

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.1, 3.10, 3.11, 3.12 Application

**Application Number:** 2014-3090  
**Application:** New EP Product Chemistry - Guarantee, Identify of Formulants, Proportion of Formulants, New Combination of TGAIs  
New Product Labels – Application Rate Increase or Decrease, Tank Mixes, New Pests, New Site or Host  
**Product:** BlackHawk Herbicide  
**Registration Number:** 32111  
**Active ingredients (a.i.):** 2,4-D (present as 2-ethylhexyl ester) and pyraflufen-ethyl  
**PMRA Document Number :** 2573596

### Purpose of Application

The purpose of this application was to register BlackHawk Herbicide containing a new combination of active ingredients 2,4-D (present as 2-ethylhexyl ester) and pyraflufen-ethyl, for use as a herbicide on terrestrial food and feed crops.

### Chemistry Assessment

BlackHawk Herbicide is formulated as an emusifiable concentrate containing pyraflufen-ethyl at 6.1 g/L and 2,4-D-ethylhexyl at 473 g/L. This end-use product has a density of 1.095 – 1.115 g/mL and a pH of 3.9. The chemistry requirements for this product have been fulfilled.

### Health Assessments

BlackHawk Herbicide is of high acute oral toxicity and low acute dermal and inhalation toxicity in rats. It is mildly irritating to the eyes and skin of rabbits. It is a dermal sensitizer in mice.

The use of the end-use product BlackHawk Herbicide on cereals, field corn, canary seed, soybean and summerfallow to control broadleaf weeds is not expected to result in potential occupational or bystander exposure over the exposure from the currently registered uses of 2,4-D.

For pyraflufen-ethyl, the uses did not fit within the currently registered use pattern. Therefore, updated cancer and non-cancer risk assessments for workers mixing, loading and applying the product were conducted as part of this review and resulted in no health risk of concern. For postapplication re-entry workers the exposure to both active ingredients is expected to be minimal based on the pre-emergent timing of application and therefore, quantitative risk assessments were not required.

No health risks of concern are expected from the use of the product, BlackHawk Herbicide, provided that workers wear the appropriate personal protective equipment and follow all label

directions.

Residue data for pyraflufen-ethyl from field trials conducted in Canada were submitted to support the use of BlackHawk Herbicide on pre-emergent cereals (wheat [spring, durum, winter], barley, oats, rye [spring and fall], and field corn), canary seed, soybeans and in summerfallow. Pyraflufen-ethyl was applied to the target crops at the approved rate and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on wheat (spring and winter), corn and soybeans were also reassessed in the framework of this petition. In addition, submitted processing studies in treated wheat, corn, barley, and soybeans were reviewed, and previously reviewed processing studies in corn, wheat and soybeans also reassessed to determine the potential for concentration of residues of pyraflufen-ethyl into processed commodities.

No new residue data for 2,4-D were required since this active ingredient is currently registered in Canada for ground or aerial applications, postemergence to weeds, preseeding, pre-emergence, or postemergence on wheat, barley, rye, corn and soybeans at equivalent or exaggerated rates and shorter preharvest intervals (PHIs). The uses on canary seed and summerfallow are non livestock feed/food uses; as such, residue trial data are not required.

#### Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for pyraflufen-ethyl was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover combined residues of pyraflufen-ethyl and the E-1 metabolite, expressed as pyraflufen-ethyl equivalents, in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Combined Residues of Pyraflufen-ethyl + the E-1 metabolite (ppm)		Experiment al Processing Factor	Currently Establishe d MRL (ppm)	Recommende d MRL (ppm)
			LAF T	HAF T			

