



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2021-5098  
**Application:** Submission subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) policy - Equivalency/Data Compensation Assessment  
**Product:** FBN 2,4-D Ester 700 EC  
**Registration Number:** 34857  
**Active ingredient (a.i.):** 2,4-D (present as low volatile esters)  
**PMRA Document Number :** 3401852

### Purpose of Application

The purpose of this application was to register a commercial end-use product, FBN 2,4-D Ester 700 EC, for the control of broadleaf weeds in various crops, pastures, and non-cropland, based on a registered precedent product.

### Chemistry Assessment

FBN 2,4-D Ester 700 EC is formulated as an emulsifiable concentrate containing 2,4-D at a concentration of 660 g/L, present as ethylhexyl ester. This end-use product has a density of 1.14 - 1.15 g/mL and pH of 3.56 - 4.30. The required chemistry data for FBN 2,4-D Ester 700 EC have been provided, reviewed and found to be acceptable.

### Health Assessments

FBN 2,4-D Ester 700 EC was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. FBN 2,4-D Ester 700 EC is considered to be of high acute toxicity via the oral route, and of low acute toxicity via the dermal and inhalation routes. FBN 2,4-D Ester 700 EC is considered to be minimally irritating to the eyes, moderately irritating to the skin, and a potential dermal sensitizer.

The use pattern of FBN 2,4-D Ester 700 EC is comparable to the registered use pattern of the precedent products. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered product of 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 2,4-D were submitted or are required to support the registration of FBN 2,4-D Ester 700 EC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the FBN 2,4-D Ester 700 EC label, including the target

crops and sites, method (ground or aerial), rates and timing of application, preharvest intervals and feeding restrictions, are comparable to those on the label of the precedent 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) and the General Maximum Residue Limit (GMRL). Consequently, dietary exposure to residues of 2,4-D is not expected to increase with the registration of FBN 2,4-D Ester 700 EC and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use of FBN 2,4-D Ester 700 EC will not pose any additional risks to the environment. The required environmental precautionary statements and spray buffer zones to mitigate risks to the environment are included in the proposed label. When used according to label directions, the environmental risks are acceptable for FBN 2,4-D Ester 700 EC.

### **Value Assessment**

Registration of a generic product may increase product competition, which may in turn reduce purchasing costs of similar products.

The formulation of FBN 2,4-D Ester 700 EC was compared to the formulations of the precedent products. The differences among the formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product labels are supported for inclusion on the FBN 2,4-D Ester 700 EC label.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of FBN 2,4-D Ester 700 EC.

### **References**

#### **PMRA**

#### **Document**

<b>Number</b>	<b>Reference</b>
3270833	2021, Data for FBN 2,4-D Ester 700 EC EP, DACO: 3.1.1,3.1.3,3.1.4,3.2.3,3.3.1,3.5.15,3.5.4,3.5.5
3270838	2021, Manufacturing Process of 2,4-D Ester 660g/L EC, DACO: 3.2.1,3.2.2 CBI
3270839	2021, Manufacturing Process 2,4-D 2-ethylhexyl ester 660g/L EC, DACO: 3.2.1,3.2.2 CBI
3270841	2021, Determination of Physical State of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.2
3270842	2021, Determination of Colour of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.1
3270843	2021, Determination of Odour of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.3

3270844	2021, Determination of Density and Specific Gravity of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.6
3270845	2021, Determination of pH of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.7
3270846	2021, Determination of Oxidizing/Reducing Properties of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.8
3270847	2021, Determination of Viscosity of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.9
3270848	2021, Determination of Accelerated Storage Stability of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.10
3270849	2021, Determination of Flash Point of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.11
3270850	2021, Determination of Explosive Properties of 2,4-D-ethylhexyl 660 g/L EC, DACO: 3.5.12
3270851	2021, Determination of Misibility of 2,4-D-ethylhexyl 660 g/L EC in Water and Organic Solvents, DACO: 3.5.13
3270852	2021, Determination of Corrosion Characteristics of 2,4-D-ethylhexyl 660 g/L EC with Packaging Material, DACO: 3.5.14
3270853	2021, Validation of Analytical Method for 2,4-D-2-ethylhexyl ester, DACO: 3.4.1
3270854	2021, Physico-chemical Properties of 2,4-D Ester 660 EC, DACO: 3.4.1,3.5.1,3.5.10,3.5.11,3.5.12,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3399257	2022, Manufacturing Process of 2,4-D Ester 660g/L EC, DACO: 3.2.1, 3.2.2 CBI
3399258	2022, Manufacturing Process 2,4-D 2-ethylhexyl ester 660g/L EC, DACO: 3.2.1, 3.2.2 CBI

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