 Herbicide have been fulfilled.

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Health Assessments
ARY-0548-019 herbicide is of low acute oral (LD_{50} (♀) > 5000mg/kg bw), dermal (LD_{50} (♂/♀) > 5000 mg/kg bw and inhalation (LC_{50} (♂/♀) > 2.08 mg/L) toxicity in the rat. It is minimally irritating to the eye and mildly irritating to the skin of the rabbit. It is not a dermal sensitizer in the guinea pig.

No new residue data were submitted for the technical actives fluroxypyr and flucarbazone-sodium, or the safener cloquintocet-mexyl to support the registration of ARY-0548-019 Herbicide. Although the application rates for fluroxypyr and flucarbazone-sodium are within the respective registered rates for use on wheat, it is not known if the presence of the safener chloquintocet-mexyl in the ARY 0548-019 Herbicide formulation will increase the magnitude of fluroxypyr and flucarbazone-sodium residues in/on treated wheat commodities. As such, confirmatory bridging data will be required to verify that residues of fluroxypyr, flucarbazone-sodium and cloquintocet-mexyl remain covered by their respective MRL on wheat. Limited (2 trials each in Regions 5, 7 and 14) side-by-side confirmatory bridging trials on wheat are required in the representative wheat growing regions with fluroxypyr and flucarbazone co-formulated with and without the safener cloquintocet-mexyl and according to the approved ARY 0548-019 Herbicide use directions.

The use of ARY 0548-019 Herbicide should not result in an increase in occupational exposure over the registered use pattern of the two active ingredients for workers mixing, loading and applying the product, as well as re-entering treated areas post-application. No unacceptable risk is expected when workers follow all label directions and precautions, such as the listed personal protective equipment, the REI and all restrictions, including those found on the tank mix partner labels.

Environmental Assessment
The application rate for ARY 0548-019 herbicide results in active ingredients rate that is lower than the currently registered maximum use rates. Although the environmental exposure from use of ARY 0548-019 herbicide is not expected to increase, the environmental risk of this product with cloquintocet-mexyl as a safener cannot be determined and more data are required in order to characterize the potential risk to non-target organisms. Additional mitigation measures may be added on the product label, once the environmental assessment is complete.

Value Assessment
The value review considered that a similar product is registered in the United States (Raze Herbicide, EPA Reg. No. 66330-405) and also considered the efficacy and non-safety adverse effects of ARY 0548-019 Herbicide which were evaluated in 18 trials conducted in 2009 and 2010 in the United States (North Dakota (2 trials) and Washington (1 trial)) and in Canada (Manitoba (2 trials), Saskatchewan (7 trials) and Alberta (6 trials)). In all trials, the efficacy and crop safety of ARY 0548-019 Herbicide, alone or with the proposed tank mixes, was directly compared to that of the registered products Everest 70 WDG Herbicide and Starane Herbicide. In all trials, all products were applied post-emergence when spring wheat and durum wheat were at the 3-leaf stage to 5-leaf and 2 tillers. ARY 0548-019 was applied to durum wheat in 3 trials and to spring wheat in 15 trials. All ARY 0548-019 treatments included a non-ionic surfactant (NIS) at 0.25% v/v.

Weed control was reported for wild oat, tame oat, green foxtail, volunteer flax, volunteer canola, kochia, cleavers, wild mustard and wild buckwheat.

Based on the information and trial reports made available for review, the value of ARY 0548-019 Herbicide has been determined acceptable for all the proposed claims as listed on the proposed label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, ARY 0548-019 Herbicide, and has found the information sufficient to conditionally register this product.

References

PMRA Document Number	Reference
2039350	2011, Method Validation for Fluroxypyr and Flucarbazone-Sodium, DACO: 3.4, 3.4.1
2039354	2010, Non-confidential: ARY-0548-019 Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0, 3.1, 3.2, 3.2.1, 3.2.2, 3.2
2039355	2010, Confidential: ARY-0548-019 Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, and Certified Limits, DACO: 3.0, 3.1, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI
2039356	2010, Physical Properties of ARY-0548-019, DACO: 3.5,3.5.1,3.5.11,3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
2039358	2011, ARY 0548-019 Herbicide Trials, DACO: 10.1, 10.2.3
2039359	2010, ARY 0548-019: Acute Oral Toxicity Up And Down Procedure In Rats, DACO: 4.6.1
2039360	2010, ARY 0548-019: Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2
2039361	2010, ARY 0548-019: Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2039362	2010, ARY-0548-019: Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2039363	2010, ARY-0548-019: Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2039364	2010, ARY-0548-019: Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6
2039367	2011, ARY-0548-019 Herbicide Value Data to Support the registration of ARY-0548-019 Herbicide Applied as a Post-Emergence Treatment in Spring Wheat (including duram wheat), DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2(B), 10.2.3.3, 10.3, 10.3.1, 10.3.2, 10.5, 10.5.2
2039368	2011, ARY-0548-019 Herbicide comprehensive data summaries, DACO: 10.1, 12.5, 12.5.5, 12.7, 3.5, 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, 3.5.7, 3.5.8, 3.5.9, 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, 4.6.6, 5.1
2059286	2011, ARY-0548-019 Herbicide Chemistry requirements for the registration of manufacturing concentrates and end-use products formulated from registered technical grade of active ingredients or integrated system products, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4, 3.4.1, 3.4.2, 3.5, 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
2059288	2011, ARY-0548-019: Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
2117028	Clarification_Email, DACO 3.2
2077401	2011, Raw Data Files: ARY-0548-019 Herbicide Value Data to Support the Registration of ARY-0548-019 Herbicide Applied as a Post-Emergence Treatment in Spring Wheat (including duram wheat), DACO: 10.1,10.2.3,10.2.3.1

ISSN: 1911-8082