



## Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4 Application

**Application Number:** 2021-3262  
**Application:** New EP Product Chemistry-Guarantee; Identity of Formulants;  
Proportion of Formulants  
**Product:** FLUOPYRAM 720 Seed Treatment  
**Registration Number:** 34651  
**Active ingredient (a.i.):** Fluopyram  
**PMRA Document Number:** 3392864

### Purpose of Application

The purpose of this application was to register FLUOPYRAM 720 Seed Treatment, a new seed treatment to control sudden death syndrome on soybeans, to suppress certain nematodes on soybeans, and to control blackleg on canola.

### Chemistry Assessment

FLUOPYRAM 720 Seed Treatment is formulated as a suspension containing fluopyram at a concentration of 720 g/L. This end-use product has a density of 1.24 – 1.28 g/mL and pH of 5.2 – 7.5 (1% solution). The required chemistry data for FLUOPYRAM 720 Seed Treatment have been provided, reviewed and found to be acceptable.

### Health Assessments

FLUOPYRAM 720 Seed Treatment was of low acute toxicity in rats by oral, dermal, and inhalation routes. In rabbits, FLUOPYRAM 720 Seed Treatment was found to be slightly irritating to the skin and non-irritating to the eye. FLUOPYRAM 720 Seed Treatment was found to not be a dermal sensitizer in pigs using the Buehler method.

The use of FLUOPYRAM 720 Seed Treatment is not expected to result in increased worker exposure when compared to the currently registered use of fluopyram. The mixer/loader/treater and planter exposure assessments on file are adequate to support the use of FLUOPYRAM 720 Seed Treatment on soybean and canola. No health risks of concern are expected, provided that workers wear the appropriate personal protective equipment and follow all label directions for use.

No new residue data for fluopyram on canola and soybeans were submitted, or are required to support the registration of FLUOPYRAM 720 Seed Treatment. The use directions on the FLUOPYRAM 720 Seed Treatment label, including the target crops, method (seed treatment), rates and timing of application, and crop rotation restrictions are comparable to the precedent end-use products.

Based on this assessment, residues are not expected to be greater than that for

the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of fluopyram is not expected to increase with the registration of FLUOPYRAM 720 Seed Treatment and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use pattern for Fluopyram 720 Seed Treatment is within the registered use pattern of fluopyram; therefore, no additional risk is expected from the use of FLUOPYRAM 720 Seed Treatment. The label includes all the required environmental precautions and directions for use information which adequately mitigate risks to the environment.

### **Value Assessment**

The extrapolation of claims from the labels of two cited precedent products to FLUOPYRAM 720 Seed Treatment was supported based on the results of bridging trials, which demonstrated that FLUOPYRAM 720 Seed Treatment will perform similarly to the two precedent products when applied at the same rate of active ingredient. The registration of FLUOPYRAM 720 Seed Treatment will provide soybean and canola growers with an alternative product for use to manage labelled diseases and nematodes.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of FLUOPYRAM 720 Seed Treatment.

### **References**

#### **PMRA**

#### **Document**

<b>Number</b>	<b>Reference</b>
3251577	2020, Fluopyram 720 ST: Group A - Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
3251578	2019, GLP Validation of Analytical Method AFR0158/01: Determination of Fluopyram (Reg No. 5203319) in FS formulations by HPLC, DACO: 3.4.1 CBI
3251579	2020, Determination of Physical/Chemical Properties of BAS 780 06 F: Accelerated Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.9
3251580	2020, BAS 780 06 F: Determination of Oxidation/Reduction, Chemical Incompatibility, DACO: 3.5.8
3251581	2019, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12
3251582	2021, Chemical and Physical Properties, DACO: 3.5.13,3.5.15,3.5.16

- 3382521 2022, Fluopyram 720 Seed Treatment / Chemistry Clarification Request  
DACO 3.2, DACO: 3.2.2 CBI
- 3251583 2020, BAS 780 06 F Acute oral toxicity study in rats, DACO: 4.6.1
- 3251588 2020, BAS 780 06 F Acute dermal toxicity study in rats, DACO: 4.6.2
- 3251584 2020, Acute inhalation toxicity study in Wistar Rats 4-Hour liquid aerosol exposure  
(nose only), DACO: 4.6.3
- 3251585 2020, BAS 780 06 F Acute eye irritation in rabbits, DACO: 4.6.4
- 3251586 2020, BAS 780 06 F Acute dermal irritation/corrosion in rabbits, DACO: 4.6.5
- 3251587 2020, BAS 780 06 F BUEHLER Test in guinea pigs, DACO: 4.6.6
- 3251592 2021, FLUOPYRAM 720 SEED TREATMENT for use in soybean for the control of  
*Fusarium virguliforme* the causal agent of Sudden Death Syndrome and suppression of  
nematodes and FLUOPYRAM 720 SEED TREATMENT for use in soybean for the  
control of *Fusarium virguliforme* the causal agent of Sudden Death Syndrome and  
suppression of nematodes, DACO:10.1,10.2.1,10.2.2,10.3,10.4, 10.5.1, 10.5.2, 10.5.3,  
10.5.4, 10.5.5
- 3251596 2021, Trial reports in support of the petition to register FLUOPYRAM 720 SEED  
TREATMENT as a fungicide seed treatment for use in canola, DACO: 10.2.3.3
- 3251597 2021, Trial reports in support of the petition to register FLUOPYRAM 720 SEED  
TREATMENT as a fungicide and nematicide seed treatment for use in soybean, DACO:  
10.2.3.3

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