

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

**Application Number:** 2015-6227  
**Application:** New end use product; new combination of TGIAs  
**Product:** Nexicor Fungicide  
**Registration Number:** 32678  
**Active ingredients (a.i.):** Fluxapyroxad, pyraclostrobin, propiconazole  
**PMRA Document Number:** 2745173

### Purpose of Application

The purpose of this application was to register an end-use product with a new combination of active ingredients (30 g/L fluxapyroxad, 200 g/L pyraclostrobin and 125 g/L propiconazole) for use as a fungicide on cereals and canola.

### Chemistry Assessment

Nexicor Fungicide is formulated as an emulsifiable concentrate containing fluxapyroxad, pyraclostrobin, propiconazole at nominal concentrations of 30 g/L, 200 g/L and 125 g/L respectively. This end-use product has a density of 1.064 g/mL and pH of 5.0 – 7.0. All the required chemistry data for Nexicor Fungicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Nexicor Fungicide is of moderate acute oral toxicity, low acute dermal toxicity and slight acute inhalation toxicity. It is mildly irritating to the eyes and moderately irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

Use of Nexicor Fungicide, on wheat (all types), triticale, barley, rye, oats and canola are not expected to result in potential increase in occupational or bystander exposure over the registered uses of fluxapyroxad and propiconazole. An updated health risk assessment for pyraclostrobin was conducted for chemical handlers to support the revised personal protective equipment and engineering controls, and no health risks of concern were identified. However, additional personal protective equipment to mitigate acute health hazard concerns were required. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as recommended on the label.

Previously reviewed residue data from field trials conducted in/on cereals and canola were reassessed in the framework of this petition. In addition, processing studies in cereals and canola were reassessed to determine the potential for concentration of residues of fluxapyroxad, propiconazole and pyraclostrobin into processed commodities. No changes to

the maximum residue limits (MRLs) currently established for fluxapyroxad, propiconazole and pyraclostrobin in/on cereals and canola are required (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>). Exposure to residues of fluxapyroxad, propiconazole and pyraclostrobin in the diet as a result of this registration will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use pattern (application rates, number of applications and use areas) and the method of application of Nexicor Fungicide are lower in the cases of fluxapyroxad and propiconazole than the currently registered uses and fall within the registered rate range of pyraclostrobin. As such, no increase in environmental risk is expected. Environmental concerns are mitigated by label statements and required spray buffer zones.

### **Value Assessment**

Nexicor Fungicide is a mixture of fluxapyroxad, pyraclostrobin and propiconazole for use on cereals and canola for the management of certain foliar diseases. A combination of efficacy data and scientific rationales were provided in support of the registration of Nexicor Fungicide.

Most claims were supported based on the current registration of pyraclostrobin alone, since the co-formulation component rate for this active falls within the currently registered rate range on a precedent label. However, for some claims on the Nexicor Fungicide label, component rates of both propiconazole and fluxapyroxad had been significantly reduced from the currently registered solo rates. Based on the Fungicide Resistance Action Committee guidelines for succinate dehydrogenase inhibitors (SDHI), quinone outer inhibitors (QoI) and demethylation inhibitors (DMI) fungicides on cereals, it is recommended that effective component rates for each active should be maintained when applied in mixtures. While considering these guidelines, certain claims were supported based on at least one of the following reasons: (i) the co-formulation rate for at least two of the active ingredients currently appears on a precedent label, (ii) the pathogen is considered low-risk for developing resistance and (iii) efficacy data provided demonstrated that the actives were effective at the proposed co-formulation rate.

Nexicor Fungicide provides another option to manage diseases on cereals and canola with three modes of action.

### **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 Nexicor Fungicide for use on cereals and canola.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
2583226	2015, Group A - Product identity, composition and analysis of BAS 734 01 F EC (Nexicor), DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1 CBI
2583227	2015, Physical and chemical properties of BAS 734 00 F including low temperature stability (7 days at 0C) and accelerated storage stability (14 days at 54°C), DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.5, 3.5.6, 3.5.7, 3.5.9
2583228	2015, BAS 734 00 F - Determination of physico-chemical properties according to Directive 94/37/EC (Regulation (EC) No. 440/2008) (Including amendment no. 1), DACO: 3.5.11, 3.5.12
2583230	2015, BAS 734 01F: Determination of oxidation/reduction, DACO: 3.5.8
2583232	2015, Toxicology Summary, DACO: 4.6
2583233	2015, BAS 734 00 F - Acute oral toxicity study in rats, DACO: 4.6.1
2583234	2015, BAS 734 01 F Bridging of acute data from BAS 734 00 F, DACO: 4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6
2583235	2015, BAS 734 01 F Bridging of acute data from BAS 734 00 F, DACO: 4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6 CBI
2583236	2015, BAS 734 00 F - Acute dermal toxicity study in rats, DACO: 4.6.2
2583237	2015, BAS 734 00 F - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure (nose only), DACO: 4.6.3
2583238	2015, BAS 734 00 F - Acute eye irritation in rabbits, DACO: 4.6.4
2583239	2015, BAS 734 00 F - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
2583240	2015, BAS 734 00 F - Skin sensitisation: Local lymph node assay, DACO: 4.6.6
2583224	2015, Trial abstracts, DACO: 10.2.3.3(D)

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