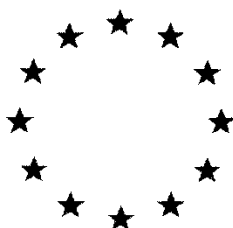


European Commission



**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 (AS)

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

Version History

When	What
2019/April	Initial DRAR

Table of contents

B.4. FURTHER INFORMATION	4
B.4.1. METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE	5
B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION	5
B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT	5
B.4.4. REFERENCES RELIED ON	5
B.4.5. APPENDIX 1	6

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).

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.

B.4.1. METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE

Please refer to safety data sheet below.

B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION

Please refer to safety data sheet below.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

Please refer to safety data sheet below.

B.4.4. 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.4.1 B.4.2 B.4.3	-	2017	Safety Data Sheet – Gibberellins GA4/7 Revision: 7 Jun 2017	N	N	N	Fine Agrochemicals	N

B.4.5. APPENDIX 1

Safety data sheet for the active substance.

Gibberellins GA4/7 Technical

Revision: 7 Jun 2017

SAFETY DATA SHEET

SECTION 1 Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- Product Name: Gibberellins GA4/7 Technical

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

- Use of the substance/mixture: Horticultural plant growth regulator for 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**

- CLP: Not Classified

2.2 Label elements

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

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 Substances**

- Gibberellins GA4/7 Technical
 - CAS Number: 8030-53-5
 - EC Number: None assigned
 - Categories: None assigned
 - H Phrases: None assigned
 - Concentration: 90% min

SAFETY DATA SHEET - Gibberellins GA4/7 Technical
Revision: 7 Jun 2017

SECTION 3 Composition/information on ingredients (....)

- GA4: Chemical Name (3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propenoazuleno[1,2,b]furan-4-carboxylic acid
CAS Number: 468-44-0
EC Number: 207-409-9
Categories: None assigned
H Phrases: None assigned
Concentration: 55% min
 - GA7: Chemical Name (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 Number: 510-75-8
EC Number: 208-117-0
Categories: None assigned
H Phrases: None assigned
Concentration: 35% max
-

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

SAFETY DATA SHEET - Gibberellins GA4/7 Technical
Revision: 7 Jun 2017

SECTION 5 Fire-fighting measures (....)

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

- 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: white, powder
 - Odour: None
-

SAFETY DATA SHEET - Gibberellins GA4/7 Technical
Revision: 7 Jun 2017

SECTION 9 Physical and chemical properties (....)

- pH: pH 3.9 at 1 % concentration
- Melting point/Range: 205-231°C
- Boiling Point/Range: No information available
- Flashpoint: None
- Evaporation Rate: Not applicable
- Flammability: Non-flammable
- Vapour Pressure: 1×10^{-5} Pa at 25°C
- Vapour Density: Not applicable
- Density: 1.27 g/cm³ at 20°C
- Solubility in water: 127mg/l at 20°C
- Partition Coefficient (n-Octanol/Water): Log Pow = 2.47 (pH4), 0.146 (pH7), -1.23 (pH10)
- Autoignition Temperature: No data
- Viscosity: Not applicable
- Explosive Properties: Non-explosive
- Oxidising Properties: Non oxidising

9.2 Other information

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) >5000mg/kg
- LC50 (inhalation) : (rat) >2.98 mg/l/4hr
- LD50 (dermal) : (rat) > 2000 mg/kg
- Contact with eyes: Non irritant
- Contact with skin: Non irritant
- Corrosivity: Non Corrosive
- Sensitisation: Sensitization (guinea pig) : None
- Repeated Dose Toxicity: NOAEL 650 mg/kg/day, 90 day study dog
- Carcinogenicity: No evidence of carcinogenic effects
- Mutagenicity: No evidence of mutagenic effects

SAFETY DATA SHEET - Gibberellins GA4/7 Technical
Revision: 7 Jun 2017

SECTION 11 Toxicological information (....)

- Reproductive Effects: (rat) NOAEL 300 mg/kg (mat), NOAEL 300 mg/kg (dev), NOAEL 1000mg/kg (repro)
-

SECTION 12 Ecological information

12.1 Toxicity

- LC50 (fish): (O mykiss) >100 mg/l (96hrs)
- EC50 (Daphnia magna): > 100mg/l (48hrs)
- EC50 (Algae): (P subcapitata) >100 mg/l (96hrs)
- EC50 (Lemna): No data
- LC50 (Bird): (Bobwhite quail) > 2250 mg/kg
- LD50 (bee) : >87µg/bee (Oral), No data (Contact)
- Earthworm: LC50 >1250 mg as/kg dw soil
- LR50 (Aphidius) : > 40g/ha
- LR50 (Typhlodromus): >40g/ha

12.2 Persistence and degradability

- Readily biodegradable

12.3 Bioaccumulation Potential

- Bioaccumulation is insignificant

12.4 Mobility in soil

- No information available

12.5 Results of PBT and vPvB assessment

- 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
-

SAFETY DATA SHEET - Gibberellins GA4/7 Technical
Revision: 7 Jun 2017

SECTION 14 Transport information (....)

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

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:

-

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 assumes no responsibility for any incidental or consequential damages arising from the use of this data and expressly disclaims any liability for loss, injury, damages or expenses arising from any failure to take into account the information or advice contained in this document.