

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.11, and 3.13 Application

Application Number: 2008-4767
Application: New / Changes Product Chemistry - Guarantee, Identity and Proportion of Formulants
New or Changes to Product Labels-New Pests and Precautions
Product: Enstar EW
Registration Number: 29661
Active ingredients (a.i.): Kinoprene (KPR)
PMRA Document Number : 1896427

Purpose of Application

The purpose of this application was to register a new end-use product, Enstar EW, based on the precedent product Enstar II Insect Growth Regulator (Reg. No. 25576), containing 65% of the technical grade active ingredient, kinoprene. Enstar EW is for use on use-site category 6, greenhouse non-food crops.

Chemistry Assessment

Enstar EW is formulated as an emulsifiable concentrate containing kinoprene at a nominal concentration of 18.42%. This end-use product has a density of 1.016 g/mL and pH of 6.60. With the exception of the storage stability study which is expected to be completed in October 2010, the chemistry requirements for Enstar EW are complete.

Health Assessments

Enstar EW is considered to be of low toxicity to rats via the oral ($LD_{50} = 2661$ mg/kg bw), the dermal ($LD_{50} > 5000$ mg/kg bw) and inhalation routes ($LC_{50} > 2.05$ mg/L). It is minimally irritating to the eye and skin of rabbits. It is not considered to be a dermal sensitizer in guinea pigs.

A risk assessment was not performed for Enstar EW because the proposed use pattern fits within the existing use profile for kinoprene. Exposure to the mixer/loader/applicator as well as the post-applicator is not expected to exceed the current exposure from the registered product.

Environmental Assessment

As the application rates of Enstar EW are equal to the current registered rates, no additional environmental risk is expected from the use of this product. Therefore, additional environmental data were not required to support the registration of Enstar EW. Environmental concerns are mitigated via label statements.

Value Assessment

Data on aphids and whiteflies demonstrated that when Enstar EW was applied to greenhouse ornamentals, it was biologically equivalent to a similar kinoprene product. One trial on mealybugs showed that kinoprene applied at 45 g ai/100 L water maintained the level of mealybugs in the treated plots while the population in the untreated control increased. The data demonstrated suppression of mealybugs.

Conclusion

The PMRA has conducted a review of the available information and can support full registration of the new end-use product, Enstar EW.

References

A. List of Studies/Information Submitted by Registrant

Chemistry Assessment

| PMRA No. | Title |
|-----------------|---|
| 1660856 | 2008, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 |
| 1660857 | 2008, RF 2067 Description of Materials and Formulation Process, DACO: 3.2.1,3.2.2 CBI |
| 1660858 | 2008, Validation of Chemical Analysis Procedure to Quantitatively Analyze S-Kinoprene in RF2067 EW and in Technical Material, DACO: 3.4.1 CBI |
| 1660860 | 2008, Color, Odor, Physical State, pH, Density and Viscosity of RF2067EW, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 |
| 1660861 | 2008, Physical and Chemical Properties, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.4,3.5.5,3.5.8 |
| 1730238 | 2009, RF 2067 Description of Material and Formulation Process, DACO: 3.2.1,3.2.2 CBI |

Health Assessment

| PMRA No. | Title |
|-----------------|---|
| 1660862 | 2008, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1 |
| 1660863 | 2008, Acute Dermal Toxicity in Rats - Limit Test, DACO: 4.6.2 |
| 1660864 | 2008, Acute Inhalation Toxicity in Rats - Limit Test, DACO: 4.6.3 |
| 1660865 | 2008, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4 |
| 1660866 | 2008, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5 |
| 1660868 | 2008, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6 |

Value Assessment

| PMRA No. | Title |
|-----------------|--|
| 1660851 | 2008, Summary Efficacy Trials and Adverse Effects, DACO: 10.2.3.1,10.3.1,10.3.2 |
| 1660853 | 2008, Efficacy of Alternate Formulations of s-Kinoprene Against Green Peach Aphid, DACO: 10.2.3.3(C) |
| 1660854 | 2007, Efficacy of Alternate Formulations of s-Kinoprene Against the Silver Leaf Whitefly, DACO: 10.2.3.3(C) |
| 1660855 | 2008, Efficacy of Alternate Formulations of s-Kinoprene Against the Citrus Mealybug, DACO: 10.2.3.3(C) |
| 1660861 | 2008, Physical and Chemical Properties, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.4,3.5.5,3.5.8 |
| 1677029 | 2008, Enstar EW Insect Growth Regulator New Category B Application Guarantee B2.1, New formulation B2.3, Value Summary, DACO: 10.1 |
| 1677030 | 2008, Enstar EW Insect Growth Regulator New Category B Application Guarantee B2.1, New formulation B2.3, Description of Pest Problem, DACO: 10.2.2 |

B. Additional Information Considered

Published Information

Health Assessment

U.S.EPA, 1996, Re-Registration Eligibility Decision: S-Kinoprene, EPA 738-R-96-030

ISSN: 1911-8082

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