

## **Evaluation Report for Category B, Subcategory 1.1 Application**

**Application Number:** 2023-1899

**Application:** Changes to Technical Grade Active Ingredient Product Chemistry

- New Source (Site) Same Registrant

**Applicant:** Fine Agrochemicals Limited

**Product:** Gibberellins A<sub>4</sub>+A<sub>7</sub> Technical Plant Growth Regulator

**Registration Number:** 28769

**Active ingredient (a.i.):** Gibberellins A<sub>4</sub> and A<sub>7</sub>

PMRA Document Number: 3596614

### Purpose of application

The purpose of this application was to change the manufacturing site for a source of Gibberellins  $A_4+A_7$  Technical Plant Growth Regulator.

#### Chemistry assessment

Common Name: Gibberellins A<sub>4</sub> and A<sub>7</sub>

IUPAC\* 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

CAS† Chemical Name: A<sub>4</sub>: (1a,2ß,4aa,4bß,10ß)-2,4a-dihydroxy-1-methyl-8-

methylenegibbane-1,10-dicarboxylic acid 1,4a-lactone

A<sub>7</sub>: (1a,2β,4aa,4bβ,10β)-2,4a-dihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-

dicarboxylic acid, 1,4a-lactone

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

Property	Result
Colour and physical state	White solid
Nominal concentration	95.74%
Odour	No detectable odour
Relative density	1.27 g/mL (20°C)



<sup>\*</sup> International Union of Pure and Applied Chemistry

<sup>†</sup> Chemical Abstracts Service

Property	Result
Vapour pressure	$1.0 \times 10^{-5} \text{ Pa (at } 25^{\circ}\text{C)}$
рН	3.83
Solubility in water	127.0 mg/L (20°C, pH 4.4)
n-Octanol/water partition coefficient	$Log K_{ow} = 2.47 (20^{\circ}C, pH 4)$

The required chemistry data for Gibberellins A4+A7 Technical Plant Growth Regulator have been provided, reviewed, and found to be acceptable.

# Health, environmental and value assessments

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

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the change in manufacturing site.

### References

PMRA Document	
Number	Reference
2859885	2009, Validation of [PRIVACY REMOVED] [CBI REMOVED]
	Determination of Impurities in Technical Gibberellins AG4/GA7 and
	Determination of GA7 in Technical Gibberellin GA4/GA7, DACO: 2.13.1
	CBI
2859886	2009, Validation of [PRIVACY REMOVED] [CBI REMOVED]
	Determination of Gibberellins GA4 and GA7 in Technical Materials and
	Formulations Validation for GA47 in GA4/GA7 Technical Gibberellin,
	DACO: 2.13.1 CBI
3463569	2023, GA47 Tech 2.11.1 to 2.11.4, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
3463572	2023, GA47 Tech 2.13.1 to 2.13.4, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3463584	2010, Validation of [PRIVACY REMOVED] "[CBI REMOVED]
	Determination of Impurities in Technical Gibberellin GA4/GA7 and
	Determination of GA7 in Technical Gibberellin GA4/GA7 and
	Formulations" for the Determination of GA7 in the Novagib Formulation,
	DACO: 2.13.1
3463586	2018, Analysis of Five Representative Production Batches of GA4/7
	Technical To Determine % GA4 and GA7, Its Associated Impurities And
	Water Content, DACO: 2.13.1,2.13.2,2.13.3 CBI
3591147	2024, GA47 Tech 2.11.1 to 2.11.4, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
3517077	2023, Gibberellins A4+A7 Technical Plant Growth Regulator: Summary of
	Microbial Contamination Testing, DACO: M2.10.2,M2.9.3 CBI

### © His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

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 Health Canada, Ottawa, Ontario K1A 0K9.