

Evaluation Report for Category B, Subcategory 2.4, 3.10, 3.11, 3.12 Application

Application Number:	2013-1930
Application:	B.2.4 – Change Chemistry – Proportion of Formulants
	B.3.10 – New Tank Mixes
	B.3.11 – New Pests
	B.3.12 - New Sites
Product:	Sombrero 600 FS
Registration Number:	30505
Active ingredients (a.i.):	Imidacloprid
PMRA Document Number	: 23475569

Purpose of Application

The purposes of this application were (1) to add three new pests (soybean aphid, bean leaf beetle, seedcorn maggot) to the Sombrero 600 FS label; (2) to add four new sites of use (wheat (durum, spring, winter), barley, oats and soybeans) and four tank mixes to the Sombrero 600 FS label based on the precedent product Alias SC (PCP # 28475) and (3) to change the formulation of the product Sombrero 600 FS.

Sombrero 600 FS is a systemic insecticide seed treatment currently registered for use on canola, mustard (condiment-type only), rapeseed and field corn.

Chemistry Assessment

Sombrero 600 FS is formulated as a suspension containing imidacloprid at a nominal concentration of 600 g/L. This end-use product has a density of 1.2345 g/mL and pH of 7.0-7.5. The chemistry requirements for this product are complete.

Health Assessments

The changes to the product label and specifications are not expected to impact the toxicological profile of Sombrero 600 FS.

No new residue data were submitted to support the amendments of the Sombrero 600 FS label to add new pests (soybean aphid, bean leaf beetle, seedcorn maggot), new crops (wheat (durum, spring, winter), barley, oats and soybeans) and new tank mixes. Based on previously submitted and reviewed field trial data, the requested label amendments will not have any impact on the expected magnitude of imidacloprid residues in/on wheat (durum, spring, winter), barley, oats, and dry soybeans.

Residues of imidacloprid will be covered by the currently established MRLs in/on cereals (CG 15) and dry soybeans of 0.05 ppm and 3.5 ppm, respectively. Therefore, the dietary exposure to cereals and soybeans treated with Sombrero 600 FS will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.



The use of Sombrero 600 FS to treat cereal and soybean seeds is not expected to result in an increase of exposure to treaters and planters compared to the exposure from the registered uses of imidacloprid (IMI). No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

The addition of wheat (durum, spring, winter), barley, oats and soybean to the Sombrero 600 FS label is at the same rate as the currently registered Alias 240 SC product. Therefore, this change falls within the current environmental risk assessment and is acceptable.

Value Assessment

Use of Sombrero 600 FS (600 g/L imidacloprid, Reg. no. 30505) on cereals (durum wheat, winter wheat, spring wheat, barley and oats) at the rate of 17-50 ml product (10-30 g a.i.)/100 kg seed for control of wireworm; and use on soybeans at the rate of 104-208 ml product (62.5-125 g a.i.)/100 kg seed for control of soybean aphid, bean leaf beetle, seedcorn maggot and wireworm is acceptable based on extrapolation from use of the precedent product Alias 240 SC.

Fungicide tank mixes proposed on barley, wheat, oats and soybean at the currently registered rates to control seed and seedling diseases, seed-borne pathogens, smuts and bunts were supported. Combining products allows the grower to control a broad spectrum of insect and fungal pests that attack cereal and soybean plants at the seedling stage and protects crop yield and quality resulting in an economic benefit to the grower.

Conclusion

The PMRA has reviewed the data provided in support of the subject application. Based on this review, the amendments to the product described above are acceptable.

References

<u>2333583</u>	2009, Physical and physic chemical properties and storage stability tests for seedoprid 600 FS uncolored (imidacloprid 600 g/l), DACO: 3.5.10, 3.5.14, CBI)	
2043175	2011, Value 10.1,10.2.2,10.2.3.1,10.3.1-2 Alias seed treatment, DACO:	
2043173	10.1,10.2.2,10.2.3.1,10.3.1	
2043176	2011, Imidacloprid durum wheat-gm, DACO: 10.2.3.1	
2043177	2011, Imidacloprid spring wheat-gm, DACO: 10.2.3.1	
2043178	2010, Evaluate the efficacy of MANA imidacloprid formulations for wheat seed	
	treatments versus standard of Admire 240 and determine any injury potential for these products., DACO: 10.2.3.3(D),10.3.2(B)	
2043179	2010, Evaluate the efficacy of MANA imidacloprid formulations for wheat seed	
2043179	treatments versus standard of Admire 240 and determine any injury potential for these products., DACO: 10.2.3.3(D),10.3.2(B)	
2043180	2011, Mana 2010-imidacloprid seed treatment for wheat, DACO: 10.2.3.3(D),10.3.2(B)	
-2-		

- 2043182 2011, (imidacloprid 240 g/L)/2010-imidacloprid-seed treatment for wheat, DACO: 10.2.3.3(D),10.3.2(B)
- 2043187 2011, (imidacloprid 240 g/L)/2010-imidacloprid-seed treatment for wheat, DACO: 10.2.3.3(D),10.3.2(B)
- 2043189 2011, (imidacloprid 240 g/L)/2010-imidacloprid-seed treatment for wheat, DACO: 10.2.3.3(D),10.3.2(B)

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.