

# Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4. B.2.6 Application

Application Number:	2008-0969
Application:	B.2.1 (New EP Product chemistry – Guarantee)
	B.2.3 (New EP Product chemistry – Identity of formulants)
	B.2.4 (New EP Product chemistry - Proportion of formulants)
	B.2.6 (New EP Product chemistry – New combination of TGAIs)
Product:	Broadband Herbicide
<b>Registration Number:</b>	29138
Active ingredients (a.i.):	Pinoxaden (PRN), Florasulam (FRA)
<b>PMRA Document Number:</b>	1722835

#### **Purpose of Application**

Syngenta has proposed a new end-use product, Broadband Herbicide, containing florasulam (Reg. No. 26888) and pinoxaden (Reg. No. 28149) for application at rates of 5 g a.i./ha and 60.3 g a.i./ha, respectively. These rates are the same as those currently registered for both active ingredients. Broadband Herbicide is to be used on spring wheat and barley for emergence control of annual grasses and broadleaf weeds in the prairie provinces and Peace River region of British Columbia.

#### **Chemistry Assessment**

Broadband Herbicide is formulated as an emulsifiable concentrate containing pinoxaden at a nominal concentration of 92.7 g/L and florasulam at a nominal concentration of 7.7 g/L. This end-use product has a density of 1.03 g/mL and pH range of 4 - 6. With the exception of the storage stability and corrosion characteristics studies that are currently in progress, the chemistry requirements for Broadband Herbicide are complete.

#### Health Assessments

Broadband Herbicide is of low toxicity via the oral (LD<sub>50</sub>: 3129 mg/kg bw), dermal (LD<sub>50</sub> > 3500 mg/kg bw), and inhalation (LC<sub>50</sub> > 2.61 mg/L) routes. It is moderately irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.



The proposed uses of the new end-use product, Broadband Herbicide, fall within the registered use pattern for the active ingredients. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

To support the registration of Broadband Herbicide containing two registered active ingredients pinoxaden and florasulam, bridging residue data on wheat and barley treated with Broadband Herbicide were submitted. The level of pinoxaden and florasulam residues was similar to the data previously submitted for the registered active ingredients. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## **Environmental Assessment**

The proposed new end-use product contains two registered active ingredients, florasulam and pinoxaden. The proposed use pattern and rate are the same as those for products registered for each active separately. Therefore, there is no increase in risk to the environment.

## Value Assessment

The value data package provided consisted of 88 trials which were conducted in 2005 (11 trials), 2006 (38 trials) and 2007 (39 trials) in Alberta, Saskatchewan and Manitoba. All trials used Randomized Complete Block Design with 4 replicates. Two formulations containing the active ingredients pinoxaden and florasulam were tested to support Broadband Herbicide. The data provided indicated the two formulations were agronomically equivalent, therefore, data from both formulations was used in the efficacy and crop tolerance assessment.

A total of eight field trials were submitted to demonstrate the value of a tank mix for the end-use product Broadband Herbicide with TILT 250E Fungicide. All of the trials were conducted in the summer of 2007 in either Alberta, Saskatchewan or Manitoba. The trials tested fungicidal efficacy against net blotch (*Pyrenophora teres*) on barley and Septoria leaf spot (*Septoria tritici*) on wheat. The results indicated that TILT 250E Fungicide efficacy was not negatively affected when applied in the proposed tank mix. Since antagonism was absent in a number of trials on two different diseases, it is reasonable to expect that the efficacy of TILT in suppressing/ controlling the other labelled diseases would be maintained. In regards to timing and rates of application, the use pattern for the proposed tank mix is compatible with the registered use pattern of TILT 250E Fungicide. From the fungicidal perspective, a tank mix of Broadband Herbicide with TILT 250E Fungicide at currently registered application rates on wheat and spring barley is supported as proposed with minor label changes.

The overall efficacy and crop tolerance of treatments testing Broadband Herbicide (i.e., tested alone or in tank-mix) was acceptable and was equivalent to currently registered herbicides containing pinoxaden and florasulam.

## Conclusion

The PMRA has evaluated all of the data submitted in support of this application and has determined that sufficient information is available to support full registration Broadband Herbicide. However, submission and review of the storage stability and corrosion characteristics studies will be required as conditions of full registration.

