



New or Changes to Product Labels-New Pests Evaluation Report for Category B, Subcategory 3.11Application

Application Number: 2015-4267
Application: B.3.11
Product: Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under
Registration Number: 25130
Active ingredients (a.i.): 9.1% imidacloprid
PMRA Document Number : 2607561

Background

Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under (Reg. No. 25130) is a spot-on domestic class product containing 9.1% imidacloprid. This product is registered for use against adult fleas on dogs, and is packaged in single doses adjusted for dogs in the specific labelled weight range. The entire dose is applied to the skin of the dog evenly in six to eight spots on the top of the back from the shoulder to the base of the tail. The product provides 4 weeks of flea control, but may be re-applied after one week if necessary.

Purpose of Application

The purpose of this application is to add the claim “for the treatment of lice infestations on dogs” to the label of Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under.

Chemistry Assessment

Not required.

Health Assessments

Not required.

Environmental Assessment

Not required.

Value Assessment

Four efficacy trials were submitted in support of the addition of lice to the Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under label. These trials were

conducted on dogs of various sizes that were infested with lice. The trials tested products which were formulated with either imidacloprid, imidacloprid and permethrin, or imidacloprid and moxidectin (an anti-helminthic drug). The tested application rates were equivalent to those which are currently registered for these products. The submitted studies demonstrated 99% to 100% control of lice until study termination at 35 or 36 days following the application of a single treatment to dogs naturally infested with *Trichodectes canis*.

The submitted information was sufficient to support the addition of the claim “for the treatment of lice infestations on dogs” to the label for Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under (Reg. No. 25130).

Conclusion

The addition of the claim “for the treatment of lice infestations on dogs” to the label for Advantage 10 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing 4.5 Kg & Under (Reg. No. 25130) was supported.

References

- 2558596 2015, VALUE ASSESSMENT of Advantage, Advantage II, K9 Advantix, and K9 Advantix II for Lice Control on Dogs, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2(C), 10.3, 10.3.1, 10.3.2, 10.4, 10.5, 10.5.1, 10.5.3

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.