Health Canada Santé Canada

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

**Application Number:** 2013-4753
**Application:** B.2.3 New / Changes EP or MA Product Chemistry-Identity of Formulants
B.2.4 New / Changes EP or MA Product Chemistry-Proportion of Formulants
B.2.6 New / Changes EP or MA Product Chemistry-New combination of TGAIs
**Product:** Vibrance Quattro
**Registration Number:** 31408
**Active ingredients (a.i.):** Difenoconazole [DFZ], Metalaxyl-M and S-isomer [MFN], Fludioxonil [FLD], Sedaxane [SDX] / Fungicides
**PMRA Document Number :** 2416172

## Purpose of Application

The purpose of this application was to register a new commercial end-use product, Vibrance Quattro, which is a premix formulation of registered active ingredients difenoconazole, metalaxyl-M and S-isomer, fludioxonil, and sedaxane, for use on cereals (Crop Group 15 including; wheat, barley, oats, rye and triticale) to control/suppress certain seed- and soil-borne diseases.

## Chemistry Assessment

Vibrance Quattro is a suspension containing the active ingredients difenoconazole, metalaxyl-M and S-isomer, sedaxane and fludioxonil at nominal concentrations of 36.8 g/L, 9.2 g/L, 15.4 g/L and 7.6 g/L, respectively. This product has a density of 1.06 g/mL and pH of 6.9. The chemistry requirements for Vibrance Quattro have been fulfilled.

## Health Assessments

Vibrance Quattro is of low acute toxicity to rats via the oral, dermal and inhalation routes. It is not irritating to the eye and minimally irritating to the skin of rabbits. Vibrance Quattro is a dermal sensitizer under the local lymph node assay study test conditions, with an $EC_3$ of 89%.

No new residue data were submitted to support the registration of Vibrance Quattro. As all active ingredients are currently registered for seed treatment use on barley, oats, rye, triticale, winter wheat, and spring wheat at similar application rates and conditions, the registration of Vibrance Quattro will not result in an increase in dietary exposure to these active ingredients and will not pose risks of concern to any segment of the population, including infants, children, adults and seniors.



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The worker exposure and risk from the commercial and on-farm seed treatment use of Vibrance Quattro were assessed. The use on barley, oats, rye, triticale, winter wheat, and spring wheat seed fits within the registered use pattern for difenoconazole, sedaxane, metalaxyl-M and fludioxonil, except for the on-farm use for fludioxonil. A quantitative risk assessment for this use was conducted, and no risks of concern were identified. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

**Environmental Assessment**

An environmental assessment of the use of Vibrance Quattro as a seed treatment on small grain cereals was performed. As the active ingredients, sedaxane, difenoconazole, metalaxyl-M, and fludioxonil in Vibrance Quattro were already registered for use as seed treatments for various, small cereal grains in equal or greater amounts than used in Vibrance Quattro, no increased environmental risk was expected. A review of the product label showed the environmental mitigation statements on the Vibrance Quattro label were consistent with the labels of other, relevant registered products.

**Value Assessment**

Two laboratory assays conducted in Alberta and Saskatchewan in 2013 were reviewed to support the proposed claim for the control of seed-borne *Fusarium* spp., specifically against virulent *F. graminearum* which is primarily responsible for the majority of *Fusarium* diseases in cereals in Canada. Vibrance Quattro significantly reduced the *Fusarium* infection by 58 – 76% compared to the non-treated control. Fludioxonil (in the end-use product Proseed Seed Treatment) applied in one assay at the registered rates also significantly reduced *Fusarium* disease by 63 – 76%. However, all other registered products failed to effectively reduce the *F. graminearum* infection in both trials, although most of them are currently registered for the control of multiple seed- or soil-borne fungi including *Fusarium* spp. and others. Since fludioxonil is registered for control of seedling disease caused by *F. graminearum* at rates of 2.5 – 5 g a.i./100 kg seed, it is reasonable to conclude that a low rate of fludioxonil (2.5 g a.i./100 kg seed) in Vibrance Quattro would not be able to provide an effective protection under high *F. graminearum* pressure.

A use history of the active ingredients related to Vibrance Quattro was also provided in the application. Vibrance Quattro provide a high level of broad-spectrum disease control with fungicides from four different chemical classes; therefore, may offer growers protection from crop losses caused by a complex of seed- and soil-borne diseases. The use of Vibrance Quattro would complement existing management practices by introducing two new fungicide seed treatment products to the market.

**Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of a new commercial end-use product, Vibrance Quattro, which is a premix formulation of registered active ingredients difenoconazole, metalaxyl-M and S-isomer, fludioxonil, and sedaxane, for use on cereals (Crop Group 15 including; wheat, barley, oats, rye and triticale) to control/suppress certain seed- and soil-borne

diseases.

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