



## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2014-2274  
**Application:** New or Changes to Product Labels – new Site or Host  
**Product:** Promalin SL Plant Growth Regulator  
**Registration Number:** 16636  
**Active ingredients (a.i.):** 6-Benzylaminopurine (or 6-benzyladenine) and Gibberellins A<sub>4</sub>A<sub>7</sub>  
**PMRA Document Number :** 2524076

### Purpose of Application

The purpose of this application was to amend the product label for Promalin SL Plant Growth Regulator to expand the existing label uses on apples, and to add uses on pears and non-bearing cherry trees to the label. The amended claims are intended to improve fruit shape, increase fruit size, reduce russet, increase fruit set after frost, and increase lateral branching and tree development for apples, pears, and non-bearing sweet cherries. In addition, the name of the product was changed to Promalin SL Plant Growth Regulator from Promalin Plant Growth Regulator Solution 1.

### Chemistry Assessment

A chemistry assessment was not required with this application.

### Health Assessments

No changes were made to the formulation of Promalin SL Plant Growth Regulator; therefore, no toxicology information was required or provided for this application.

The foliar applications to improve fruit shape, increase fruit size, reduce russet, increase fruit set after frost, and increase lateral branching and tree development for apples, pears, non-bearing sweet cherries are consistent with the currently registered foliar application to Red Delicious apples, therefore, an occupational and bystander exposure risk assessment is not required for the new uses for foliar applications.

The latex applications to apples and non-bearing sweet cherries instructs the user to mix 100 – 165.6 mL of end-use product (EP) with 500 mL latex paint and apply with a brush or sponge to terminal buds on year old growth before shoots emerge. The label specifies that users must wear long pants, a long-sleeved shirt, shoes plus socks, chemical-resistant gloves and goggles or a face shield during mixing/loading, application, clean-up, and repair activities; and that re-entry into treated areas must not be allowed until 12 hours after application. The personal protective equipment (PPE) and re-entry interval specified on the label sufficiently minimize the exposure to users and bystanders. No additional occupational or bystander exposure

information is required for the EP.

Since the Maximum Residue Limit (MRL) for Gibberellins A<sub>4</sub>A<sub>7</sub> and 6-Benzylaminopurine has been established as a general MRL of 0.1 ppm, no further data are required for the food residue exposure assessment of the uses on apples and pears.

### **Environmental Assessment**

Since the rates and use patterns for Promalin SL Plant Growth Regulator are similar to those already registered, no additional environmental exposure is expected through the requested label expansions. No further environmentally-related data or review are required.

### **Value Assessment**

Value information submitted included 39 apple trials and 35 pear trials conducted in European countries, three apple trials conducted in the USA, and 64 scientific literatures. All trials conducted in European countries were GEP (Good Experimental Practice) studies.

Value information from trials conducted in Central Europe, including 18 apple trials and 16 pear trials, was accepted for the following reasons. Trials conducted in Southern Europe were considered to be supportive.

- Central Europe is similar in latitude as the major apple and pear production regions in Canada.
- Production technology of pome fruit in Europe has been adapted in Canada and apple and pear cultivars used in Canada and Central Europe are similar.
- The formulation used in Europe is identical to that registered in Canada.

The value information from the trials conducted in Central Europe can be summarized as follows:

- The application of Promalin SL Plant Growth Regulator in a rate range of 2.5-40 ppm increased the amount (%) of apple fruit without russet and correspondingly reduced the amount of fruit in both the slight and severe skin russet categories when compared to an untreated control.
- The application of Promalin SL Plant Growth Regulator at 10 or 20 ppm increased apple fruit weight when compared to an untreated control. The increase in fruit size was as a result of the lower number of fruits.
- Pear fruit set was increased with the treatment of Promalin SL Plant Growth Regulator, with the best results at 10 ppm. This effect on fruit set increased pear yields as a result of the higher crop loads.

The value information from the trials conducted in the USA demonstrated that the application of Promalin SL Plant Growth Regulator at 1.2 or 2.4 L/ha after frosts improved apple fruit number per tree.

The inclusion of the claim of apple fruit typiness improvement has value for the following

reasons:

- The improvement of fruit typiness is currently labelled for Red Delicious apples.
- The improvement of fruit typiness is registered for apples on the US Promalin Plant Growth Regulator Solution label.
- It was concluded in a number of scientific literature that applications of 6-Benzylaminopurine (6-BA) or Gibberellins A<sub>4</sub>A<sub>7</sub> (GA) or combination of both may increase apple fruit length and diameter ratio.

Given that apple and pear genetics and environmental conditions may influence the efficacy of Promalin SL Plant Growth Regulator treatments, it is important that the use pattern be flexible to allow growers to adapt it to their orchard. Therefore, the range of application concentrations and number of applications that are proposed for Canadian registration are considered to have value.

The studies presented in the scientific literature that were published between 1959 and 2012 in a wide variety of journals pertaining to tree fruit production, plant physiology, plant cell physiology, horticulture, and plant growth regulators collectively examined the mechanisms of action and efficacy of plant growth regulators, including cytokinins and GA, on apple russetting and apple and pear fruit setting and sizing. Information presented in the scientific literature is consistent with the findings from the trials conducted in European countries and the USA.

The scientific literature and use history information from Europe indicated that the efficacy claim of lateral bud break and shoot growth increase and branch angles improvement for early cropping on apples, pears, and sweet cherries have value.

Economic data from four trials conducted in Austria indicated that Promalin SL Plant Growth Regulator applications substantially increased the mean economic return as a result of less russet and higher amounts of first grade fruit. Promalin SL Plant Growth Regulator at the 2.5, 5.0, 10, or 20 ppm rates showed mean efficacies for gross income of 119%, 120%, 112% or 142%, respectively, when compared to the untreated control with the reference treatment at 126%.

Based on the weight of evidence, the label amendments to the use patterns of Promalin SL Plant Growth Regulator, i.e., improvement of apple typiness when natural typiness is limited, reduction of apple fruit russet, increase in apple size when fruit thinning may occur, increase in apple fruit set after frost damage, increase in pear fruit set when natural fruit set is generally low, and increase in lateral bud break and shoot growth and improvement of branch angle on nursery stock and young trees of apples, pears, and sweet cherries, have value.

## **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of Promalin SL Plant Growth Regulator and has found the information sufficient to support the amendment to expand the existing product label uses on apples, and to add uses on pears and non-bearing cheery trees.

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