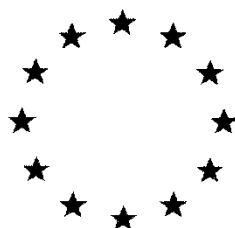


European Commission



**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.4 (PPP) – Novagib

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

Version History

When	What
2019/April	Initial DRAR

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B.4. FURTHER INFORMATION

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.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

There are no precautions needed regarding the risk to the non-target birds, mammals, bees, non-target arthropods other than bees, soil meso- and macro-fauna, microorganisms, non-target plants and other non-target organisms. The risk assessment for aquatic organisms could not be finalized; therefore it is not clear if precautions are needed.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Please refer to safety data sheet in Appendix 1 below.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

Please refer to safety data sheet in Appendix 1 below.

B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

Novagib will be packed in co-extruded blow-moulded containers made from high density polyethylene and polyacrylamide (PE/PA COEX)

Capacity: 1L, 5L, 10L and 20L containers

Opening: Wide-necked (minimum 42/63 mm)

Closure: Injection moulded induction heat sealed white screw cap

The packaging is designed for Agchem use and is acceptable for the subsidiary regulations for the transport of dangerous goods. All bottles contain a heat sealed induction cap and have been found to be stable commercially.

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING**B.4.5.1. Neutralisation procedure**

Please refer to safety data sheet in Appendix 1 below.

B.4.5.2. Controlled incineration

Dispose of contaminated packaging in accordance with governmental or local waste authority regulations. Get advice from local authorities on incineration procedures.

Appendix 1 . Safety data sheet-Novagib

Novagib

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SAFETY DATA SHEET

SECTION 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

- Product Name: Novagib

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Use of the substance/mixture: Plant growth regulator for professional use only
- Not to be used for: Anything other than professional use

1.3 Details of the supplier of the safety data sheet

- Name of Supplier: Fine Agrochemicals Limited
- Address of Supplier: Hill End House, Whittington, Worcester, WR5 2RQ. UK
- Telephone: +44 (0)1905 361800
- Responsible Person: Safety Department
- Email: sds@fine.eu

1.4 Emergency telephone number

- Emergency Telephone: +44 (0)1905 361800 (Office hours 9am-5pm GMT)
- Or call local Poison Control Centre

SECTION 2 Hazards identification

2.1 Classification of the substance or mixture

- DPD: No longer applicable
- CLP: Not Classified

2.2 Label elements

- Symbols
Signal Word: None assigned
- Hazard phrases
None assigned
- Precautionary Phrases
None assigned

2.3 Other hazards

- To avoid risks to human health and the environment, comply with the instructions for use (EUH401).

SECTION 3 Composition/information on ingredients

3.1 Mixtures

- Gibberellins A 4/7 Technical
CAS Number: 468-44-0/510-75-8
EC Number: None assigned
Categories: None assigned
H Phrases: None assigned
Concentration: 10 g/l

SAFETY DATA SHEET - Novagib

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SECTION 4 First aid measures**4.1 Description of first aid measures**

- Contact with eyes
If substance has got into eyes, immediately wash out with plenty of water for at least 15 minutes
Seek medical attention if irritation persists
- Contact with skin
Remove contaminated clothing immediately and drench affected skin with plenty of water. Then wash with soap and water
Seek medical attention if irritation persists
- Ingestion
If swallowed: Call a poison center or doctor/physician if you feel unwell, rinse mouth
- Inhalation
Keep warm and at rest, in a half upright position. Loosen clothing
Remove promptly anything of a restrictive nature
Seek medical advice if necessary

4.2 Most important symptoms and effects, both acute and delayed

- No information available

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically

SECTION 5 Fire-fighting measures**5.1 Extinguishing media**

- In case of fire use foam, carbon dioxide or dry agent

5.2 Special hazards arising from the substance or mixture

- Large volumes may penetrate soil and contaminate groundwater
- Seek expert advice for removal and disposal of all contaminated materials and wastes

5.3 Advice for firefighters

- Flammability: Non-flammable
- Wear chemical protection suit and positive-pressure breathing apparatus

SECTION 6 Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- Wear protective clothing as per section 8

6.2 Environmental Precautions

- Do not allow to enter public sewers and watercourses
- Contain spillage by any means possible
- If contamination of drainage systems or water courses is unavoidable, immediately inform appropriate authorities

6.3 Methods and material for containment and cleaning up

- Absorb spillage in suitable inert material
- Place in sealable container
- Remove contaminated material to safe location for subsequent disposal

6.4 Reference to other sections

SAFETY DATA SHEET - Novagib

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SECTION 6 Accidental release measures (....)

