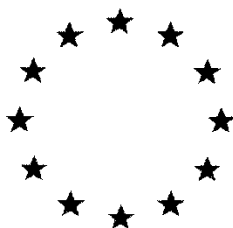


# *European Commission*



**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)**

### **List of End Points**

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

**Identity, Physical and Chemical Properties, Details of Uses, Further Information  
(Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)**

Active substance (ISO Common Name)

There is no ISO common name for this compound

Synonyms are Gibberellin(s), GA4/7, GA4/GA7, GA4/GA7

Function (*e.g.* fungicide)

Plant growth regulator

Rapporteur Member State

Slovenia

Co-rapporteur Member State

Slovakia

**Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)**

Chemical name (IUPAC)

GA<sub>4</sub>:  
(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<sub>7</sub>:  
(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

Chemical name (CA)

GA<sub>4</sub>:  
(1 $\alpha$ ,2 $\beta$ ,4 $\alpha\alpha$ ,4b $\beta$ ,10 $\beta$ )-2,4a-dihydroxy-1-methyl-8-methylenegibbane-1,10-dicarboxylic acid 1,4a-lactone

GA<sub>7</sub>:  
(1 $\alpha$ ,2 $\beta$ ,4 $\alpha\alpha$ ,4b $\beta$ ,10 $\beta$ )-2,4a-dihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-dicarboxylic acid 1,4a-lactone

CIPAC No

904

CAS No

GA<sub>4</sub>: 468-44-0

GA<sub>7</sub>: 510-75-8

GA<sub>4</sub>/GA<sub>7</sub> mixture: 8030-53-3

EC No (EINECS or ELINCS)

GA<sub>4</sub>: 207-406-9

GA<sub>7</sub>: 208-117-0

FAO Specification (including year of publication)

Not available

Minimum purity of the active substance as manufactured

1. Fine Agrochemicals Ltd.:  
GA<sub>4</sub>: 905-919 g/kg  
GA<sub>7</sub>: 19.5-27 g/kg  
**GA<sub>4</sub>/GA<sub>7</sub>: min. 924 g/kg**

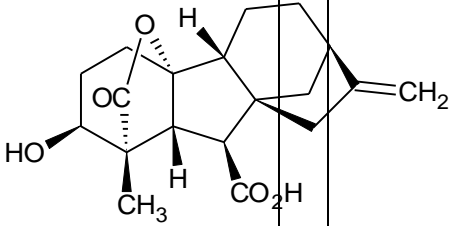
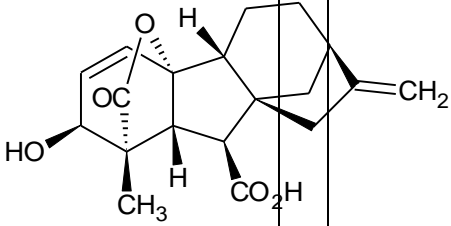
2. Globachem NV:  
GA<sub>4</sub>: 648-653 g/kg  
GA<sub>7</sub>: 248-253 g/kg  
**GA<sub>4</sub>/GA<sub>7</sub>: min. 885 g/kg**

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

Molecular formula

Molar mass

Structural formula

3. Valent Biosciences Ltd.:	GA4: 631-778 g/kg GA7: 130-288 g/kg <b>GA4/GA7: min. 852 g/kg</b>
	Fumonisin B1, B2 sum 200 µg/kg based on Commission Regulation (EC) No 1881/2006 of 19 December 2006
	GA4 = C <sub>19</sub> H <sub>24</sub> O <sub>5</sub> GA7 = C <sub>19</sub> H <sub>22</sub> O <sub>5</sub>
	GA4 332.40 g/mol GA7 330.40 g/mol
GA4	
GA7	

**Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

Melting point (state purity)	Melting point: 205.5-231 °C (99% w/w); 205.6-224.5 °C (92.5% w/w)
Boiling point (state purity)	Boiling point not applicable as decomposition was observed at $\geq 210$ °C (99% w/w) / $\geq 224.5$ °C (92.5% w/w).
Temperature of decomposition (state purity)	$\geq 210$ °C (99% w/w) / $\geq 224.5$ °C (92.5% w/w).
Appearance (state purity)	White, odourless powder (99 and 92.5% w/w)
Vapour pressure (state temperature, state purity)	c.a. $1 \times 10^{-5}$ Pa at 25 °C (99% w/w) GA4: 0.16 Pa and GA7: 0.067 Pa at 22 °C (90.8% w/w)
Henry's law constant (state temperature)	Henry's law constant (calculated): $2.0 \times 10^{-5}$ Pa m <sup>3</sup> mol <sup>-1</sup> at 20 °C (99% w/w)
Solubility in water (state temperature, state purity and pH)	At 20 °C (99% w/w): Pure water – 127 mg/L pH 4 buffer – 141 mg/L pH 7 buffer – 40 mg/L pH 9 buffer – >250 mg/L  At 20 °C (90.6% w/w): Pure water – 310 mg/L pH 4 buffer – 379 mg/L pH 7 buffer – >250 mg/L pH 9 buffer – >250 mg/L

Solubility in organic solvents  
(state temperature, state purity)

At 20 °C (99% w/w):  
n-Hexane – <0.5 mg/L  
Xylene – 78.9 mg/L  
1,2-Dichloroethane – 3380 mg/L  
Methanol – >250 g/L  
Acetone – >250 g/L  
Ethyl acetate – 56 g/L

at 20 °C (92.5% w/w):  
Pyridine – 41 g/L  
Propan-2-ol – 243 g/L  
Tetra-hydro-furfuryl alcohol – 272 g/L  
Methanol – 378 g/L  
Acetone – 186 g/L  
Ethyl acetate – 69 g/L

At 20 °C (90.6% w/w):  
Xylene – 0.0096 g/L  
1,2-Dichloroethane – 2.0 g/L  
n-Hexane – <0.0003 g/L  
n-Octanol – 70 g/L

Surface tension  
(state concentration and temperature, state purity)

64 mN/m at 114 mg/L at 20 °C (99% w/w)  
The test substance is not surface active.