<b>TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)</b>							
<b>Commodity</b>	<b>Application Method/ Total Application Rate (g a.i./ha)</b>	<b>PHI (days)</b>	<b>Combined Residues of Pyraflufen-ethyl + the E-1 metabolite (ppm)</b>		<b>Experiment al Processing Factor</b>	<b>Currently Establishe d MRL (ppm)</b>	<b>Recommende d MRL (ppm)</b>
Soybean Seed	Pre-emergent/8.6-9.3	129-133	<0.01	<0.01	No quantifiable residues observed when treated at exaggerated rates	0.01 in/on dry soybeans	0.01 in/on Crop Group 6 Legume Vegetables (Succulent or Dried) (except dry soybeans)
Podded Succulent Pea		50-61	<0.01	<0.01	Not applicable		
Shelled Succulent Pea		59-75	<0.01	<0.01			
Dried Pea		101-112	<0.01	<0.01			
Podded Succulent Bean		55-60	<0.01	<0.01			
Shelled Succulent Bean		70-81	<0.01	<0.01			
Dried Bean		89-112	<0.01	<0.01			
K+CWHR	Pre-emergent/8.6-9.4	82-94	<0.01	<0.01	No quantifiable residues observed when treated at exaggerated rates	0.01 in/on wheat and field corn	0.01 in/on Crop Group 15 (except rice, wild rice, wheat and field corn)
Field Corn Grain		135-164	<0.01	<0.01			
Wheat Grain		97-109	<0.01	<0.01			
Barley Grain		97-116	<0.01	<0.01			

LAFI = Lowest Average Field Trial; HAFI = Highest Average Field Trial

Based on this assessment, residues of pyraflufen-ethyl in edible livestock commodities will be covered by the established MRLs of 0.02 ppm in/on eggs, milk, and fat, meat and meat byproducts of cattle, goat, hogs, horses, poultry and sheep.

Maximum Residue Limits (MRLs) for residues of 2,4-D in/on treated cereals and soybeans will be covered by the established MRLs of 0.05 ppm in/on field corn, 0.02 ppm in/on dry soybeans. Residues in edible livestock commodities will be covered by the MRLs of 0.3 ppm in/on meat, fat and meat byproducts (except kidney) of cattle, goats, horses, sheep; 0.05 ppm in/on meat, fat and meat byproducts of hogs; 0.05 ppm in/on meat, fat and meat byproducts of poultry; 3 ppm in/on kidney of cattle, goats, horses, sheep; 0.01 ppm in/on eggs; and 0.03 ppm in/on milk. Residues of 2,4-D on registered crops for which an MRL is not established are covered under Part B, Division 15, subsection B.15.002(1) of the FDAR ( $\leq 0.1$  ppm ; i.e., barley, rye and wheat). Residues in these commodities resulting from the approved use will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of pyraflufen-ethyl and the E-1 metabolite, expressed as pyraflufen-ethyl equivalents. Residues in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The environmental assessment of BlackHawk Herbicide indicates that, due to a higher application rate, there is higher risk to non-target species which were identified at risk during the original review of the active ingredient pyraflufen-ethyl. These species include aquatic organisms, terrestrial plants and beneficial invertebrates. The mitigation measures in place, i.e., buffer zones and hazard statements are adequate for aquatic habitats, while terrestrial buffer zones will be increased to 2m. New label language and an updated buffer zone table are to be included on the label.

### **Value Assessment**

Value information submitted included data from six field trials conducted in the Prairie Provinces in 2012 and 2013 and scientific rationale. Efficacy of BlackHawk Herbicide was evaluated and as well compared to that of the tank mixture of Pyro Herbicide (pyraflufen-ethyl) and 2,4-D Ester in the field trials.

Data from field trials demonstrated that the efficacy of BlackHawk Herbicide was comparable to that of the tank mixture of Pyro Herbicide + 2,4-D Ester at similar a.i. rates for control of the broadleaf weeds. It can be concluded that the control of the weeds provided by pyraflufen-ethyl or 2,4-D Ester would not be reduced when they are applied as a pre-mixed product. Therefore, weeds listed for Pyro Herbicide or 2,4-D Ester are supported for inclusion on the BlackHawk Herbicide label.

