

## Evaluation Report for Category B, Subcategory B.1.2 Application

**Application Number:** 2006-2211  
**Application:** Category B, Subcategory B.1.2 Application  
**Product:** Gibberellins A4+A7 Technical Plant Growth Regulator  
**Registration Number:** 28769  
**Active ingredients (a.i.):** Gibberellins A4+A7 [GIB]  
**PMRA Document Number:** 1763728

### Background

Fine Agrochemicals Limited has requested registration of a new source of the currently registered active ingredient, Gibberellins A4+A7 (PCP# 25532). The new source is subsequent to PSR but a different manufacturing process has resulted in the product containing a substantially different ratio of gibberellin A4 to gibberellin A7 compared to the currently registered product. The percentages of A4 to A7 is 73% to 18.7% respectively in the current registered source of the active ingredient, whereas the new source contains 91.2% A4 and 2.4% A7.

The original source of Gibberellins A<sub>4</sub> + A<sub>7</sub> technical grade active ingredient, “Gibberellins A<sub>4</sub> + A<sub>7</sub> Powder” (Reg. No. 25532) was first registered in 1998.

### Purpose of Application

The purpose of this application is to register a new technical source of Gibberellins A<sub>4</sub> + A<sub>7</sub>. This new source of technical grade active ingredient, “Gibberellins A<sub>4</sub> + A<sub>7</sub> Technical Plant Growth Regulator” (Reg. No. 28769) is intended for use in the manufacture of Fresco Plant Growth Regulator Solution (reviewed under application no. 2006-2207) and Perlan Plant Growth Regulator Solution (reviewed under application no. 2006-2210).

### Chemistry Assessment

Common Name: No ISO common name was assigned to this active  
Chemical Name: A<sub>4</sub>: (3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-b]furan-4-carboxylic acid  
A<sub>7</sub>: (3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid

Gibberellins A<sub>4</sub> + A<sub>7</sub> Technical Plant Growth Regulator has the following properties:

Property	Result										
Colour and physical state	White powder										
Nominal concentration	93.1%										
Odour	Non detectable odour										
Specific gravity	1.27										
Vapour pressure	$1.0 \times 10^{-5}$ Pa (at 25 °C)										
pH	3.83 (1% dispersion in water)										
Solubility in water	<table border="0"> <thead> <tr> <th><u>Solvent</u></th> <th><u>Solubility</u></th> </tr> </thead> <tbody> <tr> <td>Pure Water (pH = 4.4)</td> <td>127 mg/L</td> </tr> <tr> <td>pH 4 buffer</td> <td>141 mg/L</td> </tr> <tr> <td>pH 7 buffer</td> <td>40.0 g/L</td> </tr> <tr> <td>pH 9 buffer</td> <td>&gt; 250 g/L</td> </tr> </tbody> </table>	<u>Solvent</u>	<u>Solubility</u>	Pure Water (pH = 4.4)	127 mg/L	pH 4 buffer	141 mg/L	pH 7 buffer	40.0 g/L	pH 9 buffer	> 250 g/L
<u>Solvent</u>	<u>Solubility</u>										
Pure Water (pH = 4.4)	127 mg/L										
pH 4 buffer	141 mg/L										
pH 7 buffer	40.0 g/L										
pH 9 buffer	> 250 g/L										
n-Octanol/water partition coefficient	<table border="0"> <thead> <tr> <th><u>pH</u></th> <th><u>log Kow</u></th> </tr> </thead> <tbody> <tr> <td>4</td> <td>2.47</td> </tr> <tr> <td>7</td> <td>0.146</td> </tr> <tr> <td>9</td> <td>-1.23</td> </tr> </tbody> </table>	<u>pH</u>	<u>log Kow</u>	4	2.47	7	0.146	9	-1.23		
<u>pH</u>	<u>log Kow</u>										
4	2.47										
7	0.146										
9	-1.23										

The chemistry requirements for Gibberellins A<sub>4</sub> + A<sub>7</sub> Technical Plant Growth Regulator have been completed.

### Health Assessments

A new source of the active ingredient gibberellins A<sub>4</sub>+A<sub>7</sub> has been proposed by the applicant. The percentages of A<sub>4</sub> to A<sub>7</sub> will no longer be 73 % to 18.7 %, as in the currently registered source (PCP # 25532), but will now be 91.2 % to 2.4 %. Based on available information, it is not anticipated that the alteration in the ratio of A<sub>4</sub> to A<sub>7</sub> gibberellins will have a significant effect on the toxicological profile of the active ingredient.