Partition coefficient  
(state temperature, pH and purity)

Log P<sub>ow</sub> at 20 °C (99% w/w):  
pH 4 – 2.47  
pH 7 – 0.146  
pH 10 – -1.23

Log P<sub>ow</sub> at 20 °C (90.6% w/w):  
pH 4 – 2.5  
pH 7 – -0.05  
pH 10 – -1.2

Dissociation constant (state purity)

pK<sub>a</sub> = 4.3 at 23 °C (99% w/w)  
The dissociated species is the corresponding carboxylate anion.

UV/VIS absorption (max.) incl.  $\epsilon$   
(state purity, pH)

The IR, <sup>1</sup>H NMR, <sup>13</sup>C NMR and MS spectra of GA4/7 support the chemical structure of gibberellins.

A methanol solution of GA4/7 absorbed wavelengths at <250 nm. No maxima were observed >210 nm. Molar absorption coefficients ( $\epsilon$ ) at or above 298 nm were <10 L cm<sup>-1</sup> mol<sup>-1</sup>.

GA4 and GA7 are enantiomerically pure but given large number of stereogenic centres, analysis in plain polarised light would not confirm optical purity.

Flammability (state purity)

Not highly flammable (99 and 90.8% w/w)
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Explosive properties (state purity)

Not explosive (99 and 90.8% w/w)
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Oxidising properties (state purity)

Not oxidising (99 and 90.8% w/w)
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**Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)**  
**(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	g a.s. /hL min-max (l)	Water L/ha min-max	g a.s./ha min-max (l)		
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)

- |   |  |
|---|--|
| <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|--|

**Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)**

**Regulation (EC) N° 1107/2009 Article 8.1(g)**

**Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
None.															

- |   |   |
|---|---|
| <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|---|



**Further information, Efficacy**

**Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)**

No 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.

**Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)**

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.

**Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)**

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.

**Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)**

Activity against target organism

Not applicable

## Methods of Analysis

### Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	<ol style="list-style-type: none"> <li>1) Direct injection with internal standard. Quantification by HPLC-UV at 210 nm</li> <li>2) Direct injection method. Quantification by HPLC-UV at 204 nm</li> <li>3) Direct injection method. Quantification by HPLC-UV at 210 nm</li> </ol>
Impurities in technical a.s. (analytical technique)	<ol style="list-style-type: none"> <li>1) LC-MS, <math>m/z = 722.3 \rightarrow 334.3</math> for Fumonisin B1</li> <li>2) LC-MS/MS, <math>m/z = 722 \rightarrow 352</math> for Fumonisin B1 <math>m/z = 722 \rightarrow 334</math> for Fumonisin B1 LC-MS/MS, <math>m/z = 706 \rightarrow 336</math> for Fumonisin B2 <math>m/z = 706 \rightarrow 318</math> for Fumonisin B2</li> <li>3) LC-MS/MS, <math>m/z = 720.5 \rightarrow 157</math> for Fumonisin B1 <math>m/z = 704.5 \rightarrow 157</math> for Fumonisin B1</li> </ol>
Plant protection product (analytical technique)	<ol style="list-style-type: none"> <li>1) Direct injection internal standard method. Quantification by HPLC-UV at 210 nm</li> <li>2) Direct injection internal standard method. Quantification by HPLC-UV at 206 nm</li> </ol>

### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	Not required as no MRLs proposed and not possible to distinguish exogenous and natural gibberellins
Food of animal origin	Not required as no MRLs proposed and not possible to distinguish exogenous and natural gibberellins
Soil	GA4 and GA7
Sediment	N/A
Water surface	GA4 and GA7
drinking/ground	GA4 and GA7
Air	GA4 and GA7
Body fluids and tissues	Not required. Gibberellin GA4/7 is a non-volatile, low risk active substance that is not classified as toxic (T) or very toxic (T+).

#### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no residue definition and no MRLs are proposed.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no residue definition and no MRLs are proposed.

Soil (analytical technique and LOQ)	<p>Extracted with water:methanol:formic acid mixture. LC-MS/MS. Ion transitions (m/z):331→243 (GA4) and 329→223 (GA7) (quantification); 331→225 (GA4) and 329→241 (GA7) (confirmation) LOQ: 0.01 mg/kg</p>
Water (analytical technique and LOQ)	<p>Surface and drinking water: Extracted with SPE cartridge (C18, polar). LC-MS/MS. LOQ: 10 µg/L (drinking), 0.11 µg/L (surface).</p>
Air (analytical technique and LOQ)	<p>Not required. Gibberellin GA4/7 is a non-volatile, low risk active substance that is not classified as T+, T, Xi or Xn.</p>
Body fluids and tissues (analytical technique and LOQ)	<p>Not required. Gibberellin GA4/7 is a non-volatile, low risk active substance that is not classified as toxic (T) or very toxic (T+).</p>

**Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)**

Substance	Gibberellins GA4, GA7
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>1</sup> :	None
Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	none

<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>2</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

