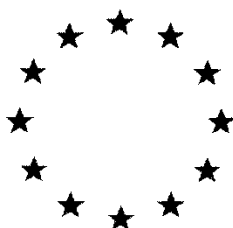


# *European Commission*



**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 (PPP) – Novagib**

Rapporteur Member State : SCovenia  
Co-Rapporteur Member State: SCovakia

## Version History

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

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**Introduction**

This document has been prepared to evaluate the European Gibberellin 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).

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

The representative formulation “Novagib” contains 10 g/L pure gibberellin and is formulated as soluble concentrate (SC). The formulation is plant growth regulator used on apples and pears.

**Previous EU assessment**

The dossier to support the first inclusion of gibberellin 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 August 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**

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 gibberellin 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. IDENTITY****B.1.1. IDENTITY OF THE PLANT PROTECTION PRODUCT**

<b>B.1.1.1. Applicant</b>	<p>Name: EU Gibberellin Task Force (EGTF) represented by TSGE Consulting Ltd, UK  Address: TSGE Consulting, Concordia House,  St James Business Park,  Grimbald Crag Court,  Knaresborough, N Yorkshire,  HG5 8QB, UK</p> <p>Contact: [REDACTED]  [REDACTED]</p> <p>Tel: [REDACTED]  [REDACTED] (direct line)</p> <p>email: [REDACTED]</p> <p>Alternative contact: [REDACTED]  Address: Fine Agrochemicals Limited, Hill End  House, Whittington, Worcester, WORCS.  WR5 2RQ</p> <p>Tel: [REDACTED]  E-mail: [REDACTED]</p>
<b>B.1.1.2. Producer of the plant protection product</b>	<p>Fine Agrochemicals Ltd  Address: Hill End House, Whittington,  Worcester, WR5 2RQ, UK</p>
<b>B.1.1.3. Trade name or proposed trade name and producer's development code number of the plant protection product</b>	<p>Trade name: Novagib  Code number: -</p>
<b>B.1.1.4. Detailed quantitative and qualitative information on the composition of the plant protection product</b>	

B.1.1.4.1. <i>Composition of the plant protection product</i>	Pure active substance	
	content of pure active substance:	10 g / l  (1% w / w)
	limits :	8.5-11.5 g/l  0.85 – 1.15% w/w
	Technical active substance	
	content of technical active substance :	11.1 g / l  (1.11 % w / w)
	limits :	9.435-12.765 g/l  (0.9435 – 1.2765% w / w)
	at a minimum purity of the technical active substance of 90%	
B.1.1.4.2. <i>Information on the active substances</i>	Type	Name/Code Number
	ISO common name	Gibberellins, GA4/7
	CAS No	GA4: 468-44-0 GA7: 510-75-8 GA4A7 mixture: 8030-53-3
	EC No	GA4: 207-406-9 GA7: 208-117-0
	CIPAC No	904
	Salt, ester anion or cation present	NA
B.1.1.4.3. <i>Information on safeners, synergists and co-formulants</i>	CONFIDENTIAL information – please see Vol.4	
B.1.1.5. <b>Type and code of the plant protection product</b>	soluble concentrate (code: SC)	
B.1.1.6. <b>Function</b>	Plant growth regulator	
B.1.1.7. <b>Field of use envisaged</b>	Agriculture, orchards.	
B.1.1.8. <b>Effects on harmful organisms</b>	Not applicable for Novagib. Novagib containing gibberellins (GA4/GA7). Gibberellins (GA4/GA7) is plant growth regulator and does not act against harmful organisms, against weeds, insects, fungi or other pests. The mode of action of gibberellins is complex and the molecular basis of their effect of cell elongation is currently not fully understood. However, it is known that they induce the transcription of genes responsible for cell elongation in plants and upregulate expression of enzymes known to loosen cell wall structures. Increased plasticity of cellular wall structures then enhance cell expansion. The biological activity of different groups of gibberellins varies with plant species. For example, while golden delicious apple russet was significantly reduced by GA4/GA7, GA3 showed no significant effect (Werthheim 1982).	

**B.1.2. REFERENCES RELIED ON**

<b>Data Point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
-	-	-	-	-	-	-	-	-