



## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2020-2417  
**Application:** New End-use Product (Product Chemistry) - New combination of Technical Grade Active Ingredients  
**Product:** SPHAEREX  
**Registration Number:** 34263  
**Active ingredients (a.i.):** Metconazole, Prothioconazole  
**PMRA Document Number :** 3262151

### Purpose of Application

The purpose of this application is to register a new end-use product, SPHAEREX, for use on wheat (winter, spring, and durum), triticale, barley, rye and oats.

### Chemistry Assessment

SPHAEREX is formulated as an emulsifiable concentrate containing metconazole at a concentration of 112.5 g/L and prothioconazole at 187.5 g/L. This end-use product has a density of 1.031 g/ L and pH of 5.24. The required chemistry data for SPHAEREX have been provided, reviewed and found to be acceptable.

### Health Assessments

SPHAEREX is of low acute toxicity via the oral, dermal, and inhalation routes. It is moderately irritating to the eyes and skin. SPHAEREX is not a potential dermal sensitizer.

No new residue data for metconazole or prothioconazole in cereals were submitted to support the registration of these actives on the SPHAEREX label. Previously reviewed residue data from field trials conducted in/on wheat, barley, oats, and rye were reassessed in the framework of this petition. In addition, processing studies in treated wheat were also reassessed to determine the potential for concentration of residues of metconazole and prothioconazole into processed commodities. Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of metconazole and prothioconazole is not expected to increase with the registration of the new end-use product SPHAEREX and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

The use pattern on cereals for SPHAEREX fits within the registered use pattern of the active ingredients, metconazole and prothioconazole. As such, potential exposure to these active ingredients for mixers, loaders, applicators and postapplication workers is not expected to exceed that of the registered uses of these active ingredients. No health risks of concern are expected when workers wear the appropriate personal protective equipment and follow all label directions for use.

## Environmental Assessment

The registration of a new commercial class fungicide end-use product, SPHAEREX, for the control or suppression of labelled fungal diseases of cereals [wheat (spring, winter, and durum), barley, oats, rye and triticale] will not pose any additional risks to the environment. The required environmental precautions and hazards statements to mitigate risks to the environment are included in the proposed label. When used according to label directions, the environmental risks are acceptable for SPHAEREX.

## Value Assessment

Rationales and efficacy data from 32 trials conducted in Canada in 2018 – 2020 were submitted in support of the use claims on the SPHAEREX label. Efficacy of SPHAEREX on the target diseases demonstrated an acceptable level of disease control or suppression under adequate disease pressure for the diseases tested on wheat, barley and oats. A similar level of disease control can also be expected for uses against listed other diseases on wheat, barley and oats, and listed diseases on rye and triticale as stated in the rationales.

The supporting evidence confirmed the value of SPHAEREX for suppression of fusarium head blight, and for control or suppression of other foliar diseases on listed crops. The registration of SPHAEREX will provide Canadian growers with a new product to manage these important diseases on wheat, barley, oats, rye and triticale. All claims are supported as proposed or with modifications.

## 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 SPHAEREX.

## References

PMRA Document Number	Reference
3129455	2020, Determination of Physical/Chemical Properties of BAS 840 01 F Accelerated Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.1, 3.5.10, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.9
3129457	2020, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11, 3.5.12, 3.5.8
3129453	2020, BAS 840 01 F Group A - Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3129454	2020, Validation of Analytical Method AFR0136/02 and Certification of Active Ingredient Content in BAS 840 01 F, lot FD-200121-1046, DACO: 3.4.1

<b>PMRA Document Number</b>	<b>Reference</b>
3129459	2020, BAS 840 01 F Acute oral toxicity study in rats, DACO: 4.6.1
3129460	2020, BAS 840 01 F Acute dermal toxicity study in rats, DACO: 4.6.2
3129461	2020, BAS 840 01 F Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure (nose only), DACO: 4.6.3
3129462	2020, BAS 840 01 F Acute eye irritation in rabbits, DACO: 4.6.4
3129463	2020, BAS 840 01 F Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
3129464	2020, BAS 840 01 F BUEHLER Test in guinea pigs, DACO: 4.6.6
3129466	2020, DACO 10 - Value SPHAEREX (BAS 840 F Fungicide) for Use in Cereals, DACO: 10.1
3129469	2020, DACO 10 - Trial Reports - 2018, DACO: 10.2.3.3(D),10.3.2(B)
3129470	2020, DACO 10 - Trial Reports - 2019-2020, DACO: 10.2.3.3(D),10.3.2(B)

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