## Impact on Human and Animal Health

### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability

Toxicokinetics

40% in females and 18% in males (based on urinary excretion within 48h in bale cannulated rats).		
	Low dose (65 mg/kg bw)	High dose (1000 mg/kg bw)
C <sub>max</sub> (µg eq/g)	5.3 (males) 7.9 (females)	154 (males) 141 (females)
T <sub>max</sub> (h)	1	2
	In some cases a second maximum was observed	
Initial T <sub>1/2</sub> (h)	1.1 to 1.8	4
Terminal T <sub>1/2</sub> (h)	5 to 6	
AUC (µg*h/g)	26.5 (males) 29.8 (females)	1223 (males) 1648 (females)
Distribution	Widely distributed (highest levels in kidney and liver)	
Potential for bioaccumulation	No evidence of accumulation.	
Rate and extent of excretion	Rapid and extensive (approximately 96%) within 24h; mainly via urine (18 – 39%), faeces (3 – 12%) and bile (56-73%).	
Metabolism in animals	Hydroxylation and glucuronide conjugation of parent compounds and hydroxyls.	
<i>In vitro</i> metabolism	No data available.	
Toxicologically relevant compounds (animals and plants)	Parent compound (GA4, GA7)	
Toxicologically relevant compounds (environment)	Parent compound (GA4, GA7)	

### Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD<sub>50</sub> oral

Rat LD<sub>50</sub> dermal

Rat LC<sub>50</sub> inhalation

Skin irritation

Eye irritation

Skin sensitisation

Phototoxicity

> 5000 mg/kg bw	
> 2000 mg/kg bw	
> 2.98 mg/L air/4h (nose only)	
Non-irritant	
Moderate irritant	Eye Irrit. 2, H319
Non-sensitising (M & K)	
Not phototoxic	

**Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)**

Target organ / critical effect	Liver (hepatocellular vacuolation in rats; increased weight in dogs) Kidney (tubule-interstitial nephritis and cortical fibrosis in rats and increased weight in dogs) Reduced food consumption and body weight gain (rats and dogs)	
Relevant oral NOAEL	90-day dog: 720 mg/kg bw/d 90-day rat: 500 mg/kg bw/d	
Relevant dermal NOAEL	Not required	
Relevant inhalation NOAEL	Not required	

**Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)**

<i>In vitro</i> studies	Not genotoxic	
<i>In vivo</i> studies	Not genotoxic	
Photomutagenicity	Not required	
Potential for genotoxicity	Probably Not genotoxic	

**Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)**

Long-term effects (target organ/critical effect)	No data available.	
Relevant long-term NOAEL	-	
Carcinogenicity (target organ, tumour type)	No data available.	
Relevant NOAEL for carcinogenicity	-	

**Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)****Reproduction toxicity**

Reproduction target / critical effect	<u>Parental</u> : kidney (nephropathy, urothelial medullary papilla hyperplasia, tubular epithelium medullary hyperplasia, tubular dilatation, medullary basophilic interstitium and medullary fibroplasia) and reduced body weight gain and food consumption. <u>Reproductive</u> : none <u>Offspring</u> : reduced body weight, body weight gain, spleen weight (F1, F2) and thymus weight.	
Relevant parental NOAEL	300 mg/kg bw/d	
Relevant reproductive NOAEL	1000 mg/kg bw/d	

Relevant offspring NOAEL	600 mg/kg bw/d	
<b>Developmental toxicity</b>		
Developmental target / critical effect	<u>Rabbit:</u> Maternal: mortality, clinical signs, reduced body weight gain and food consumption Developmental: results not reliable. <u>Rat:</u> no data.	
Relevant maternal NOAEL	Rabbit: 300 mg/kg bw/day (rabbit)	
Relevant developmental NOAEL	Rabbit: ≥300 mg/kg bw/day	

### Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No data available; not expected to be neurotoxic	
Repeated neurotoxicity	No data available; not expected to be neurotoxic	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Not needed	

### Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Not required
Endocrine disrupting properties	For the EATS modalities, although adversity was not observed, the dataset was not sufficient for both adversity and endocrine activity.
Studies performed on metabolites or impurities	Not required

### Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Manufacturing plant personnel are monitored annually. Medical exams are performed annually or every 3 years dependent upon role, and include spirometry, complete blood count and blood chemistry. No adverse reactions have been documented or reported and there have been no medical surveillance abnormalities to date (approximately 30 years).

### Summary<sup>3</sup> (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.3 mg/kg bw/d	Rat, multigeneration	1000
Acute Reference Dose (ARfD)	Not required		

<sup>3</sup> If available include also reference values for metabolites

Acceptable Operator Exposure Level (AOEL)	0.18 mg/kg bw/d	Rat, multigeneration; rabbit, developmental	300 x 0.18*
Acute Acceptable Operator Exposure Level (AAOEL)	Not required		

\* Including correction for limited oral absorption/bioavailability (18%).

### Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (Novagib, SC, 10 g/L GA4, GA7)

No data available; EFSA (2017) default values:  
Concentrate: 50%  
Spray dilution: 50%

### Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Tractor mounted spray application:  
7.12% of the AOEL without PPE (Work wear (arms, body and legs covered) M/L and A) (EFSA Calculator AOEM)

Manual knapsack application:  
210 % of the AOEL with PPE (Work wear (arms, body and legs covered), FP2, P2 and similar, gloves M/L and A)(EFSA Calculator AOEM)

Workers

8% of the AOEL without PPE but workers wearing work wear (EFSA Calculator)

Bystanders and residents

Bystander: not required  
Resident:  
Child, sum of all pathways (mean): 10 % of the AOEL per (EFSA Calculator)  
Adult, sum of all pathways (mean): 3 % of the AOEL (EFSA Calculator)

### Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Gibberellins (GA4/GA7)

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>4</sup> :

No listed in Annex VI

Peer review proposal <sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

Eye Irrit. 2, H319

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>5</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

## Residues in or on treated products food and feed

### Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

<b>Primary crops</b> (Plant groups covered) <b>OECD Guideline 501</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>Application(s)</b>	<b>DAT (days)</b>
	Fruit crops			
	Root crops			
	Leafy crops			
	Cereals/grass crops			
	Pulses/Oilseeds			
	Miscellaneous			
	The metabolism of gibberellins GA <sub>4</sub> in plants primarily involves conjugation with glucose to form 3-O-glucosides and glucosyl esters. Similarly from GA <sub>7</sub> metabolites like GA <sub>7</sub> -3-O-glucoside are formed. Further studies are not necessary.			
<b>Rotational crops</b> (metabolic pattern) <b>OECD Guideline 502</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>PBI (days)</b>	<b>Comments</b>
	Root/tuber crops			
	Leafy crops			
	Cereal (small grain)			
	Other			
Rotational crop and primary crop metabolism similar?	Since residues in treated apples and pears were <0.05 mg/kg no studies are required.			
<b>Processed commodities</b> (standard hydrolysis study) <b>OECD Guideline 507</b>	<b>Conditions</b>			
	20 min, 90°C, pH 4			
	60 min, 100°C, pH 5			
	20 min, 120°C, pH 6			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Since residues in treated apples and pears were <0.05 mg/kg no studies are required.			
Plant residue definition for monitoring (RD-Mo)	None.			
Plant residue definition for risk assessment (RD-RA)	None.			



Conversion factor (monitoring to risk assessment)

/

**Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)**

<b>OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)</b>	<b>Animal</b>	<b>Dose</b> (mg/kg bw/d)	<b>Duration</b> (days)	<b>N rate/comment</b>
<b>Animals covered</b>	Laying hen			
	Goat/Cow			
	Pig			
	Fish	mg/kg DM		
	Studies in poultry, pigs and ruminants are not necessary, since it is not possible to distinguish GA <sub>4</sub> /GA <sub>7</sub> in products of animal origin, resulting from consumption of naturally occurring residues, from those resulting from the use of plant growth regulators.			
Time needed to reach a plateau concentration in milk and eggs (days)	/			
Animal residue definition for monitoring (RD-Mo)	None.			
<b>OECD Guidance, series on pesticides No 31</b>				
Animal residue definition for risk assessment (RD-RA)	None.			
Conversion factor (monitoring to risk assessment)	/			
Metabolism in rat and ruminant similar (Yes/No)	/			
Fat soluble residues (Yes/No) <b>(FAO, 2009)</b>	/			

**Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)**

<b>Confined rotational crop study</b> (Quantitative aspect) <b>OECD Guideline 502</b>	No studies are required since orchards are permanent crops.
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**Field rotational crop study**  
**OECD Guideline 504**

No studies are required since orchards are permanent crops.

**Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)**  
**OECD Guideline 506**

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
			30 months			
High water content	apples, pears	-18	X			
High oil content						
High protein content						
High starch content						
High acid content						
Animal	Animal commodity	T (°C)	Stability (Month/Year)			
	Muscle					
	Liver					
	Kidney					
	Milk					
	Egg					
No studies were conducted on animal tissues, eggs and/or milk. Studies are not required.						

**Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator**

<b>Crop</b>	<b>Region/ Indoor (a)</b>	<b>Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)</b>	<b>Recommendations/comments (OECD calculations)</b>	<b>MRL proposals (mg/kg)</b>	<b>HR (mg/kg) (c)</b>	<b>STMR (mg/kg) (d)</b>
<b>Representative uses</b> (row to be deleted if not relevant)						
Apples	North EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
Apples	South EU	<b>5 x &lt;0.05</b>	None	None	0.05	0.05
Pears	North EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
Pears	South EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
<b>Summary of the data on formulation equivalence OECD Guideline 509</b>						
<b>Crop</b>	<b>Region</b>	<b>Residue data (mg/kg)</b>	<b>Recommendations/comments</b>			
Apples	North EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
Apples	South EU	<b>5 x &lt;0.05</b>	None	None	0.05	0.05
Pears	North EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
Pears	South EU	<b>2 x &lt;0.05</b>	None	None	0.05	0.05
<b>Summary of data on residues in pollen and bee products</b> (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
<b>Product(s)</b>	<b>Region</b>	<b>Residue data (mg/kg)</b>	<b>Recommendations/comments</b>			
Honey	China	GA <sub>4</sub> : 0.000053, 0.000067, 0.000218, 0.000393, 0.000411, 0.000412, 0.000469, 0.000469, 0.000471, 0.000474, 0.000475, 0.000479, 0.000493, 0.000507, 0.000518, 0.000523, 0.000582		None	0.000471	0.000582
Honey	China	GA <sub>7</sub> : 17 x n.d. (LD = 0.0000147 mg/kg)		None	0.000015	0.000015

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
- (b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring and Risk Assessment**.
- (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).
- (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

### **Inputs for animal burden calculations**

No calculations are required.

**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)  
OECD Guideline 505 and OECD Guidance, series on pesticides No 73**

No calculations are required.

### **STMR calculations**

No calculations are required.

Conversion Factors (CF) for monitoring to risk assessment

Not applicable.



**Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)**  
**OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96**

Studies are not required since residues are <LOQ.

**Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)**  
**Including all uses** (representative uses and uses related to an MRL application).

**ADI**

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

0.3 mg/kg bw per day

Highest TMDI: 1.3 % ADI (FR, toddler)

No calculations are necessary.

No calculations are necessary

No calculations are necessary

LOQ (0.05 mg/kg) for plant and animal products.

**ARfD**

IENTI (% ARfD), according to EFSA PRIMo

NESTI (% ARfD), according to (to be specified)

Factors included in IENTI and NESTI

Not allocated.

No calculations are necessary

No calculations are necessary

/

**Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L**

Not relevant.

**Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)**

GA<sub>4/7</sub> is temporarily included on Annex IV Regulation (EC) No. 396/2005. Applicant and RMS propose that GA<sub>4/7</sub> should remain on Annex IV Regulation (EC) No. 396/2005.

## Environmental fate and behaviour

### Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	GA4: 39.2-55.4% AR after 58 days (4 soils, 20°C) GA7: 27.8-50.4% AR after 58 days (4 soils, 20°C)
Non-extractable residues after 100 days	GA4: 37.0-48.9% AR after 58 days (4 soils, 20°C) GA7: 42.0-53.9% AR after 58 days (4 soils, 20°C)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Although several major metabolites were observed (>10% AR), these are considered to be of no environmental concern due to the natural occurrence of the active substance.

### Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	No data submitted, not required
Non-extractable residues after 100 days	No data submitted, not required
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted, not required

### Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted, not required
Mineralisation at study end	No data submitted, not required
Non-extractable residues at study end	No data submitted, not required

**Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

Parent	Dark aerobic conditions						
Soil type	OC	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	DT <sub>90</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	Chi2err (%)	Method of calculation
<b>Gibberellins GA4</b>							
Speyer 5M	1.0	7.3	20 / pF2	0.171	0.568	3.188	SFO
Speyer 2.2	1.8	5.5	20 / pF2	0.347	1.153	20.75	SFO
Brierlow	3.6	5.6	20 / pF2	0.392	1.303	18.61	SFO
South Witham	4.1	7.4	20 / pF2	0.104	0.346	28.78	SFO
Soil LUFA 2.1	0.63	5.12	20 / 45 % MWHC	1.542	5.083	7.2	SFO
Soil LUFA 2.2	1.42	5.85	20 / 45 % MWHC	1.125	12.583	7.2	DFOP
Soil LUFA 2.3	0.72	6.22	20 / 45 % MWHC	1.000	5.333	14.7	FOMC
Soil LUFA 6S	1.87	7.14	20 / 45 % MWHC	1.083	3.625	5.6	SFO
Geometric mean (if not pH dependent)				<b>0.510</b>			
pH dependence, <i>No</i>							
<b>Gibberellins GA7</b>							
Speyer 5M	1.0	7.3	20 / pF2	0.060	0.200	13.57	SFO
Speyer 2.2	1.8	5.5	20 / pF2	0.064	0.212	13.20	SFO
Brierlow	3.6	5.6	20 / pF2	0.132	0.440	16.67	SFO
South Witham	4.1	7.4	20 / pF2	0.011	0.036	1.005	SFO
Soil LUFA 2.1	0.63	5.12	20 / 45 % MWHC	0.500	1.625	11.2	SFO
Soil LUFA 2.2	1.42	5.85	20 / 45 % MWHC	0.292	0.917	12.2	DFOP
Soil LUFA 2.3	0.72	6.22	20 / 45 % MWHC	0.167	0.583	5.2	FOMC
Soil LUFA 6S	1.87	7.14	20 / 45 % MWHC	0.583	1.917	11.3	SFO
Geometric mean (if not pH dependent)				<b>0.130</b>			
pH dependence, <i>No</i>							

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

**Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

Met 1	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was <i>xxx</i>							
Soil type	<i>X</i> <sup>7</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>f</sub> / k <sub>dp</sub>	DT <sub>50</sub> (d) 20 °C pF2/10kPa <sup>b)</sup>	St. (χ <sup>2</sup> )	Method of calculation
/	/	/	/	/	/	/	/	/
Geometric mean (if not pH dependent)								
Arithmetic mean								
pH dependence, <i>Yes or No</i>								

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

**Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)**

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	<i>X</i> <sup>6</sup>	pH <sup>a)</sup>	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	St. (χ <sup>2</sup> )	DT <sub>50</sub> (d) Norm <sup>b)</sup> .	Method of calculation
/	/	/	/	/	/	/	/	/	/
Geometric mean (if not pH dependent)									
pH dependence, <i>Yes or No</i>									

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

Met 1	Aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was <i>xxx</i>									
Soil type	Location	<i>X</i> <sup>8</sup>	pH <sup>a)</sup>	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	St. (χ <sup>2</sup> )	DT <sub>50</sub> (d) Norm <sup>b)</sup> .	f. f. k <sub>f</sub> / k <sub>dp</sub>	Method of calculation
/	/	/	/	/	/	/	/	/	/	/

<sup>6</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Met 1		Aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was .xxx								
Soil type	Location	$X^8$	pH <sup>a)</sup>	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	St. ( $\chi^2$ )	DT <sub>50</sub> (d) Norm <sup>b)</sup> .	f. f. k <sub>f</sub> / k <sub>dp</sub>	Method of calculation
Geometric mean (if not pH dependent)										
Arithmetic mean										
pH dependence, Yes or No										

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

**Combined laboratory and field kinetic endpoints for modelling (when not from different populations)\***

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

No data submitted, not required

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

Kinetic formation fraction (f. f.  $k_f / k_{dp}$ ) of transformation products, arithmetic mean

\* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

**Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)**

Soil accumulation and plateau concentration

No data submitted, not required

**Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

Parent	Dark anaerobic conditions						
Soil type	X <sup>7</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20 °C <sup>b)</sup>	St. ( $\chi^2$ )	Method of calculation
/	/	/	/	/	/	/	/
Geometric mean (if not pH dependent)							

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Normalised using a Q10 of 2.58

<sup>7</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

**Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

Met 1	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was xxx.							
Soil type	X <sup>10</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>f</sub> / k <sub>dp</sub>	DT <sub>50</sub> (d) 20°C <sup>b)</sup>	St. (χ <sup>2</sup> )	Method of calculation
/	/	/	/	/	/	/	/	/
Geometric mean (if not pH dependent)								
Arithmetic mean								

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58

**Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)**

Parent	Soil photolysis					
Soil type	X <sup>8</sup>	pH <sup>a)</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) calculated at ??°N	St. (χ <sup>2</sup> )	Method of calculation
/	/	/	/	/	/	/

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>8</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

**Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

Parent							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
<b>Gibberellins GA4</b>							
Empingham	5.2	7.4	0.17	/	0.19	4	0.9614
Kenslow	3.8	7.3	0.19	/	0.19	5	0.9673
Brierlow	2.7	5.6	0.45	/	0.46	17	0.9706
Worsop	0.8	3.8	1.26	/	1.32	165	0.9611
Geometric mean (if not pH dependent)*					<b>0.38</b>	<b>15.4</b>	<b>0.9651</b>
Arithmetic mean (if pH dependant)						<b>47.75</b>	
pH dependence, <i>YES, increasing sorption with decreasing pH</i>							
<b>Gibberellins GA7</b>							
Empingham	5.2	7.4	0.25	/	0.22	4	1.0464
Kenslow	3.8	7.3	0.23	/	0.22	6	1.0296
Brierlow	2.7	5.6	0.50	/	0.50	18	0.9822
Worsop	0.8	3.8	1.27	/	1.33	166	0.9992
Geometric mean (if not pH dependent)*					<b>0.42</b>	<b>16.4</b>	<b>1.0096</b>
Arithmetic mean (if pH dependant)						<b>48.5</b>	
pH dependence, <i>YES, increasing sorption with decreasing pH</i>							

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

\* Only relevant after implementation of the published EFSA guidance.

**Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

Metabolite 1							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
/	/	/	/	/	/	/	/
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)							
pH dependence, <i>Yes or No</i>							

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

\* Only relevant after implementation of the published EFSA guidance.



**Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

Column leaching

No data submitted, not required

**Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

Column leaching

No data submitted, not required

**Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)**

Lysimeter/ field leaching studies

No data submitted, not required
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**Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)**

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 4 GA <sub>4</sub> : Stable to hydrolysis at 50°C (extrapolated DT <sub>50</sub> >1 year at 20°C) GA <sub>7</sub> : Declined to <i>ca.</i> 50% of initial value after 5 days at 50°C
pH 7 GA <sub>4</sub> : Stable to hydrolysis at 50°C (extrapolated DT <sub>50</sub> >1 year at 20°C) GA <sub>7</sub> : Stable to hydrolysis at 50°C (extrapolated DT <sub>50</sub> >1 year at 20°C)
pH 9 GA <sub>4</sub> : Stable to hydrolysis at 50°C (extrapolated DT <sub>50</sub> >1 year at 20°C) GA <sub>7</sub> : Completely degraded after 5 days at 50°C

**Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)**

Photolytic degradation of active substance and metabolites above 10 %

GA<sub>4/7</sub>  
DT<sub>50</sub>: 104-267 days at 25°C (pH 5, 7 and 9)  
GA<sub>4</sub>  
DT<sub>50</sub>: 101-163 days at 25°C (pH 5, 7 and 9)  
GA<sub>7</sub>  
DT<sub>50</sub>: 57-145 days at 25°C (pH 5, 7 and 9)

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

/

**‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)**

Readily biodegradable  
(yes/no)

No. On the basis of conflicting results from two studies the active substance GA<sub>4/7</sub> cannot be reliably classified as readily biodegradable. However, based on the degree of biodegradation observed in the non-positive test (in conjunction with the rapid and extensive microbial degradation and ultimate complete mineralisation via other natural components observed in the soil and aquatic metabolism studies), it is concluded that GA<sub>4/7</sub> can be considered inherently biodegradable.

**Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)**

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. ( $\chi^2$ )	Method of calculation
				At study temp	Normalise d to <i>x</i> °C <sup>c)</sup>		At study temp	Normalis ed to x °C <sup>c)</sup>		
Fountains Abbey (low app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	16.9/56	6.77	SFO
Fountains Abbey (high app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	17.2/57.2	4.85	SFO

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

<sup>c)</sup>Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

<i>Unknown AM1</i>	Max in total system 51.7 % after 58 days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. ( $\chi^2$ )	Method of calculation
				At study temp	Normalise d to x °C <sup>c)</sup>		At study temp	Norma lised to x °C <sup>c)</sup>		
Fountains Abbey (low app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	497/1. 66E+0 3	6.04	SFO
Fountains Abbey (High app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	213/70 6	9.13	SFO

<i>Unknown AM2</i>	Max in total system 40.3 % after 58 days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. ( $\chi^2$ )	Method of calculation
				At study temp	Normalise d to x °C <sup>c)</sup>		At study temp	Norma lised to x °C <sup>c)</sup>		
Fountains Abbey (low app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	500/1. 66E+0 3	7.88	SFO

