Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.5, 3.11, 3.4 Application

Application Number: 2013-3747
Application: Product Chemistry – Identify of Formulants
Product Chemistry – Proportion of Formulants
Product Chemistry – Formulation Type
Product Labels – New Pests
Product Labels – Application Method
Product: Fruitone L
Registration Number: 31460
Active ingredients (a.i.): 1-naphthaleneacetic acid
PMRA Document Number: **2408876**

Purpose of Application

The purpose of this application was to register a new plant growth regulator, Fruitone L, containing 1-naphthaleneacetic acid (3.1% a.i., present as sodium salt; formulated as a solution), based on the precedent end-use product Fruitone N (Registration No. 14630; 3.1% a.i., formulated as a solid), for use to control pre-harvest drop of apples and for thinning of ornamental crabapples.

Chemistry Assessment

Fruitone L is formulated as a solution containing 1-naphthaleneacetic acid at a nominal concentration of 3.1%, present as sodium salt. This end-use product has a density of 1.00 – 1.02 g/cm^3 and pH of 8.5 – 10.5. The chemistry requirements for Fruitone L have been fulfilled.

Health Assessments

Fruitone L is of moderate toxicity to rats via the oral route ($LD_{50♀}$ = 933 mg/kg bw) and of low toxicity to rabbits via the dermal route ($LD_{50♂♀}$> 2000 mg/kg bw). It is moderately toxic to rats via inhalation route ($LC_{50♂♀}$> 0.45 mg/L [maximum attainable concentration]). It is minimally irritating to the eye and it is non-irritating to skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use of Fruitone L on apples and ornamental crabapples as a plant growth regulator for thinning, return bloom and to control pre-harvest drop is not expected to result in potential occupational or bystander exposure over the registered use of 1-naphthaleeacetic acid. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

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No new residue data were submitted to support Fruitone L. Given that Fruitone L is applied to commercial apples for fruit thinning, control of pre-harvest drop and return to bloom activities, and as the application rates are the same or reduced with no changes to the timing of application with respect to the registered uses of 1-naphthaleneacetic acid, the new end-use product is not anticipated to have an impact on the magnitude of the residues in the registered crop. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The maximum target rate of 20 ppm for two applications per season is consistent with the rate for the registered product Fruitone N. Hence, additional environmental risks are not anticipated with the use of Fruitone L. Furthernore, no additional data are required at this time for products containing naphthalene acetates according to the Re-Evaluation Decision RVD2009-06 - *Naphthalene Acetates*.

Value Assessment

Value information consisting of data, rationales and history of use were submitted for review. The PMRA can support the registration of Fruitone L, based in part on the precedent product Fruitone N, and data bridging the formulations to one another. The Directions For Use for Fruitone L can be supported based on the precedent label of Fruitone N and the rationales and use history information provided by the applicant.

The registration of Fruitone L will provide apple growers with a more user-friendly end-use product, with up-to-date directions for use and a more flexible rate structure.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of the plant growth regulator, Fruitone L, containing 1-naphthaleneacetic acid, for use to control pre-harvest drop of apples and for thinning of ornamental crabapples.

References

PMRA Document Number	References
2325034	2012, Product Identity and Composition of 3.5% Aqueous Sodium NAA Formulation, DACO: 3.1 CBI
2325036	2012, formulation Process for 3.5% Aqueous Sodium NAA Formulation, DACO: 3.2.2 CBI
2325040	1986, 1-Naphthalene Acetic Acid Sodium Salt, DACO: 3.4.1,3.4.2 CBI
2376965	2012, Formulation Process for 3.5% Aqueous Sodium NAA, DACO: 3.2.2 CBI
2325032	2002, Potassium 1-Naphthaleneacetate+ 6.25%LC Storage Stability and Corrosion Characteristics, DACO: 2.14.14 CBI
2325033	2008, UV/visible Absorption of 1-Naphthaleneacetic Acid and its Codium, Potassium, Ammonium Salts, DACO: 2.14.12 CBI
2325035	2012, Materials Used for Production of 3.5% Aqueous Sodium NAA Formulation, DACO: 2.11.1,2.11.2,2.11.3 CBI
2325037	2012, Formation of Impurities: 3.5% Aqueous Sodium NAA Formulation, DACO: 2.11.4 CBI
2325038	2012, Certified Limits for 3.5% Aqueous Sodium NAA Formulation, DACO: 2.12.1 CBI
2325039	2012, Physical Chemical Properties for 3.5% Aqueous Sodium NAA Formulation, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2325028	1982, NAA (Naphthalene Acetic Acid) Sodium Salt Acute Toxicity and Irritancy Studies, DACO: 4.6.1,4.6.2,4.6.5
2325029	1983, An Acute Inhalation Toxicity Study of 1-Napthalene Acetic Acid in the Rat, DACO: 4.6.3
2325030	1992, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2325031	1984, Naphthalene Acetic ACID (NAA) Dermal Sensitization Study in the Guinea Pig, DACO: 4.6.6
2325020	Fruitone L, Apple Growth Regulator for Fruit Thinning, Return Bloom, Early Harvest Management and Pre-harvest Drop Prevention. Also for thinning of Ornamental Crabapples, DACO: 10.1
2325021	2009, Crop Load Regulation Research Report 2008, DACO: 10.2.3
2325022	2008, Evaluation of Fruitone Liquid for Stop Drop Control and Fruit Quality Enhancement, DACO: 10.2.3
2325023	2008, Evaluation of Fruitone Liquid for Fruitlett Thinning, DACO: 10.2.3
2325024	2009, Fruitone L - Stop Drop Summary, DACO: 10.2.3.1
2325025	2009, Fruitone L – Thinning Summary, DACO: 10.2.3.1
2369499	Agricultural Use History Template for Fruitone L, DACO: 10.2.4

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