

## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2011-3079  
**Application:** New end-use product – New combination of active ingredients  
**Product:** Pre-Pare Plus Herbicide  
**Registration Number:** 30663  
**Active ingredients (a.i.):** Flucarbazone (present as flucarbazone-sodium) and tribenuron-methyl  
**PMRA Document Number:** 2196777

### Purpose of Application

The purpose of this application was to register a new end-use product, Pre-Pare Plus Herbicide, containing flucarbazone (present as flucarbazone-sodium) and tribenuron-methyl, for preplant and preemergence use on spring wheat (excluding durum wheat) in Alberta, Manitoba, Saskatchewan and Peace River Region of British Columbia, to control grass and broadleaf weeds.

Pre-Pare Plus Herbicide is a pre-mix of Nuance Herbicide (Registration number 29468) and Everest 70 WDG (Registration number 26447).

### Chemistry Assessment

Pre-Pare Plus Herbicide is a wettable granule containing the active ingredients tribenuron-methyl and flucarbazone, present as flucarbazone-sodium, at nominal concentrations of 23.9% and 45.0%, respectively. This product has a density of 0.6075 g/mL. The product contains the allergens sulfites and milk. The chemistry requirements for Pre-Pare Plus Herbicide have been completed.

### Health Assessments

For the purpose of this application, no new data were submitted or required. Pre-Pare Plus Herbicide is considered to be toxicologically equivalent to the precedent products. Pre-Pare Plus Herbicide is of low acute toxicity in rats via oral ( $LD_{50} > 2000$  mg/kg), dermal ( $LD_{50} > 2000$  mg/kg) and inhalation ( $LC_{50} > 5.11$  mg/kg). It is minimally irritating to the eyes and mildly irritating to the skin of rabbits. Pre-Pare Plus Herbicide is not a dermal sensitizer.

The use on spring wheat should not result in an increase in potential occupational or bystander (re-entry) exposure over registered uses of flucarbazone and tribenuron-methyl since the application rate, number of applications, frequency of application and method of application are similar to currently registered products. No unacceptable risk is expected when workers follow the label direction and wear the personal protective equipment identified on the label.

No new residue data were submitted to support the registration of the new end-use product Pre-Pare Plus Herbicide, containing flucarbazone and tribenuron-methyl. As both active ingredients are currently registered for wheat at similar application rates and conditions, the registration of Pre-Pare Plus Herbicide will not result in an increase in dietary exposure to these active ingredients.

### **Environmental Assessment**

Pre-Pare Plus Herbicide consists of two registered active ingredients which are already registered in other end-use products for use on spring wheat at similar application rates and conditions within the same ecoregions. Therefore, it was concluded that Pre-Pare Plus Herbicide and its use will not change environmental exposure for either active ingredient. The buffer zone requirement on the label is adequate to mitigate environmental concerns.

### **Value Assessment**

Data from a total of 13 field trials conducted in Alberta, Montana, North Dakota, South Dakota, and Saskatchewan in 2008 and 2009 were submitted. The efficacy of Pre-Pare Plus Herbicide applied alone at 22.5 g a.i./ha (15 g a.i./ha flucarbazone + 7.5 g a.i./ha tribenuron-methyl) or in tank mix with Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Registration number 27487) at 450 g a.e./ha was evaluated for pre-emergence control of volunteer canola, shepherd's-purse, flixweed, narrow-leaved hawk's beard, and suppression of wild oats, dandelion, and volunteer flax.

Claims of control of volunteer canola, shepherd's-purse, and narrow-leaved hawk's beard and claims of suppression of wild oats and dandelion with a pre-plant or post-plant pre-emergence application of Pre-Pare Plus Herbicide at 22.5 g a.i./ha are supported based on the trial data and the cited precedent registrations.

Efficacy claims for Pre-Pare Plus Herbicide in tank mix with glyphosate are supported for the following reasons:

- The efficacy claims for Pre-Pare Plus Herbicide at 22.5 g a.i./ha (i.e. 15 g a.i./ha flucarbazone + 7.5 g a.i./ha tribenuron-methyl) in tank mix with glyphosate at 450 g a.e./ha are also registered for tribenuron methyl (e.g. Express Toss-N-Go; Registration number 27532) at 7.5 g a.i./ha in tank mix with glyphosate at 450 g a.e./ha.

- The tank mixtures of tribenuron-methyl (e.g. Express Toss-N-Go) + glyphosate, flucarbazone (e.g. Pre-Pare 70 WDG; Registration number 29500) + glyphosate, and flucarbazone (e.g. Everest 70 WDG; Registration number 26447) + tribenuron-methyl containing herbicides (e.g. Express Pack; Registration number 22335) are presently registered.

The tolerance of eight spring wheat varieties following a pre-plant application of Pre-Pare Plus Herbicide alone at the labeled rate of 22.5 g a.i./ha or in tank mix with glyphosate at 450 g a.e./ha and Pre-Pare Plus Herbicide alone at the exaggerated rate of 45 g a.i./ha or in tank mix with glyphosate at 900 g a.e./ha was assessed in ten trials. Slight crop injury or no injury was observed for these treatments. Yield data confirmed that spring wheat exhibited an adequate margin of crop safety to a pre-plant application of Pre-Pare Plus Herbicide applied in accordance with the label.

The tolerance of six spring wheat varieties following a post-plant pre-emergence application of the same herbicide treatments was reported in seven trials. Minor crop injury was observed for these treatments at the earliest rating but had disappeared by later ratings. Yield data confirmed that spring wheat exhibited an adequate margin of crop safety to a post-plant pre-emergence application of Pre-Pare Plus Herbicide applied in accordance with the label.

The rotational crop tolerance claims that are registered for Pre-Pare 70 WDG can be extrapolated to Pre-Pare Plus Herbicide because the rotational crop tolerance claims for Pre-Pare 70 WDG are more restrictive as compared to those of tribenuron-methyl containing herbicides, e.g. Express Toss-N-Go.

Based on the evidence made available, the registration of Pre-Pare Plus Herbicide applied alone or in a tank mix with glyphosate herbicide in accordance with the label is supported from a value standpoint.

## **Conclusion**

The PMRA has completed an assessment of available information for Pre-Pare Plus Herbicide and has found the information sufficient to support the registration of Pre-Pare Plus Herbicide.

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