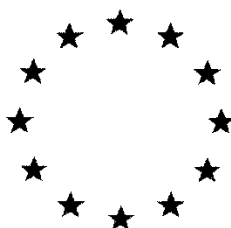


European Commission



**Combined Draft (Renewal) Assessment Report prepared according to
Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report)
according to Regulation (EC) N° 1272/2008**

GIBBERELLINS (GA4, GA7)

Volume 3 – B.1 (AS)

Rapporteur Member State: Slovenia
Co-Rapporteur Member State: Slovakia

Version History

When	What
2019/April	Initial DRAR including co-RMS suggestions

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B.1. IDENTITY

Introduction

This document has been prepared to evaluate the European Gibberellins Task Force (Valent Biosciences Corporation (Sumitomo Chemical Agro Europe), Fine Agrochemicals Ltd, Globachem NV) application for EU renewal of the Annex I inclusion of active substance gibberellins (GA4, GA7). The document supplements and updates the corresponding Annex B section of the Draft Assessment Report produced during the first review of gibberellins (2005 - 2011).

Gibberelin has been identified as a presumed low-risk active substance in the Commission working document on the AIR-IV renewal programme (SANTE-2016-10616-rev 8). The EU Gibberellin Task Force (EGTF) proposes that Gibberelin is a low risk active substance according to Regulation (EC) 1107/2009 as amended by Commission Regulation 2017/1432.

In this report studies submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC and for the renewal of the approval of gibberellins have been evaluated.

Previous EU assessment

The dossier to support the first inclusion of gibberellins in Annex I to Directive 91/414/EEC was submitted to Hungary as the Rapporteur Member State in June 2005. The Draft Assessment Report is dated July 2006. Final Addendum to Draft Assessment Report, containing all individually submitted addenda on gibberellins, was compiled by EFSA in October 2011.

Structure of this document

Summaries of available data and overall assessments of each sub-section, as well as the exposure assessments, generally are not included in this document. Instead these parts of the assessment are included in Vol. 1, Level 2. The reason behind this structure is to avoid repetition and facilitate revisions of the assessment. As a result, this Annex B only contains the presentation and evaluation of individual study reports on the active substance.

In each section of this document, the following headings (a-b)) occur:

a) Previous evaluation (2005-2011)

Under this heading study reports submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC are summarised. These studies have been re-evaluated for the purpose of the renewal in the light of current scientific and technical knowledge. The endpoints from the studies were also re-assessed and if considered relevant, re-calculated. However, full details from each study have not been repeated in this DRAR - therefore this DRAR is not a "stand-alone document" and for full reference sometimes the reader needs to consult the DAR (2005-2011).

b) Evaluation of additional data for the purpose of renewal of Annex I inclusion

Under this heading studies submitted prior to Annex I inclusion, but no evaluation of such material was presented in the form of Addenda to the DAR and studies that were submitted to support the application for renewal of Annex I inclusion are evaluated, i.e. new studies.

B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE**Applicant**

European Gibberellins Task Force (EGTF), comprising:

- Valent Biosciences Corporation (Sumitomo Chemical Agro Europe)
- Fine Agrochemicals Ltd
- Globachem NV

TSGE Consulting, UK acts on behalf of the EGTF

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(b) Alternative contact: [REDACTED]

Address: Fine Agrochemicals Ltd, Hill End House, Whittington, Worcester, WR5 2RQ, United Kingdom

