Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.12 Application

Application Number: 2014-4413
Application: New EP Product Chemistry –Guarantee, Identity of Formulants, Proportion of Formulants, Formulation Type
New Product Labels-New Site
Product: Force 25CS Insecticide
Registration Number: 32084
Active ingredients (a.i.): tefluthrin
PMRA Document Number : 2577132

Purpose of Application

The purpose of this application was to register the end-use product, Force 25CS Insecticide containing the active ingredient tefluthrin as a microcapsule suspension, for the control of various insects in corn.

Chemistry Assessment

Force 25CS Insecticide is formulated as a microcapsule suspension containing tefluthrin at a nominal concentration of 250 g/L. This end-use product has a density of 1.06 g/mL and pH of 7.9. The chemistry requirements for this product have been fulfilled.

Health Assessments

Force 25CS Insecticide is highly acutely toxic via the oral route, of low acute toxicity via the dermal and inhalation routes, minimally irritating to the eyes, mildly irritating to the skin, and is a potential skin sensitizer.

No new residue data for tefluthrin were submitted to support the registration of Force 10CS Insecticide. Previously reviewed residue data from field trials conducted in/on field and sweet corn were reassessed in the framework of this petition. In addition, a processing study in treated field and sweet corn was also reassessed to determine the potential for concentration of residues of tefluthrin into processed commodities.

Maximum Residue Limit(s)

As the use pattern of Force 25CS Insecticide does not differ from the registered use pattern of Force 3.0G Insecticide, the current established tefluthrin maximum residue limit (MRL) of 0.06 ppm on field corn and sweet corn kernels plus cob with husks removed will be extended to popcorn grain.

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Residues of tefluthrin and the metabolite Ia, in corn commodities, at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The occupational exposure and risk from Force 25CS Insecticide were assessed. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

The maximum application rate of 147.5 g a.i./ha per year is equivalent to the maximum registered rate of 150 g a.i./ha per year. The uses and methods of application are identical to the registered uses of the precedent product. Therefore, no additional environmental risk is anticipated and no additional environmental data are required.

The formulation contains Proxel GXL as a preservative at 0.017% w/w, which is a TSMP Track 1 substance. The required label statement is present on the label.

Value Assessment

Six trials were provided to demonstrate the agronomic equivalence of two formulations of tefluthrin, a granular and a microcapsule suspension version, when applied as surface band or in-furrow application. The data provided from five trials conducted in major corn producing regions of the US and one trial conducted in Southern Ontario were sufficient to establish agronomic equivalence between the two formulations.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Force 25CS Insecticide, and has found the information sufficient to register this new end-use product.

References

PMRA Document Number	Reference
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2461836	2014, Starting Materials and Certification of Limits, DACO: 3.2.1,3.3.1 CBI
2461839	2014, Description of Formulation Process, DACO: 3.2.2 CBI
2461840	2014, Analytical Methodology, DACO: 3.4.1 CBI
2461841	2014, Impurities of Human Health and Environmental Concern, DACO: 3.4.2 CBI
2461842	2014, Chemical and Physical Properties, DACO: 3.5,3.5.1,3.5.10,3.5.11,3.5.12, 3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2504367	2015, Description of Formulation Process - Encapsulation, DACO: 3.2.2 CBI

2516519	2012, Enforcement Analytical Method - Certificate of Analysis, DACO: 3.4.1 CBI
2461844	2005, Acute Oral Toxicity Up And Down Procedure in Rats with Tefluthrin CS (250) (A14974A), DACO: 4.6.1
2461845	2005, Acute Dermal Toxicity Study in Rats with Tefluthrin CS (250) (A14974A), DACO: 4.6.2
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2461848	2005, Primary Skin Irritation Study in Rabbits with Tefluthrin CS (250) (A14974A), DACO: 4.6.5
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2461946	2014, Efficacy Summary Table, DACO: 10.2.3.1

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