



Evaluation Report for Category B, Subcategory 2.1 & 2.5 Application

Application Number: 2006-2205
Application: Commercial
Product: Exilis Plus Plant Growth Regulator Solution
Registration Number: 29210
Active ingredients (a.i.): 6-Benzylaminopurine (2.0 % w/w)
PMRA Document Number: 1702144

Background

MaxCel Plant Growth Regulator was first registered in 2007. The use pattern for the active ingredient 6-benzylaminopurine includes use in apple production for enhancement of fruit size and for fruit thinning, sizing and enhanced return bloom. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this application was to register Exilis Plus Plant Growth Regulator Solution, an end use product for post bloom thinning of apples. The product is intended for application at a rate of 76 mg ai/ha. The use patterns will be identical to the use patterns registered on the MaxCel Plant Growth Regulator Solution (Reg. No. 28851) label, containing 1.9% by weight, 6-benzylaminopurine. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Exilis Plus Plant Growth Regulator is a liquid formulation containing 6-benzylaminopurine as the active ingredient at a nominal concentration of 2.0%. This product has a specific gravity of 1.043 and pH of 4.16. The chemistry requirements for Exilis Plus Plant Growth Regulator are complete.

Health Assessments

Although 6-Benzylaminopurine (99 %) is moderately toxic in female rats, having an oral $LD_{50} = 814$ mg/kg bw, the acute oral toxicity of a gibberellic acid $GA_{4/7}$ (1.9 %) and 6-benzylaminopurine (1.9 %) mixture is low in rats, with an $LD_{50} = 3.0$ g/kg bw. The acute dermal toxicity of 6-benzylaminopurine (99 %) is also low, with an $LD_{50} > 2000$ mg/kg bw in rats. Similarly, the acute inhalation toxicity for 6-benzylaminopurine (99 %) is low, with an

LC₅₀ > 5.25 mg/L in rats. As such, Exilis Plus Plant Growth Regulator Solution is expected to have low acute toxicity, regardless of the route of exposure.

The primary eye irritation of 6-benzylaminopurine (99 %) may be categorized as minimally irritating in rabbits. With respect to skin irritation, 6-benzylaminopurine (99 %) was found to be non-irritating to rabbits. The end use product may be categorized minimally irritating to the eye but non-irritating when applied to the skin.

6-Benzylaminopurine (99 %) was not found to be a dermal sensitizer in guinea pigs. The end use product will not be considered a dermal sensitizer.

The current label statements for Exilis Plus Plant Growth regulator Solution, considered adequate, coupled with the low toxicity are considered adequate to address any potential risk due to exposure of the mixer, loader, applicator, and/or bystander to the end-use product.

As per the re-evaluation document, PACR2005-11, *Re-evaluation of 6-Benzylaminopurine*, there are currently no dietary concerns related to the ingestion of 6-benzylaminopurine on food crops.

Maximum Residue Limit

6-Benzylaminopurine is currently registered in Canada and has an established Maximum Residue Limit (MRL) of 0.1 ppm for the parent compound and related metabolites.

Environmental Assessment

This product is for use on apples to increase fruit size, as a fruit thinning agent, and to enhance the return bloom. The product can be applied 1 to 2 times per season, at a maximum single rate of 76 mg ai/ha, at an interval of 7 to 10 days. The product is to be applied when the average diameter of king fruitlets is between 5 to 10 mm. This period may be extended from approximately 7 to 21 days after full bloom.

Value Assessment

Based on the similarity of Exilis Plus Plant Growth Regulator and other registered products containing 6-benzyladenine, no value data were required in support of this registration.

Conclusion

The PMRA has completed an assessment of the subject application and has found the information sufficient to support the registration of Exilis Plus Plant Growth Regulator Solution.

References

A. List of Studies/Information Submitted by Registrant

- 1162043 1997, *BAP 99 % technical acute oral toxicity to the rat*. Huntingdon Life Science Ltd. F
- 1162192 1997, *GA_{4/7} + BAP 19 g/l formulation acute toxicity to the rat*. Huntingdon Life Science Ltd.
- 1162044 1997, *BAP 99 % technical acute dermal toxicity to the rat*. Huntingdon Life Science Ltd.
- 1162045 1977 *Acute inhalation toxicity to rats of BAP 99 %*. Huntingdon Life Science Ltd.
- 1162046 1997, *BAP 99 % technical eye irritation to the rabbit*. Huntingdon Life Science Ltd.
- 162047 1997, *BAP 99 % technical skin irritation to the rabbit*. Huntingdon Life Science Ltd.
- 1162048 1997, *6-BAP(6-benzylaminopurine): Magnusson & Kligman Maximization study in the guinea pig*.
- 1171634 2001, SIDS: 1,2-dihydroxypropane.
- 1324372 2006, DACO 5.2 - Use description/scenario (application and post application) Exilis Plant Growth Regulator.
- 1162078 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
- 162079 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.2.1 CBI
- 1162080 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.2.2 CBI
- 1162081 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.2.3 CBI
- 1162082 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.3.1 CBI
- 1162084 2005, Validation of Analytical Method M496 "HPLC Determination of 6-Benzylaminopurine (BAP) in Formulations and Technical Material" - for the "Exilis" Formulation. Final report., J15472, DACO: 3.4.1 CBI
- 1162085 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.4.2 CBI
- 1162086 2006, Product Chemistry Data to Support the Registration of Exilis Plus Plant Growth Regulator, DACO: 3.5 CBI
- 1162181 2000, Determination of the Physico-Chemical Properties of Perlan MPG Formulation, 18916, DACO: 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9 CBI
- 1162185 2001, Determination of the Long-Term Storage Stability Characteristics of Perlan Formulations, CEMS-1086, DACO: 3.5.10, 3.5.14 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2009

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.