

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2021-6646  
**Application:** Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment  
**Product:** FBN Fluroxypyr 333 EC  
**Registration Number:** 35125  
**Active ingredient (a.i.):** Fluroxypyr (present as 1-methylheptyl ester)  
**PMRA Document Number:** 3453025

### Purpose of Application

The purpose of this application was to register a new end-use product, FBN Fluroxypyr 333 EC, for postemergent control of annual broadleaved weeds including cleavers and certain ALS-resistant broadleaved weeds such as kochia and suppression of hemp-nettle, common chickweed and wild buckwheat in spring wheat, durum wheat, winter wheat, spring barley, oats, rangeland, permanent pasture, rights-of-way, industrial and other non-crop areas of Canada, based on a registered precedent.

### Chemistry Assessment

FBN Fluroxypyr 333 EC is formulated as an emulsifiable concentrate containing fluroxypyr, present as 1-methylheptyl ester, at a concentration of 333 g/L. This end-use product has a density of 1.071 g/mL and pH of 5.07. The required chemistry data for FBN Fluroxypyr 333 EC have been provided, reviewed and found to be acceptable.

### Health Assessments

Fluroxypyr 333 EC is considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is non-irritating to the eyes and skin and it is not considered a dermal sensitizer.

The use pattern of FBN Fluroxypyr 333 EC is comparable to the registered use pattern of the precedent product. *Therefore, potential exposures for mixers, loaders, applicators, bystanders and postapplication workers are not expected to exceed the current exposures to the registered products containing this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.*

No new residue data for fluroxypyr (present as 1-methylheptyl ester) were submitted or are required to support the registration of FBN Fluroxypyr 333 EC. Previously reviewed residue data were re-assessed to support this application.

The use directions on the FBN Fluroxypyr 333 EC label, including the target crops, method (ground, aerial), rates and timing of application, preharvest intervals, grazing 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 fluroxypyr (present as 1-methylheptyl ester) is not expected to increase with the registration of the new end-use product FBN Fluroxypyr 333 EC and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The uses of FBN Fluroxypyr 333 EC are not expected to result in risks to the environment when used as directed on the label.

### **Value Assessment**

The availability of FBN Fluroxypyr 333 EC provides growers with an alternative option to manage broadleaf weeds in certain cereal crops, rangeland, permanent pasture and certain non-crop areas in Canada. Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of FBN Fluroxypyr 333 EC was compared to the formulation of a cited precedent product. It was concluded that differences in the formulations would be unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of FBN Fluroxypyr 333 EC.

## References

### PMRA

#### Document

Number	Reference
3303786	2021, FBN FLUROXYPYR 333 EC - Physical and Chemical Properties and Waiver Requests, DACO: 3.1.1,3.1.3,3.1.4,3.2.3,3.3.1,3.5.12,3.5.13,3.5.15,3.5.5
3303788	2021, Physico-chemical Properties of Fluroxypyr 333 EC, DACO: 3.4.1,3.5.1,3.5.10,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3303789	2021, Flash Point of Fluroxypyr 333 EC, DACO: 3.5.11 CBI
3303790	2021, Declaration of Formulation, DACO: 3.2.1 CBI
3303791	2021, Manufacturing process of fluroxypyr 333g/L EC, DACO: 3.2.1,3.2.2 CBI
3303805	2021, 45.5% Fluroxypyr MHE EC: Acute Dermal Toxicity Study in Wistar Rats, DACO: 4.6.2
3303806	2021, 45.5% Fluroxypyr MHE EC: Acute Inhalation Toxicity Study in Wistar Rats, DACO: 4.6.3
3303807	2021, 45.5% Fluroxypyr MHE EC: Acute Eye Irritation / Corrosion Study in New Zealand White Rabbits, DACO: 4.6.4
3303808	2021, 45.5% Fluroxypyr MHE EC: Acute Dermal Irritation / Corrosion Study in New Zealand White Rabbits, DACO: 4.6.5
3303809	2021, 45.5% Fluroxypyr MHE EC: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, DACO: 4.6.6

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