

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 Application

**Application Number:** 2015-7109  
**Application:** B.2.1: New Guarantee  
B.2.3: New Identity of Formulants  
B.2.4: New Proportion of Formulants  
B.2.5: New Formulation Type  
**Product:** Gallery SC Herbicide  
**Registration Number:** 32587  
**Active ingredients (a.i.):** Isoxaben  
**PMRA Document Number:** 2719534

### Purpose of Application

The purpose of this application was to register the end use product, Gallery SC Herbicide, containing isoxaben at 500 g/L for selective pre-emergent control of certain broadleaf weeds in conifer bare-root and container nursery stock for listed trees, shrubs and groundcovers grown for silviculture purposes, and containerized ornamentals grown in nurseries.

### Chemistry Assessment

Gallery SC Herbicide is formulated as a suspension containing isoxaben at a nominal concentration of 500.0 g/L. This end use product has a density 1.11 g/mL and pH of 7.7. The required chemistry data for Gallery SC Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

In rats, Gallery SC Herbicide in the rat is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is non-irritating to the rabbit eye and slightly irritating to the rabbit skin. The formulation causes an allergic reaction in guinea pigs.

The end-use product Gallery SC Herbicide, containing the active ingredient isoxaben in a suspension concentrate formulation, is an expansion of use for isoxaben. Updated quantitative exposure risk assessments have been conducted and the potential exposure to isoxaben from Gallery SC Herbicide for mixers/loaders/applicators and post-application re-entry workers is not expected to result in risks of concern.

## **Environmental Assessment**

The application rate, number of applications and application method for isoxaben in Gallery SC Herbicide are the same as other registered product containing this active ingredient. Environmental concerns have been mitigated through adequate statements on the product label.

The end-use product, Gallery SC Herbicide, contains the preservative 1,2-benzisothiazolin-3-one which contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP.

## **Value Assessment**

Value information, including data from four replicated field trials and use history information from five sources, demonstrated that the product performance, both efficacy and crop tolerance, of Gallery SC is agronomically equivalent to that of Gallery 75DF when applied in accordance with the label instructions.

## **Conclusion**

PMRA has reviewed information provided in support of the registration of Gallery SC. Based on this review the registration of Gallery SC is acceptable for registration.

## References

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