

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2007-4747
Application: B.2.1 - New EP or MA product chemistry guarantee
B.2.3 - New EP or MA product chemistry - identity of formulants
B.2.4 - New EP or MA product chemistry - proportion of formulants
B.3.1 - New or Changes to product label - application rate increase
Product: Progibb 40 SG
Registration Number: 29359
Active ingredients (a.i.): Gibberellic acid A₃ (GIA)
PMRA Document Number: 1779588

Purpose of Application

Valent BioSciences Corporation has submitted an application to register a new product, ProGibb 40 SG, a water soluble granular formulation containing 40% Gibberellin A₃. The technical active ingredient is registered in Canada (PCP # 28509).

Chemistry Assessment

ProGibb 40 SG is a product formulated in a form of soluble granules containing the active ingredient gibberellin A₃ at a nominal concentration of 40%. This product has a density of 0.54 g/mL and pH of 2.82 (10% slurry). The chemistry requirements for ProGibb 40 SG have been completed.

Health Assessments

The acute oral LD₅₀ for ProGibb 40 SG has been reported as > 5000 mg/kg bw against female albino Sprague-Dawley rats. Male and female (5/sex) albino Sprague-Dawley rats were used for the acute dermal studies and the LD₅₀ has been found to be > 5000 mg/kg bw. These results show that ProGibb 40 SG has low acute oral and dermal toxicity. All the test animals remained healthy and active and no mortalities were observed during the study period i.e., 14 days. The NOAEL for clinical findings would be 5000 mg/kg bw, by default. In addition, there were no signs of gross abnormalities found in any of the test animals when necropsied.

Male New Zealand albino rabbits were used for primary eye irritation studies. The MAS (maximum average score) was calculated to be as 1.33/110 based on individual scores for ocular irritation at 24, 48 and 72 hours of exposure. Therefore, the end-use product is considered as non to minimally irritating.

The dermal irritation was also done on New Zealand albino rabbits (2 males and 1 female). The MAS was calculated to be 0.22/8 based on the individual skin irritation scores recorded at 24, 48 and 72 hours of exposure. The dermal irritation is considered minimal for this end-use product. Edema was not observed in any of the test animals, but very slight erythema was observed after 30-60 minutes, which was completely resolved by 48 hours after the patch was removed.

The dermal sensitization study was done on young adult, albino Hartley guinea pigs (20 males for the test group and 10 males for the control group). The outcome of the study showed that the proposed end use product is not a dermal sensitizer.

On the basis of the above results it can be concluded that ProGibb 40 SG is of low acute toxicity regardless of the route of exposure i.e. oral, dermal or inhalation. The ocular and dermal irritation is minimal and the end-use product is not a dermal sensitizer.

Environmental Assessment

ProGibb 40 SG is a new plant growth regulator (biopesticide) containing 40% gibberellic acid (GA3) as TGAI, which is currently registered (PCP # 28509) in Canada. The use of ProGibb 40 SG on cherries is not expected to pose additional risk to the environment. The formulants in the formulation of ProGibb 40 SG are not expected to pose a TSMP concern.

Value Assessment

ProGibb 40 SG Plant Growth Regulator is an end-use product for 1) application to sweet cherry trees to delay fruit ripening (thus lengthening the picking period and delaying period of susceptibility to rain cracking), to increase fruit firmness and to increase resistance to postharvest disorders; and 2) annual application to yellows virus infected standard-sized 'Montmorency' sour cherry trees to maintain and extend high fruiting capacity by promoting spur formation and reducing the occurrence of blind nodes.

Data were submitted from four field trials conducted on sweet cherry in Ontario (2 trials) and BC (2 trials) in which ProGibb 40 SG was applied at 40, 80, and 120 g ai/ha once in either 4000 L (Ontario trials) or 2000 L (BC trials) water/ha using ground application equipment.

In the two Ontario trials, plant growth regulators had little if any effect on the assessed parameters. In one of two BC trials, ProGibb 40 SG appeared to slow colour development and numerically increase fruit firmness, particularly at first harvest. Fruit firmness and colour values were comparable between the treatment of 40 g ai/ha ProGibb 40 SG and the included registered treatment, 36.8 g ai/ha Activol (Reg. No. 11904). In the second BC trial, there did not appear to be any consistent effect of gibberellic acid on sweet cherry fruit except that fruit treated with ProGibb 40 SG or Activol were firmer than untreated fruit.

The data suggest that response of sweet cherry to ProGibb 40 SG is comparable to that to Activol.

While the response of sour cherry to ProGibb 40 SG was not assessed, it is not anticipated that response to ProGibb 40 SG and Activol would differ given the comparable response of sweet cherry to the two products.

Conclusion

The Agency has completed an assessment of the subject application and has found the information sufficient to register ProGibb 40 SG plant growth regulator for use on sweet cherry and sour cherry trees.

References

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- 1465132 Method Validation, DACO: 3.4.1
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- 1448175 2005, Acute Dermal, 18150, DACO: 4.6.2
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- 1611207 PMRA, Re-evaluation Decision Document Gibberellin A4A7 and Gibberellic Acid, DACO: RDD_PDF_E.

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