- See Section 8

SECTION 7 Handling and storage**7.1 Precautions for safe handling**

- Ensure adequate ventilation
- Keep away from food, drink and animal feedingstuffs
- The usual precautions for handling chemicals should be observed
- Use good personal hygiene practices
- Wash thoroughly after use

7.2 Conditions for safe storage, including any incompatibilities

- Keep in a cool, dry, well ventilated place
- Stable in original container for at least 2 years at 18 - 22°C

7.3 Specific end use(s)

- Restricted to professional users

SECTION 8 Exposure controls/personal protection**8.1 Control parameters**

- To avoid risks to man and the environment comply with instructions for use

8.2 Exposure controls

- No respiratory protection is needed if ventilation/extraction is adequate, otherwise wear approved dust mask
- Wear suitable protective clothing and gloves
- Contaminated clothing should be laundered before reuse

SECTION 9 Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Appearance: colourless, mobile, Liquid
- Odour: Odourless
- pH: pH 4-6 at 1 % concentration
- Melting point/Range: Not applicable
- Boiling Point/Range: 180 °C (solvent)
- Flashpoint: 86 °C
- Evaporation Rate: No information available
- Flammability: Not applicable
- Vapour Pressure: 10.7 Pa @ 20°C (solvent)
- Vapour Density: No information available
- Density: 1.04 g/ml
- Solubility in water: Miscible with water
- Partition Coefficient (n-Octanol/Water): -0.92 log Pow (solvent)
- Autoignition Temperature > 400°C
- Viscosity: 57,8 mm²/s
- Explosive Properties: Non-explosive
- Oxidising Properties: Non oxidising

9.2 Other information

SAFETY DATA SHEET - Novagib

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SECTION 10 Stability and reactivity

10.1 Reactivity

- Stable in original container for at least 2 years at 18 - 22°C

10.2 Chemical stability

- Considered stable under normal conditions

10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose

10.4 Conditions to avoid

- Keep away from heat and sources of ignition

10.5 Incompatible materials

- Incompatible with strong oxidizing substances

10.6 Hazardous Decomposition Products

- Decomposition products may include toxic and irritant fumes

SECTION 11 Toxicological information

11.1 Information on toxicological effects

- LD50 (oral) : (rat) >4000 mg/kg
- LC50 (inhalation) : (rat) >5.41 mg/l/4hr
- LD50 (dermal) : (rat) >4000 mg/kg
- Contact with eyes: (rabbit) Mildly irritating to eyes (not sufficient for classification)
- Contact with skin: (rabbit) Non irritant
- Corrosivity: Non Corrosive
- Sensitisation: Sensitization (guinea pig) : None
- Repeated Dose Toxicity: No information available
- Carcinogenicity: No evidence of carcinogenic effects
- Mutagenicity: No evidence of mutagenic effects
- Reproductive Effects: No evidence of reproductive effects

SECTION 12 Ecological information

12.1 Toxicity

- LC50 (fish): >100 mg/l (24hr)
- EC50 (Daphnia magna): > 100 mg/l (48hr)
- EC50 (Algae): 60 mg/l (72hr)
- EC50 (Lemna): >100 mg/l (7day)
- LC50 (Bird): >2250 mg/kg (ai)
- LD50 (bee) : >87 µg/bee (ai) (Oral), >100 µg/bee (ai) (Contact)
- Earthworm: > 48 mg a.s/kg dw soil
- LR50 (Aphidius) : >40 L/ha (48hr)
- LR50 (Typhlodromus): >80 L/ha (7 day)

12.2 Persistence and degradability

- Readily biodegradable

12.3 Bioaccumulation Potential

- No information available

12.4 Mobility in soil

- No information available

12.5 Results of PBT and vPvB assessment

SAFETY DATA SHEET - Novagib

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SECTION 12 Ecological information (....)

- Not applicable
- 12.6 Other Adverse Effects
- No information available

SECTION 13 Disposal considerations

- 13.1 Waste treatment methods
- Do not discharge into drains or the environment, dispose to an authorised waste collection point
- Incineration by an approved method could be considered
- Do not reuse empty containers

SECTION 14 Transport information

- 14.1 UN Proper Shipping Name
- UN No.: Not Classified
- 14.2 Proper Shipping Name
- Proper Shipping Name: Not Classified
- 14.3 Transport hazard class(es)
- Hazard Class: Not Classified
- 14.4 Packing group
- Packing Group: Not Classified
- 14.5 Environmental hazards
- Not classified as hazardous for marine transport
- 14.6 Special precautions for user
- Restricted to professional users
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code
- Not applicable

SECTION 15 Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Registered under regulation 1107/2009/EC
- 15.2 Chemical Safety Assessment
- A chemical safety report is not required since the product is already registered under the crop protection regulation 1107/2009/EC.

SECTION 16 Other information

For further information on the product and product use refer to the product label.

Reason for Revision: New format, Removal of DPD data / new data

The information provided in this Safety Data Sheet is accurate as of the date indicated and is compiled on the basis of Fine Agrochemicals' current knowledge and experience. It does not purport to be an exhaustive assessment. The data is supplied in good faith and is intended to provide health and safety guidance on the handling, storage, transportation and disposal of the material in / from the package in which it is supplied. It is not a substitute for the product label which must be consulted in tandem when applying the material. The information is specific to the material only and may not be valid when it is mixed or used with other materials. Fine Agrochemicals

SAFETY DATA SHEET - NovagibRevision: 26 Oct 2016

SECTION 16 Other information (....)

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B.4.6. REFERENCES RELIED ON

None.