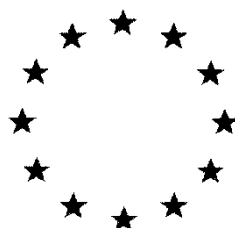


European Commission



**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.3 (PPP) – Novagib

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

Version History

When	What
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B.3. DATA ON APPLICATION AND EFFICACY

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.3.1. FIELD OF USE ENVISAGED

Plant protection product Novagib (product code: -) is used outdoors as plant growth regulator in agriculture, in orchards: apples and pears as representative uses for reduction of russet and fruit cracking, improvement of fruit and fruit set quality.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

Not applicable for Novagib. Novagib containing gibberellins (GA4/GA7) at a concentration of 10 g/L. 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.3.3. DETAILS OF INTENDED USE

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/ha)	Water l/ha min max	g a.i./ha min max (*) (g/ha)		
Apple (<i>Malus domestica</i> MABS)	EU	Novagib	F	Plant growth regulator. Reduction of russet and cracking, Improvement of fruit quality / skin finish	SL	10	Spraying	From BBCH 69 to BBCH 74 (April-July)	a) 1 b) 4	7 days	a) 0.25-1.66 b) 1-6.64	300-1,000	a) 2.5-5 b) 10-20	n.a.	Dose rate: 25-50 mL PPP/100 L (=0.25-0.5 L PPP/ha)
Pear (<i>Pyrus communis</i> PUYCO)	EU	Novagib	F	Plant growth regulator. Fruit set improvement	SL	10	Spraying	BBCH62-BBCH69 (March-May)	a) 1 b) 1	-	a) 1.2-4 b) 1.2-4	300-1,000	a) 12 b) 12	n.a.	Dose rate: 120 mL PPP/100 L (=1.2 L PPP/ha)
Pear (<i>Pyrus communis</i> PUYCO)	EU	Novagib	F	Plant growth regulator. Fruit set improvement	SL	10	Spraying	BBCH62-BBCH69 (March-May)	a) 1 b) 2	3 days	a) 0.6-2 b) 1.2-4	300-1,000	a) 6 b) 12	n.a.	Dose rate: 60 mL PPP/100 L (=0.6 L PPP/ha)

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

B.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Novagib is applied to apples at 2.5 - 5 g a.s./ha (0.25-0.5 L PPP/ha) and to pears at 6 -12 g a.s./ha (0.6-1.2 L PPP/ha). GA4/7 is present in plant protection product Novagib at a concentration of 10 g/L.

B.4.1. METHOD OF APPLICATION

Novagib is intended to be applied using tractor mounted orchard sprayer and using water volumes of 300 - 1000 l/ha for apples and pears.

B.4.2. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

Maximum number of applications:

For Apples: Up to 4 applications at 7 to 10 day intervals are recommended.

For Pears: One to two applications are recommended depending on the growth stage.

Timing of applications and growth stages of crops or plants to be protected:

For Apples: BBCH 69 – 74 (April – July)

For Pears: BBCH 62 – 69 (March – May)

Duration of protection:

No relevant, Novagib is a plant growth regulator.

B.5. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

Not relevant as apples and pears are permanent crops.

B.5.1. PROPOSED INSTRUCTIONS FOR USE

Propose instructions for use were not provided for the renewal of the active substance. The applicant refers to product label but product label was not included. However, detailed consideration of proposed instructions for use will be fully assessed in the context of subsequent product authorisation process.

B.5.2. EFFECTIVENESS

No effectiveness data were provided for the renewal of the active substance. Detailed consideration of efficacy will be fully assessed in the context of subsequent product authorisation process when a full biological assessment dossier will be required.

B.5.3. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

No data were provided for the renewal of the active substance. Detailed consideration of information on the development of resistance will be fully assessed in the context of subsequent product authorisation process when a full biological assessment dossier will be required. Gibberellins (GA4/GA7) is plant growth regulator and does not act against weeds, insects, fungi or other pests and therefore occurrence of resistance is not relevant. However, based on the function of gibberellins (GA4/GA7) as plant growth regulator, there is no expectation of resistance in treated crops.

B.5.4. ADVERSE EFFECTS ON TREATED CROPS

No data were provided for the renewal of the active substance. Detailed consideration of adverse effects on treated crops will be fully assessed in the context of subsequent product authorisation process when a full biological assessment dossier will be required.

B.5.5. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

No data were provided for the renewal of the active substance. Detailed consideration of observations on other undesirable or unintended side-effects will be fully assessed in the context of subsequent product authorisation process when a full biological assessment dossier will be required.

B.5.6. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.3.9.	anonym	2005	Result of the trial with plant strengtheners on fruit trees 2004. No. 04905W57001/02/03/04 GEF, unpublished	N	N	N	Globoc hem	IIA, 3.4/04 in original DAR