Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2019-5606
Application: New / Changes EP or MA Product Chemistry-Identity and Proportion of Formulants
Product: Nyguard IGR Concentrate
Registration Number: 25490
Active ingredient (a.i.): Pyriproxyfen
PMRA Document Number : 3109395

Purpose of Application

The purpose of this application was to amend the formulation of Nyguard IGR Concentrate.

Chemistry Assessment

Nyguard IGR Concentrate is formulated as an emulsifiable concentrate containing pyriproxyfen at a concentration of 10.00%. This end-use product has a density of 0.943 g/cm^3 and pH of 6.02. The required chemistry data for Nyguard IGR Concentrate have been provided, reviewed and found to be acceptable.

Health Assessments

NyGuard IGR Concentrate is of low toxicity via the oral, dermal, and inhalation routes, mildly irritating to the eyes and skin, and not a dermal sensitizer.

Occupational and exposure assessments were not required for this application.

Environmental Assessment

The risks associated with the formulation changes for NyGuard IGR Concentrate are acceptable from an environmental perspective when the product is used according to the label directions.

Value Assessment

The efficacy of the new formulation of Nyguard IGR Concentrate was supported based on extrapolation from the registered product. The new formula of Nyguard IGR Concentrate is expected to provide equivalent efficacy as the precedent formulation for the control of fleas indoors and modes of transport.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the registration of Nyguard IGR Concentrate for the formulation.

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References

PMRA Document Number	Reference
3038061	2019, Description of formulation process, DACO: 3.2,3.2.2 CBI.
3038063	2018, Product Chemistry of Nylar 10 EC, DACO: 3.4.1,3.4.2,3.5.1,3.5.11,3.5.12, 3.5.13,3.5.15,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI.
3038064	2018, Accelerated Storage Stability Evaluation of NYLAR 10 EC, DACO: 3.5.10,3.5.14 CBI
3157657	2001, Method Validation for (Ref-48) Nylar in Technical Material and Formulations by GLC-FID Packed Columns., DACO: 3.4.1
3157658	2003, Product Chemistry of NYLAR 10EC, DACO: 3.4.1
3157659	2019, APPENDIX 1 - Product Chemistry of NYLAR 10EC, DACO: 3.4.1
3157660	2020, Information regarding the Product Chemistry and Analytical Method Validation for Nylar 10EC (F-2482) (Nyguard) Revision 5, DACO: 3.4.1
3038067	2007, Acute Oral Toxicity Up and Down Procedure In Rats., DACO: 4.6.1
3038068	2007, Acute Dermal Toxicity Study in Rats- Limit Test., DACO: 4.6.2
3038069	2007, Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.6.3
3038070	2007, Primary Eye Irritation Study in Rabbits., DACO: 4.6.4
3038071	2007, Primary Skin Irritation Study in Rabbits., DACO: 4.6.5
3038072	2007, Dermal Sensitization Study in Guinea Pigs (Buehler Method)., DACO: 4.6.6
3038058	2019, DACO 10 VALUE, DACO: 10.1