

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

**Application Number:** 2019-6874  
**Application:** New EP Product Chemistry – Guarantee, Identity of Formulants, Proportion of Formulants  
**Product:** Novagib 5L Plant Growth Regulator Solution  
**Registration Number:** #####  
**Active ingredient (a.i.):** Gibberellins A4 and A7  
**PMRA Document Number :** 3174618

### Purpose of Application

The purpose of this application was to register Novagib 5L Plant Growth Regulator for use on apples to reduce russetting and pre-harvest cracking.

### Chemistry Assessment

Novagib 5L Plant Growth Regulator Solution is formulated as a solution containing gibberellins A4 and A7 at a concentration of 5.0%. This end-use product has a density of 1.06-1.08 g/mL and pH of 7.2. The required chemistry data for Novagib 5L Plant Growth Regulator Solution have been provided, reviewed and found to be acceptable.

### Health Assessments

Potential exposure to gibberellins A4 and A7 may occur by applying the end-use product or entering treated sites. The Pest Management Regulatory Agency (PMRA) considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed.

Novagib 5L Plant Growth Regulator Solution is of low acute toxicity by the oral, dermal, and inhalation routes, non-irritating to minimally irritating to eyes, non-irritating to the skin, and is not a dermal sensitizer.

Occupational exposure to individuals handling Novagib 5L Plant Growth Regulator Solution is expected to result in acceptable risk when the product is used according to label directions. Precautionary and personal protective equipment statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any potential risk due to occupational exposure.

Bystander exposure is expected to result in acceptable risk when the product is used according to label directions.

Health risks to individuals in residential areas are considered acceptable when the product is used according to label directions.

## Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, the PMRA must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. The PMRA specifies science-based MRLs to ensure the food Canadians eat is safe.

The PMRA has previously established an MRL of 0.1 ppm for gibberellins A4 and A7 on apples. Residues of gibberellins A4 and A7 in harvested apple crops at the established MRL will not pose an unacceptable risk.

## Environmental Assessment

The PMRA has concluded that the environmental risks associated with the use of Novagib 5L Plant Growth Regulator Solution are acceptable when used according to the label directions.

## Value Assessment

Value information consisted of a precedent registration, a rationale, and data from field trials conducted in the US. This information collectively demonstrated that the performance of Novagib 5L Plant Growth Regulator Solution is agronomically similar to that of the cited precedent product when they were applied at a similar rate on an active ingredient basis. Therefore, all uses and claims registered on the precedent product label are supported for inclusion on the Novagib 5L Plant Growth Regulator Solution label.

Since Novagib 5L Plant Growth Regulator Solution contains a higher concentration of the active ingredient, the registration of this product allows growers to apply less amount of product per hectare while providing the same level of efficacy as the precedent product. This reduces the amount of the product that needs to be handled.

## Conclusion

The PMRA has completed an assessment of the information provided and has found it sufficient to support the registration of Novagib 5L Plant Growth Regulator Solution.

## References

PMRA Document Number	References
3065934	2019, 3.3.1 Establishing Certified Limits, DACO: 3.3.1 CBI
3065944	2019, Manufacturing process Novagib 5L, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI

3065949 2016, Physical and chemical properties of FAL 477, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9

3065950 2017, Physical and Chemical Properties of FAL 477: Storage Stability for up to 52 weeks at 20C stored in 500ml HDPE bottles., DACO: 3.5.10,3.5.14

3065964 2016, Validation of Analytical Method FALM012/A for the Quantitative Determination of the Active Ingredients in FAL 477, DACO: 3.4.1 CBI

3085440 2020, Phys-chem properties Novagib 5L, 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

3065936 2016, FAL 477 Acute Dermal Toxicity in Rats, DACO: 4.6.2

3065937 2016, FAL 477 Acute Dermal Irritation in Rabbits, DACO: 4.6.5

3065938 2016, FAL 477 Acute Eye Irritation in Rabbits, DACO: 4.6.4

3065939 2016, FAL 477 Acute Inhalation Toxicity in Rats, DACO: 4.6.3

3065940 2016, FAL 477 Acute Oral Toxicity (UDP) in Rats, DACO: 4.6.1

3065941 2016, FAL 477 Skin Sensitization in Guinea Pigs, DACO: 4.6.6

3065963 2019, Use Description/Scenario (Application and Post Application), DACO: 5.2

3085438 2020, DACO 10 Value (applicable to each pest/site or host combination), DACO: 10.1.

3126261 2020, DACO 10 Efficacy Novagib 5L, DACO: 10.1.

3126262 2020, Trial 1 results, DACO: 10.2.3.3.

3126263 2020, Trial 2 results, DACO: 10.2.3.3.

3126266 2020, Trial 3 results, DACO: 10.2.3.3.

3126267 2020, Trial 4 results, DACO: 10.2.3.4.

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