Based on data from one efficacy trial and mode of action of pyraflufen-ethyl herbicide, a claim of mallow control is supported for labelling.

Crop tolerance to BlackHawk Herbicide is expected to be acceptable given that use pattern, rates, and crops listed for BlackHawk Herbicide are similar to those for Pyro Herbicide and 2,4-D Ester.

BlackHawk Herbicide is a pre-mix containing two active ingredients, pyraflufen-ethyl and 2,4-D Ester. The two modes of action (Group 14 and 4) provide an excellent weed control option as well as a useful tool for resistance management.

Based on the weight of evidence, the registration of BlackHawk Herbicide for control of the emerged broadleaf weeds in wheat, barley, oats, rye, field corn, canary seed, soybean, and summerfallow has value and can be supported.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of BlackHawk Herbicide.

## References

PMRA Document Number	References
2445409	2014, BlackHawk Herbicide: Product Identification and Selected Chemical and Physical Properties, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.5,3.5.12,3.5.13,3.5.15,3.5.4,3.5.5,3.5.8 CBI
2445411	2014, NUP-12130 Herbicide Physical and Chemical Characteristics, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI
2445412	2014, NUP-12130 Herbicide: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
2445410	2014, NUP-12130: Enforcement Analytical Method for the Determination of Pyraflufen-ethyl and 2,4-D 2-ethylhexyl by Gas Liquid Chromatography, DACO: 3.4.1 CBI
2445413	2014, BlackHawk Tox Summary_31JUL2014, DACO: 4.1
2445414	2014, NUP 12130 Herbicide: Acute Oral Toxicity UP and Down Procedure in Rats, DACO: 4.2.1,4.6.1
2445415	2014, NUP 12130 Herbicide: Acute Dermal Toxicity Study in Rats, DACO: 4.2.2,4.6.2
2445416	2014, NUP 12130 Herbicide: Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.2.3,4.6.3
2445417	2014, NUP 12130 Herbicide: Primary Eye Irritation Study in Rabbits, DACO: 4.2.4,4.6.4
2445418	2013, NUP 12130 Herbicide: Primary Skin Irritation Study in Rabbits, DACO: 4.2.5,4.6.5
2445419	2014, NUP 12130 Herbicide: Local Lymph Node Assay in Mice, DACO: 4.2.6,4.6.6
2445421	2014, Use Description Scenario for BlackHawk Herbicide (pyraflufen-ethyl, 2,4-

- D EHE), DACO: 5.2
- 2445860 2014, Magnitude of the Residue of Pyraflufen-ethyl and its Metabolite (E-1) in/on Legume Vegetables Raw Agricultural and Processed Commodities Following One Preemergence Application of Pyraflufen-ethyl 2.5% EC (2013), DACO 7.4.1, 7.4.5.
- 2445861 2014, Magnitude of the Residue of Pyraflufen-ethyl and its Metabolite (E- 1) in/on Cereal Grains Raw Agricultural and Processed Commodities Following One Preemergence Application of Pyraflufen-ethyl 2.5% EC (2013), DACO 7.4.1, 7.4.5.
- 2445862 2014, Magnitude of the Residue of Pyraflufen-ethyl and its Metabolite (E-1) in/on Canola Raw Agricultural and Processed Commodities Following One Preemergence Application of Pyraflufen-ethyl 2.5% EC (2013), DACO 7.4.1, 7.4.5.
- 2445863 2014, A Rationale Supporting a Request for Waiver from the Requirement of Additional Supervised Residue Trial Studies with Pyraflufen-ethyl for Selected Crops, DACO 7.8.
- 2445422 2014, A rationale based on trial data to support the use of BlackHawk Herbicide (pyraflufen-ethyl + 2,4-D ethyl-hexyl ester) for broadleaf weed control in a pre-seeding application, DACO: 10.2.2, 10.2.3.1, 10.2.3.3.

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