

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2018-0435  
**Application:** Application subject to the Protection of Proprietary Interests in Pesticide Data Policy  
**Product:** Evergreen II Spot On for Extra Large Dogs  
**Registration Number:** 33738  
**Active ingredients (a.i.):** Imidacloprid, permethrin, and pyriproxyfen  
**PMRA Document Number:** 3047521

### Purpose of Application

The purpose of this application was to register a new spot-on insecticide/acaricide product to control flea, tick, lice, mosquito and stable flies on dogs weighing at least 25 kg, based on a precedent product.

### Chemistry Assessment

Evergreen II Spot On for Extra Large Dogs is formulated as a solution containing imidacloprid at 7.12%, permethrin at 35.6%, and pyriproxyfen at 0.36%. The end-use product has a density of 1.171 g/cm<sup>3</sup> and pH of 5.17. The required chemistry data for Evergreen II Spot On for Extra Large Dogs, have been provided, reviewed and found to be acceptable.

### Health Assessments

Evergreen II Spot On for Extra Large Dogs is of low acute toxicity via the oral, dermal, and inhalation routes. It is mildly irritating to the eye and minimally irritating to the skin, and is not considered to be a dermal sensitizer. Evergreen II Spot On for Extra Large Dogs is considered to be safe for use on dogs aged 12 weeks and older when applied according to the label directions.

The use of Evergreen II Spot On for Extra Large Dogs to control flea, tick, lice, mosquito and stable flies fits within the registered use pattern for imidacloprid, permethrin and pyriproxyfen. Therefore, risks from application and post-application (including children) exposure are not expected to exceed those from the precedent product when used according to label directions.

A food residue assessment was not required for this application.

### Environmental Assessment

An environmental assessment was not required for this application.

## **Value Assessment**

Data from trials and extrapolation from a precedent product supported the use of Evergreen II Spot On for Extra Large Dogs against fleas, ticks, lice, mosquitoes and stable flies on dogs weighing at least 25 kg and older than twelve weeks of age.

## **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 Evergreen II Spot On for Extra Large Dogs.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
2845381	2016, Storage Stability and Package Compatibility of RF2259 CDSO, DACO: 3.5.10
2845385	2018, DACO 3 Extras for Evergreen II Spot On, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.5.4, 3.5.5
2845394	2016, Group A Product Chemistry for Evergreen II Spot On for Dogs, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
2845395	2016, Analytical Method for Evergreen II Spot On for Dogs, DACO: 3.4.1, 3.4.2 CBI
2845396	2016, Summary of Group B Product Chemistry and Waivers for Evergreen II Spot On for Dogs, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7
2845397	2016, Physical and Chemical Characteristics for Evergreen II Spot On For Dogs, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.9, 3.7 CBI
3009634	2019, pH of RF2259 CDSO (Evergreen II Spot On for Dogs), DACO: 3.5.7
3023653	2019, Validation of a Chemical Analysis Procedure for the Assay of the Active Ingredients in RF2259 CDSO (Everygreen II Spot On for Dogs), DACO: 3.4.1
2945477	2018, Evergreen II Spot On for Dogs Acute Oral Toxicity (Udp) In Rats, DACO 4.6.1
2944078	2018, Evergreen II Spot On for Dogs Acute Dermal Toxicity In Rats, DACO 4.6.2
2945475	2018, Evergreen II Spot On for Dogs Acute Inhalation Toxicity In Rats, DACO 4.6.3
2944079	2018, Evergreen II Spot On for Dogs Acute Irritation In Rabbits, DACO 4.6.4
2944080	2018, Evergreen II Spot On for Dogs Acute Dermal Irritation In Rabbits, DACO 4.6.5
2944081	2018, Evergreen II Spot On for Dogs Skin Sensitization: Local Lymph Node Assay In Mice, DACO 4.6.6
2945476	2018, Companion Animal Safety Study in Beagle Dogs Evergreen II Spot On for Dogs, DACO 4.6.9
2947976	2016, Efficacy of Dermal Treatments Applied to Dogs against Cat Fleas ( <i>Ctenocephalides felis</i> ) and Brown Dog Ticks ( <i>Rhipicephalus sanguineus</i> ), DACO: 10.2.3.2(C)
2963153	2019, Efficacy Evaluation of Evergreen II Spot On for Dogs against Fleas and Ticks on Dogs, DACO: 10.2.3.2(C)

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