As per the re-evaluation document PACR2005-09, *Re-evaluation of Gibberellin A<sub>4</sub>A<sub>7</sub> and Gibberellic Acid*, there are currently no dietary concerns related to the ingestion of gibberellins A<sub>4</sub>+A<sub>7</sub> on food crops. The proposed change in the percentage of A<sub>4</sub> to A<sub>7</sub> is not anticipated to result in dietary concerns from the ingestion of treated food products.

### Maximum Residue Limit

Gibberellins A<sub>4</sub>+A<sub>7</sub> is currently registered in Canada and has an established Maximum Residue Limit (MRL) of 0.1 ppm for the parent compound and related metabolites. This MRL will remain in place for the new source of the active ingredient.

## **Environmental Assessment**

Regarding the chemical equivalence between the new source of gibberellins ( $A_4 + A_7$  ; 91.2% and 2.4%) and the registered source ( $A_4 + A_7$  ; 73% and 18.7%), and considering that the existing environmental data supporting the registered source of gibberellins is based entirely on gibberellic acid (gibberellin  $A_3$ ), and that gibberellins  $A_4 + A_7$  and gibberellin  $A_3$  were considered jointly under the re-evaluation (PACR2005-09), the environmental risk is considered to be similar to that of the original registered technical source of gibberellic acid.

## **Value Assessment**

A value assessment was not required since there were no efficacy or crop tolerance claims associated with the technical grade active ingredient.

## **Conclusion**

The PMRA has completed an evaluation of the subject application and has found the information sufficient to support the chemical equivalence of the new formulation of Gibberellins  $A_4 + A_7$  Technical Plant Growth Regulator to the currently registered formulation of Gibberellins  $A_4 + A_7$  Technical Plant Growth Regulator (Reg. No. 25532).

## References

### Chemistry Assessment

PMRA Document Number: 1162149

Reference: 1997, Ga4/7 (99% Technical): Determination Of The Physico-chemical Properties, 96/fna052/1221, Data Numbering Code:

2.14.1,2.14.10,2.14.11,2.14.12,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9  
Confidential Business Information

PMRA Document Number: 1162150

Reference: 1997, Ga4/7 (99% Technical): Determination Of The Physico-chemical Properties, Fna 32/962647/se, Data Numbering Code: 2.16 Confidential Business Information

PMRA Document Number: 1162151

Reference: 1997, Ga4/7 (99% Technical): Determination Of The Physico-chemical Properties, Fna053/970060, Data Numbering Code: 2.14.13 Confidential Business Information

PMRA Document Number: 1162141

Reference: 2002, Analysis Of 5 Batches Of Technical Gibberellin And Specified Impurities With Associated Validation In Compliance With Good Laboratory Practice., Ao00863, Data Numbering Code: 2.13.1,2.13.2,2.13.3 Confidential Business Information

PMRA Document Number: 1162144

Reference: 2003, Determination Of Gibberellin A24 In Five Batches Of Gibberellin A4 Technical Material, J14579, Data Numbering Code: 2.13.1,2.13.2,2.13.3 Confidential Business Information

PMRA Document Number: 1162148

Reference: 2006, Chemical And Physical Properties Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.14 Confidential Business Information

PMRA Document Number: 1162139

Reference: 2006, Establishing Certified Limits Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.12.1 Confidential Business Information

PMRA Document Number: 1162147

Reference: 2006, Impurities Of Toxicological Concern Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.13.4 Confidential Business Information

PMRA Document Number: 1162133

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 Confidential Business Information

PMRA Document Number: 1162134

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.11.1 Confidential Business Information

PMRA Document Number: 1162135

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.11.2 Confidential Business Information

PMRA Document Number: 1162136

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.11.3 Confidential Business Information

PMRA Document Number: 1162137

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.11.4 Confidential Business Information

PMRA Document Number: 1162138

Reference: 2006, Product Chemistry Data To Support The Registration Of Gibberellins A4+a7 Technical Plant Growth Regulator, Data Numbering Code: 2.12 Confidential Business Information

PMRA Document Number: 1162143

Reference: Batch Data: Note To Reviewer, Data Numbering Code: 2.13.3 Confidential Business Information

PMRA Document Number: 1171569

Reference: Ga4/7 (99% Technical): Physico-chemical Properties, Data Numbering Code: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9 Confidential Business Information

PMRA Document Number: 1162152

Reference: Ga4/7 (99% Technical): Storage Stability Data Waiver Request., Data Numbering Code: 2.14.14 Confidential Business Information

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.