

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2009-2387
Application: New/Changes to the technical grade active ingredient – new source (site) same registrant
Product: Gibberellic Acid Technical Plant Growth Regulator
Registration Number: 29087
Active ingredients (a.i.): Gibberellic Acid [GIA]
PMRA Document Number: 1895150

Purpose of Application

The purpose of this application is to add a new source of the active ingredient Gibberellic Acid to the currently registered product, Gibberellic Acid Technical Plant Growth Regulator (Reg. No. 29087), by the same registrant.

Chemistry Assessment

Common name: Gibberellic acid
Chemical name: (1 α ,2 β ,4 $\alpha\alpha$,4 $\beta\beta$,10 β)-2,4a,7-trihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-dicarboxylic acid 1,4a-lactone

Gibberellic Acid Technical Plant Growth Regulator has the following properties:

Property	Results						
Colour and physical state	Off white						
Nominal concentration	90.0%						
Odour	No noticeable odour						
Melting range	236°C						
Density	0.80 g/mL						
pH	2.78						
Vapour pressure at 20°C	2.06 x 10 ⁻¹³ mm Hg at 25°C (estimated)						
Ultraviolet (UV)-visible spectrum	No absorbance at $\lambda > 300$ nm						
Solubility in water at 20°C	4.28 g/L						
Solubility in organic solvents at 20°C (g/100 mL)	<table border="1"> <thead> <tr> <th>Solvent</th> <th>Solubility (g/L)</th> </tr> </thead> <tbody> <tr> <td>ethanol</td> <td>361.58</td> </tr> <tr> <td>hexane</td> <td>0.159</td> </tr> </tbody> </table>	Solvent	Solubility (g/L)	ethanol	361.58	hexane	0.159
Solvent	Solubility (g/L)						
ethanol	361.58						
hexane	0.159						

n-Octanol-water partition coefficient (K_{ow})	$\log K_{ow} = 0.24$
Dissociation constant (pK_a)	$pK_a = 4.0$

The chemistry requirements for Gibberellic Acid Technical Plant Growth Regulator are complete.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new source for the production of Gibberellic Acid Technical Plant Growth Regulator is acceptable.

References

- 1777607 2009, Part 2.11.1 Chemistry CBI Attachment, DACO: 2.11.1 **CBI**
- 1777608 2009, Part 2.11.2 Chemistry CBI Attachment, DACO: 2.11.2 **CBI**
- 1777609 2009, Part 2.11.3 Chemistry CBI Attachment, DACO: 2.11.3 **CBI**
- 1777610 2009, Part 2.11.4 Chemistry CBI Attachment, DACO: 2.11.4 **CBI**
- 1777611 2009, Part 2.12.1 Chemistry CBI Attachment, DACO: 2.12.1 **CBI**
- 1777612 2009, Part 2.12.2 Chemistry CBI Attachment, DACO: 2.12.2 **CBI**
- 1777615 2009, Part 2.13.1 Chemistry CBI Attachment, DACO: 2.13.1 **CBI**
- 1777616 2009, Part 2.13.2 Chemistry CBI Attachment, DACO: 2.13.3 **CBI**
- 1876683 2008, Validation of GC Laboratories Ltd. Analytical Method M547/A, DACO: 2.13.1 **CBI**
- 1876684 2008, Validation of GC Laboratories Analytical Method M647 HPLC Determination of Impurities in Technical Gibberellin GA3, DACO: 2.13.1 **CBI**

ISSN: 1911-8082

Catalogue number: xxxxxxxxxxx (xxxxxxxx)

© **Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2006**

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.