Fountains Abbey (High app. Rate)	7.88	/	20 ± 2°C	/	/	/	20 ± 2°C	2.63e+ 183/8. 75E+1 83	9.81	SFO

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

<sup>c)</sup>Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Mineralisation and non-extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation <i>x</i> % after <i>n</i> d. (end of the study).	Non-extractable residues. max <i>x</i> % after <i>n</i> d (suspended sediment test)	Non-extractable residues. max <i>x</i> % after <i>n</i> d (end of the study) (suspended sediment test)
			50% AR in 7 days >85 % at 58 days		

**Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)**

Parent	Distribution (59 DAT < 2 % present in whole system)									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> water	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. ( $\chi^2$ )	Method of calculation
Calwich Abbey	7.8	7.4	20± 2°C	10.9/36.3	8.03	/	/	/	/	SFO
Emperor Lake	7.0	5.8	20± 2°C	11.2/37.3	8.78	/	/	/	/	SFO
Geometric mean at 20°C <sup>b)</sup>										

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58

Metabolite	Five major metabolites were observed in the water / sediment systems with ultimate degradation leading to the formation of carbon dioxide and un-extractable sediment bound residues. These metabolites are considered to be of no environmental concern due to the natural occurrence of the active substance.									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> water	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. ( $\chi^2$ )	Method of calculation
/	/	/	/	/	/	/	/	/	/	/
Geometric mean at 20°C <sup>b)</sup>										

<sup>a)</sup>Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup>Normalised using a Q10 of 2.58

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Five major metabolites were observed in the water / sediment systems with ultimate degradation leading to the formation of carbon dioxide and un-extractable sediment bound residues. These metabolites are considered to be of no environmental concern due to the natural occurrence of the active substance.			12.3-25.4% AR after 100 days (n=2)	24.5-25.8% AR after 100 days (n=2)	a.s. max in sediment 10.3% after 7 days

#### **Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)**

Direct photolysis in air	Not studied - no data requested.
Photochemical oxidative degradation in air	DT <sub>50air</sub> : 0.98 hours (Atkinson calculation)
Volatilisation	Not studied - no data requested.
	Not studied - no data requested.
Metabolites	Not studied - no data requested.

#### **Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)**

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Gibberellins GA4/7 Surface water: Gibberellins GA4/7 Sediment: Gibberellins GA4/7 Ground water: Gibberellins GA4/7 Air: Gibberellins GA4/7
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#### **Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)**

Gibberellins GA<sub>4</sub> and Gibberellins GA<sub>7</sub> only (although several major (>10% AR) metabolites were observed in soil these are considered to be of no environmental

concern due to the natural occurrence of the active substance)
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**Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)**

Soil (indicate location and type of study)	No data available.
Surface water (indicate location and type of study)	No data available.
Ground water (indicate location and type of study)	No data available.
Air (indicate location and type of study)	No data available.

**PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)**

Parent Method of calculation	<p>Worst-case maximum initial PEC(soil) assuming a single application of the total seasonal dose (i.e. no dissipation between applications)</p> <p>Depth of soil layer: 5 cm</p> <p>Soil bulk density: 1.5 g/cm<sup>3</sup></p> <p>Short and long term actual and time-weighted average PEC values are not required for the risk assessment and have therefore not been calculated.</p> <p>PEC(soil) were calculated for GA<sub>4/7</sub> assuming 100% content of both GA<sub>4</sub> and GA<sub>7</sub>.</p>
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## Application data

Crop: Apples (application at GS 69-74)  
Application rate: 4 x 5 g a.s./ha, 7-day application interval  
Crop interception: 60%

Crop: Apples (earliest application – 1-Apr)  
Application rate: 4 x 5 g a.s./ha, 7-day application interval  
Crop interception: 50%

Crop: Pears (application at GS 62-69)  
Application rate: 1 x 12 g a.s./ha  
Crop interception: 60%

Crop: Pears (earliest application – 1-Apr)  
Application rate: 1 x 12 g a.s./ha  
Crop interception: 50%

Crop: Pears (application at GS 62-69)  
Application rate: 2 x 6 g a.s./ha, 3-day application interval  
Crop interception: 60%

Crop: Pears (earliest application – 1-Apr)  
Application rate: 2 x 6 g a.s./ha, 3-day application interval  
Crop interception: 50%

**PEC<sub>(s)</sub> (mg/kg)**  
**Apples (early appln)**  
**(4 x 5 g a.s./ha)**

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.0133	-	-	-

**PEC<sub>(s)</sub> (mg/kg)**  
**Pears (GS 62-69)**  
**(1 x 12 g a.s./ha)**

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.0064	-	-	-

**PEC<sub>(s)</sub> (mg/kg)**  
**Pears (early appln)**  
**(1 x 12 g a.s./ha)**

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.0080	-	-	-

**PEC<sub>(s)</sub> (mg/kg)**  
**Pears (GS 62-69)**  
**(2 x 6 g a.s./ha)**

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.0064	-	-	-

**PEC<sub>(s)</sub> (mg/kg)**  
**Pears (early appln)**  
**(2 x 6 g a.s./ha)**

Initial

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.0080	-	-	-

### PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

Modelling using FOCUS models with appropriate FOCUS GW scenarios, according to FOCUS guidance.  
 Models used: PEARL v 4.4.4, PELMO v 5.5.3 and MACRO v. 5.5.4  
 Scenarios (list of names): All scenarios  
 Crop scenario: apples (pome fruit)  
 The ratio of GA<sub>4</sub> and GA<sub>7</sub> in the active substance can vary between sources. Therefore, as a worst-case separate calculations for each component were conducted to consider alternate situations where the active substance is 100% GA<sub>4</sub> and separately 100% GA<sub>7</sub>.

