

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2011-5145

Application: B.2.6 (New combination of TGAIs)

Product: Optill **Registration Number:** 30756

Active ingredients (a.i.): Imazethapyr (IMP) and Saflufenacil (SFF)

PMRA Document Number: 2135829

Purpose of Application

The purpose of this application was to register the new end-use product Optill containing the registered active ingredients imazethapyr (50.2%) and saflufenacil (17.8%). Optill was proposed for the control of annual grass and broadleaf weeds in soybeans.

Chemistry Assessment

Optill is formulated as water dispersible granules containing saflufenacil at 17.8% and imazethapyr at 50.2%. The end-use product has a density between 0.46-0.56 g/mL and a pH between 3.0-4.5. The chemistry requirements for Optill are complete.

Health Assessments

Optill is of low acute toxicity to rats via the oral ($LD_{50} > 2000$ mg/kg bw), dermal ($LD_{50} > 2000$ mg/kg), and inhalation routes ($LC_{50} > 5.1$ mg/L). It is mildly irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The new agricultural end-use product Optill, containing the active ingredients saflufenacil and imazethapyr for the control of annual and broadleaf weeds in soybeans, can be supported from an occupational exposure perspective. Updated risk assessments were performed for commercial mixers, loaders and applicators, and there were no risks of concern identified. Post application exposure is expected to be minimal since the product is to be applied before planting and no risks of concern are identified. No unacceptable risk is expected when workers follow label directions and wear the personal protective equipment noted in the required label amendments.

No new residue data were submitted for imazethapyr and saflufenacil to support the registration of the new-end use product Optill. The application rates for each active on soybeans are within the registered rates, and the use restrictions are similar to those on the registered labels of imazethapyr and saflufenacil. Based on this assessment, dietary exposure to residues of imazethapyr and saflufenacil should not increase, and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.



Environmental Assessment

Optill is not expected to adversely affect the environment if used according to the recommended environmental instructions.

Value Assessment

The efficacy and non-safety adverse effects of Optill Herbicide were evaluated in 32 trials conducted in 2008, 2010 and 2011 in the Ontario and Québec. In all trials, Optill Herbicide was directly compared to the registered tank mix of Eragon Herbicide + Pursuit Herbicide + glyphosate + Merge and all products were applied at identical rates. In all trials, both treatments, Optill Herbicide + glyphosate + Merge and the tank mix of Eragon Herbicide + Pursuit Herbicide + glyphosate + Merge were applied surface pre-plant in soybean. Weed control was reported for redroot pigweed, common ragweed, shepherd's purse, lamb's quarters, Canada fleabane, prickly lettuce, broadleaf plantain, common chickweed, dandelion, large crabgrass, barnyard grass and giant foxtail.

The evaluation of data made available for review support the subject application to register a new end-use product, Optill herbicide to provide control or suppression of the grassy and broadleaf weeds listed on the label as a surface pre-plant application in soybean; therefore, the registration of Optill Herbicide was determined to be acceptable from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of Optill, a new end-use product containing the active ingredients imazethapyr and saflufenacil, for the control of annual grass and broadleaf weeds in soybeans.

References

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2119644	2011, Description of Formulations of Optill, DACO: 3.2.1,3.7 CBI
2119645	2007, GLP Validation of Analytical Method AFR0067/01 and Certification of
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	2,10.5.3

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