

Evaluation Report for Category B, Subcategory 2.1, 3.11 Application

Application Number: 2011-1416
Application: New EP Product Chemistry-Guarantee
New to Product Labels-New Pests
Product: Novagib 10L Plant Growth Regulator Solution
Registration Number: 30403
Active ingredients (a.i.): Gibberellins A4A7 [GIB]
PMRA Document Number: 2142035

Purpose of Application

The purpose of this application was to register a new end-use product, Novagib 10L Plant Growth Regulator Solution, containing Gibberellins A4A7. The commercial product is for use on apples to reduce russeting and suppression of pre-harvest cracking in “Stayman” cultivar.

Chemistry Assessment

Novagib 10L Plant Growth Regulator Solution is formulated as a solution containing gibberellins A4 + A7 at a nominal concentration of 0.9674%. This end-use product has a specific gravity of 1.04 and pH of 4.1 for a 1% solution. The chemistry requirements for Novagib 10L Plant Growth Regulator Solution have been fulfilled.

Health Assessments

Novagib 10L Plant Growth Regulator Solution is of low acute toxicity with respect to the oral route ($LD_{50} > 5.0$ g/kg bw in rats), the dermal route ($LD_{50} > 4.0$ g/kg bw in rats), and by inhalation ($LC_{50} > 5.41$ mg/L in rats). Treatment related effects were not observed in any of the limit tests. The information suggests that at the concentration of the active ingredient proposed for the end use product, the acute toxicity of Novagib 10L Plant Growth Regulator Solution is low regardless of the route of exposure.

Novagib 10L Plant Growth Regulator Solution was determined to be minimally irritating to the eye (mean Maximum Irritation Score (MIS) = 10.7/110 @ 1 hour in rabbits) and non-irritating to the skin (MIS = 0/8 in rabbits). It is not a dermal sensitizer in guinea pigs.

The current label statements for Novagib 10L Plant Growth Regulator Solution as per PACR2005-09, *Re-evaluation of Gibberellin A4A7 and Gibberellic Acid*, coupled with the low toxicity of the end-use product and a standard buffer statement regarding environmental conditions required for application are considered adequate to address any potential risk from exposure of mixers, loaders, applicators, individuals responsible for any clean-up activities, and/or bystanders to the end-use product.

As per the re-evaluation document PACR2005-09, *Re-evaluation of Gibberellin A4A7 and Gibberellic Acid*, there are currently no dietary concerns related to the ingestion of Gibberellins A4A7 on food crops.

Maximum Residue Limit

Gibberellins A4A7 is currently registered in Canada and according to PACR2005-09, *Re-evaluation of Gibberellin A4A7 and Gibberellic Acid*, the current Maximum Residue Limit (MRL) for gibberellins A4A7 and gibberellic acid and their metabolites is 0.1 ppm, which is a general MRL described in Regulation B.15.002(1) of the Canadian Food and Drug Regulation.

Environmental Assessment

An environmental risk assessment was not required for this application.

Value Assessment

A total of 3 trials were reviewed to support the claim of reduction of russetting on apples. In the efficacy trials, the use of Novagib 10L Plant Growth Regulator Solution at the proposed rate of 1.5 to 1.9 L increased the percent of clean apples (apples without russets) by 14 to 26% compared to the untreated control.

Publicly available data, as well as a rationale was provided to support the suppression of preharvest cracking in ‘Stayman’ apples. In an experiment conducted over a 5 year-period, gibberellins applied in five biweekly sprays reduced cracking in ‘Stayman’ apples an average of 52% compared to the untreated control. The level of control obtained was reported to be variable depending on the year, orchard, and trees. However, only a small reduction in cracking can be tolerated by the growers due to its direct impact on the marketability of the fruits.

Conclusion

Based on the information reviewed, the PMRA has determined that full registration of Novagib 10L Plant Growth Regulator Solution, containing gibberellins A4A7 for use on apples to reduce russetting and suppression of pre-harvest cracking in “Stayman” cultivar can be supported.

References

PMRA #	Reference
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2034629	2011, Description of the Formulation Process, DACO: 3.2.2 CBI
2034630	2011, Discussion of the Formation of Impurities of Toxicological Concern, DACO: 3.2.3
2034631	2011, Establishing Certified Limits, DACO: 3.3.1 CBI
2034632	2011, Enforcement Analytical Method, DACO: 3.4.1 CBI
2034633	2011, Impurities of Toxicological Concern, DACO: 3.4.2 CBI
2034634	2011, Colour, DACO: 3.5.1
2034635	2011, Physical State, DACO: 3.5.2
2034636	2011, Odour, DACO: 3.5.3
2034637	2011, Formulation Type, DACO: 3.5.4
2034638	2011, Container Material and Description, DACO: 3.5.5
2034639	2011, Density or Specific Gravity, DACO: 3.5.6
2034640	2011, pH, DACO: 3.5.7
2034641	2011, Oxidizing or Reducing Agent (Chemical Incompatibility), DACO: 3.5.8 CBI
2034642	2011, Viscosity, DACO: 3.5.9
2034643	2011, Storage Stability Data, DACO: 3.5.10
2034644	2011, Flammability, DACO: 3.5.11
2034645	2011, Explodability, DACO: 3.5.12
2034646	2011, Miscibility, DACO: 3.5.13
2034647	2011, Corrosion Characteristics, DACO: 3.5.14
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2034665	1997, GA _{4/7} 10G/L Formulation Acute Oral Toxicity to the Rat, DACO: 4.6.1
2034666	1997, GA _{4/7} 10G/L Formulation: Acute Dermal Toxicity to the Rat, DACO: 4.6.2
2034667	1997, Acute inhalation toxicity to rats of GA _{4/7} 10 g/l Formulation, DACO: 4.6.3
2034668	1997, GA _{4/7} 10 g/l Formulation: Eye irritation to the rabbit, DACO: 4.6.4
2034669	1997, GA _{4/7} 10 g/l Formulation: Skin Irritation to the Rabbit, DACO: 4.6.5
2034670	1997, GA _{4/7} G/L Formulation Skin Sensitization in the Guinea Pig, DACO: 4.6.6
2034657	2011, Use Description/Scenario, DACO: 5.2
2034675	2011, efficacy: small-scale trials, DACO: 10.2.3.3
2034676	2011, efficacy: small-scale trials, efficacy summary in tabular form, DACO: 10.2.3.3
2060544	2011, rationale to support reduction of Preharvest Fruit Cracking in 'Stayman' Apples.

- Miller SS (2007). Prohexadione-calcium inhibits shoot growth but reduces the efficacy of gibberellins A4 + A7 in suppressing 'Stayman' apple cracking. Horttechnology 17(4): 523-531.
- Miller S (1996). Plant growth regulators that modify tree and fruit growth. In: Kleiner WC, Greene GM, editors. Using Plant Growth Regulators in Orchards for Profit. (1996 PSU Fruit School). University Park (PA): Pennsylvania State University, pp. 12-1 to 12-8.
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