#### References

PMRA 1567031	2007, A15351A 100.4EC Herbicide: Identification, DACO: 3.1.1,3.1.3,3.1.4
PMRA 1567032	2007, A15351A 100.4EC Herbicide: Identification - Formulating Plant Name
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PMRA 1567033	2007, A15351A 100.4EC Herbicide: Starting Materials, DACO: 3.2.1 CBI
PMRA 1567034	2007, A15351A 100.4EC Herbicide: Manufacturing Process, DACO: 3.2.2
	CBI
PMRA 1567035	2007, A15351A 100.4EC Herbicide: Discussion of Formation of Impurities,
	DACO: 3.2.3 CBI
PMRA 1567036	2007, A15351A 100.4EC Herbicide: Certification of Limits, DACO: 3.3.1
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PMRA 1567037	2007, Analytical Method SF-229/1: Determination of ASF822, CGA185072,
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PMRA 1567038	2007, A15351A - Validation of Analytical Method SF-229/1, T001327-07,
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PMRA 1567039	2007, A15351A 100.4EC Herbicide: Chemical and Physical Properties,
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	3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9
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	DACO: 3.5.2,3.5.3,3.5.7,3.5.9 CBI
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PMRA 1567043	2007, A15351A - Flash Point, HT07/121, DACO: 3.5.11
PMRA 1567044	2007, A15351A - Explosive Properties, HT07/122, DACO: 3.5.12
PMRA 1567046	Pinoxaden/Florasulam EC (092.75/007.73) & S:CGA185072 (023.19)
	(A15351A) - Acute Oral Toxicity Study in Rats. Laboratory Report No.
	10848-07. Study report date: 18-July-2007. DACO 4.6.1.
PMRA 1567047	Pinoxaden/Florasulam EC (092.75/007.73) & S:CGA185072 (023.19)
	(A15351A) – Acute Dermal Toxicity Study in Rats. Laboratory Report No.
	10849-07. Study report date: 18-July-2007. DACO 4.6.2.
PMRA 1567048	Pinoxaden/Florasulam EC (092.75/007.73) & S:CGA185072 (023.19)
	(A15351A) – Acute Inhalation Toxicity Study in Rats. Laboratory Report No.
	10850-07. Study report date: 18-July-2007. DACO 4.6.3.
PMRA 1567049	Pinoxaden/Florasulam EC & S:CGA185072 (A15351A): Acute Eye Irritation
	Study in Rabbits (Final Report). Laboratory Report No. 9732-06. 24-April-
	2006. Syngenta Report No. T014055-05. DACO 4.6.4.
PMRA 1567050	Pinoxaden/Florasulam EC & S:CGA185072 (A15351A). Acute Dermal
	Irritation Study in Rabbits (Final Report). Laboratory Report No. 9733-06.

	24-April-2006. Syngenta Report No. T014055-05. DACO 4.6.5.	
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	Laboratory Report No. 10851-07. 24-April-2006. DACO 4.6.6.	
PMRA 1567091	2008, A15351A 100.4EC Herbicide –	
Value Summary, DACO: 10.1		
PMRA 1537092	2008, A15351A 100.4EC Herbicide - Trial Efficacy Bridging Summary,	
	DACO: 10.2.3.1	
PMRA 1567094	2008, A15351A 100.4EC Herbicide - Trial Efficacy Full Summary, DACO:	
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PMRA 1567096	2008, A15351A 100.4EC Herbicide - Efficacy Trial Data Table, DACO:	
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PMRA1567099	2008. A15351A 100.4EC Herbicide and TILT 250E Fungicide – Efficacy	
	Summary. 10pp. 10.2.1, 10.2.2, 10.2.3.1	
PMRA1567103	2007. A15351A 100.4EC Herbicide and TILT 250E Fungicide - Efficacy	
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PMRA 1567104	2008, A15351A 100.4EC Herbicide - Efficacy Trials - Weeds, DACO:	
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PMRA 1567106	2008, A15351A 100.4EC Herbicide - Crop Tolerance Trials, DACO: 10.2.3.3	
PMRA 1567107	2008, A15351A 100.4EC Herbicide - Crop Tolerance Bridging Summary,	
	DACO: 10.3.1	
PMRA 1567109	2008, A15351A 100.4EC Herbicide - Crop Tolerance Full Summary,	
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