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EUGATE II Member	Contact person
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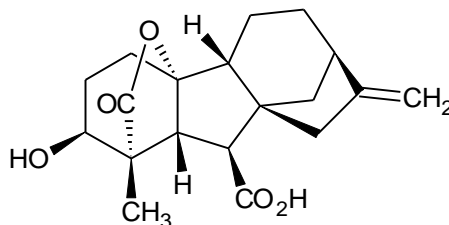
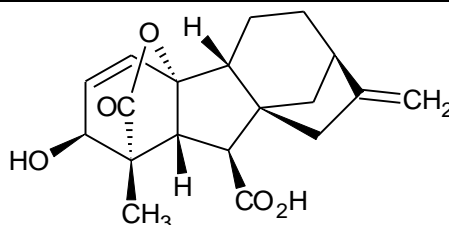
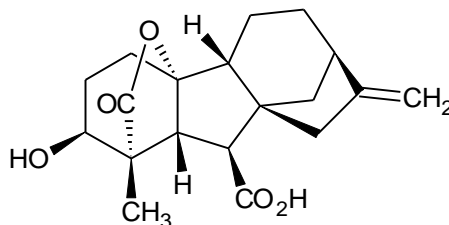
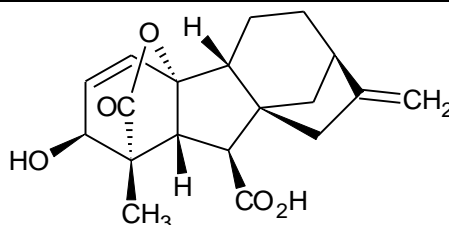
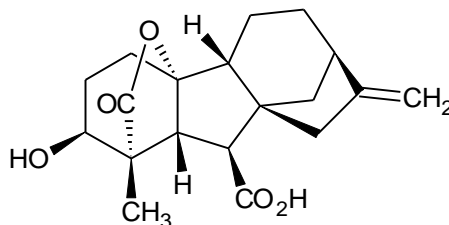
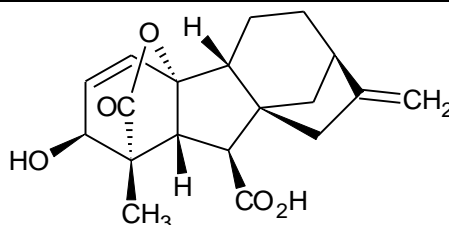
- Fine Agrochemicals Ltd.**

Address: Hill End House, Whittington,
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- Globachem NV**

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Lichtenberglaan 2019
3800 Sint-Truiden
Belgium

B.1.1.1. Common name proposed or ISO-accepted and synonyms	There is no ISO common name for this compound Synonyms are Gibberellins, GA4/7
B.1.1.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	GA ₄ : (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 GA ₇ : (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
CA	GA ₄ : (1 α ,2 β ,4 $\alpha\alpha$,4b β ,10 β)-2,4a-dihydroxy-1-methyl-8-methylenegibbane-1,10-dicarboxylic acid 1,4a-lactone GA ₇ :

	(1 α ,2 β ,4 $\alpha\alpha$,4 $\beta\beta$,10 β)-2,4a-dihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-dicarboxylic acid 1,4a-lactone					
B.1.1.3. Producer’s development code number	EU Gibberellic Acid Task Force: Not applicable					
B.1.1.4. CAS, EEC and CIPAC numbers						
CAS	GA4: 468-44-0 GA7: 510-75-8 GA4/GA7 mixture: 8030-53-3					
EEC	GA4: 207-406-9 GA7: 208-117-0					
CIPAC	904					
B.1.1.5. Molecular and structural formula, molecular mass						
Molecular formula	GA4 = C ₁₉ H ₂₄ O ₅ GA7 = C ₁₉ H ₂₂ O ₅					
Structural formula	<table><tr><td>GA4</td><td></td></tr><tr><td>GA7</td><td></td></tr></table>		GA4		GA7	
GA4						
GA7						
Molecular mass	GA4 332.40 g/mol GA7 330.40 g/mol					
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information - data provided separately (Vol.4)					
B.1.1.7. Specification of purity of the active substance in g/kg	CONFIDENTIAL information - data provided separately (Vol.4)					
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities						
<i>B.1.1.8.1. Additives</i>	CONFIDENTIAL information - data provided separately (Vol.4)					
<i>B.1.1.8.2. Significant impurities</i>	CONFIDENTIAL information - data provided separately (Vol.4)					
<i>B.1.1.8.3. Relevant impurities</i>	CONFIDENTIAL information - data provided separately (Vol.4)					

B.1.1.9. Analytical profile of batches	CONFIDENTIAL information - data provided separately (Vol.4)
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B.1.2. REFERENCES RELIED ON

None