

# **Evaluation Report for Category L, Subcategory 1.2 Application**

**Application Number:** 2022-1716

**Application:** Submissions subject to Protection of Proprietary Interests in

Pesticide (PPIP) Data Policy – Equivalency/Data Compensation

**Product:** Start 25 WDG

**Registration Number:** 34969 **Active ingredient (a.i.):** Florasulam **PMRA Document Number:** 3467683

# **Purpose of Application**

The purpose of this application was to register Start 25 WDG, a commercial class end-use product for post-emergent control of labelled broadleaf weeds in spring wheat (including durum), spring barley, winter wheat, and oats, based on a registered precedent product.

### **Chemistry Assessment**

Start 25 WDG is formulated as wettable granules containing florasulam at a concentration of 25%. This end-use product has a density of 0.511-0.556 g/mL and pH of 4.6. The required chemistry data for Start 25 WDG have been provided, reviewed and found to be acceptable.

### **Health Assessments**

Start 25 WDG is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is considered to be a moderate eye irritant and is not considered to be a dermal sensitizer.

The registered use pattern of Start 25 WDG is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of florasulam. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for florasulam were submitted or were required to support the registration of Start 25 WDG. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Start 25 WDG label, including the uses, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent end-use product.



Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of florasulam is not expected to increase with the registration of Start 25 WDG and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The uses on the Start 25 WDG label are within the currently registered use pattern of florasulam. Therefore, no additional risk is expected when Start 25 WDG is used in accordance with the label, which includes statements to mitigate risks to the environment.

### Value Assessment

The availability of Start 25 WDG provides growers with an alternative option for the post-emergent control/suppression of annual broadleaf weeds, including cleavers, wild buckwheat, and chickweed in pre-seed application of spring wheat (including durum), spring barley, winter wheat, and oats. Registration of a generic product, such as Start 25 WDG, may increase competition in the market, which may result in a reduction in the purchasing cost of similar products, thus lowering growers' overall input cost.

The formulation of Start 25 WDG was compared to the formulation of the precedent product. It was concluded that the differences in formulations would be unlikely to result in any significant impact on product performance, in regards to efficacy and crop tolerance. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Start 25 WDG label.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Start 25 WDG.

# References

PMRA Document Number	Reference
3345728	2022, Manufacturing Process - Florasulam 250 WDG, DACO: 3.2.1,3.2.2, 3.2.3,3.3.1 CBI
3345729	2022, Physico-Chemical Properties of Florasulam 25% WDG, DACO: 3.5.11, 3.5.12,3.5.6,3.5.8
3345730	2022, Accelerated Storage Stability Test by Heating at 54±2°C of Florasulam 25% WDG, DACO: 3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3448046	2023, Manufacturing Process - Florasulam 250 WDG, DACO: 3.2.1,3.2.2, 3.2.3,3.3.1 CBI
3448047	2023, Additional Product Chemistry for Start 25 WDG – Revised, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.4,3.5.5,3.5.9

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