**GA<sub>4</sub>**  
 Molecular weight (g/mol): 332.4  
 Water solubility (mg/L at 20°C): 340  
 Vapour pressure (Pa at 20°C): 0 (worst-case assumption)  
 K<sub>FOC</sub> (mL/g): 4.0 (worst-case, pH dependent, n=4)  
 1/n: 0.97 (mean, n=4)  
 DT<sub>50</sub> soil (days): 2 (worst-case assumption)  
 Crop uptake factor: 0 (worst-case assumption)

**GA<sub>7</sub>**  
 Molecular weight (g/mol): 330.4  
 Water solubility (mg/L at 20°C): 340  
 Vapour pressure (Pa at 20°C): 0 (worst-case assumption)  
 K<sub>FOC</sub> (mL/g): 4.0 (worst-case, pH dependent, n=4)  
 1/n: 1.01 (mean, n=4)  
 DT<sub>50</sub> soil (days): 2 (worst-case assumption)  
 Crop uptake factor: 0 (worst-case assumption)



## Application rate

Crop: Apples (application at GS 69-74)  
Application rate: 4 x 5 g a.s./ha, 7-day application interval  
Crop interception: 60%  
Application dates:  
Châteaudun = 7-Jul, 14-Jul, 21-Jul, 28-Jul  
Hamburg: = 3-Jun, 10-Jun, 17-Jun, 24-Jun  
Jokioinen: = 7-Jul, 14-Jul, 21-Jul, 28-Jul  
Kremsmünster: = 3-Jun, 10-Jun, 17-Jun, 24-Jun  
Okehampton: = 13-Jul, 20-Jul, 27-Jul, 3-Aug  
Piacenza: = 16-Jul, 23-Jul, 30-Jul, 6-Aug  
Porto: = 6-Aug, 13-Aug, 20-Aug, 27-Aug  
Sevilla: = 11-Jul, 18-Jul, 25-Jul, 1-Aug  
Thiva: = 2-Aug, 9-Aug, 16-Aug, 23-Aug

To cover potential early applications to apples (i.e. as early as 1-Apr) additional simulations were also conducted assuming 50% crop interception and application on 1-Apr, 8-Apr, 15-Apr and 22-Apr in all scenarios.

Crop: Pears (application at GS 62-69)  
Application rate: 1 x 12 g a.s./ha  
Crop interception: 60%  
Application dates:  
Châteaudun = 8-Jun  
Hamburg: = 19-May  
Jokioinen: = 4-Jun  
Kremsmünster: = 19-May  
Okehampton: = 21-Jun  
Piacenza: = 10-Jun  
Porto: = 8-Jul  
Sevilla: = 9-Jun  
Thiva: = 7-Jul

To cover potential early applications to pears (i.e. as early as 1-Apr) additional simulations were also conducted assuming 50% crop interception and application on 1-Apr in all scenarios.

Crop: Pears (application at GS 62-69)  
Application rate: 2 x 6 g a.s./ha, 3-day application interval  
Crop interception: 60%  
Application dates:  
Châteaudun = 8-Jun, 11-Jun  
Hamburg: = 19-May, 22-May  
Jokioinen: = 4-Jun, 7-Jun  
Kremsmünster: = 19-May, 22-May  
Okehampton: = 21-Jun, 24-Jun  
Piacenza: = 10-Jun, 13-Jun  
Porto: = 8-Jul, 11-Jul  
Sevilla: = 9-Jun, 12-Jun  
Thiva: = 7-Jul, 10-Jul

To cover potential early applications to pears (i.e. as early as 1-Apr) additional simulations were also conducted assuming 50% crop interception and application on 1-Apr and 4-Apr in all scenarios.

**PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)**

PEARL, PELMO, MACRO/Apples, Pears	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			<i>Met I</i>	<i>Met II</i>	<i>Met III</i>
	Chateaudun	< 0.001 µg/L	/	/	/
	Hamburg	< 0.001 µg/L	/	/	/
	Jokioinen	< 0.001 µg/L	/	/	/
	Kremsmunster	< 0.001 µg/L	/	/	/
	Okehampton	< 0.001 µg/L	/	/	/
	Piacenza	< 0.001 µg/L	/	/	/
	Porto	< 0.001 µg/L	/	/	/
	Sevilla	< 0.001 µg/L	/	/	/
	Thiva	< 0.001 µg/L	/	/	/

**PEC<sub>(gw)</sub> From lysimeter / field studies**

Parent	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year
Annual average (µg/L)	/	/	/

Metabolite X	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year
Annual average (µg/L)	/	/	/

**PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)**

Parent

Parameters used in FOCUSsw step 1 and 2

The ratio of GA<sub>4</sub> and GA<sub>7</sub> in the active substance can vary between sources. Therefore, as a worst-case separate calculations for each component were conducted to consider alternate situations where the active substance is 100% GA<sub>4</sub> and separately 100% GA<sub>7</sub>.

**GA<sub>4</sub>**

Molecular weight (g/mol): 332.4

Water solubility (mg/L): 340

K<sub>FOC</sub> (mL/g): 4.0 (worst-case, pH dependent, n=4)

DT<sub>50</sub> soil (days): 2 (worst-case assumption)

DT<sub>50</sub> sediment-water system (days): 1000 (conservative default)

DT<sub>50</sub> water (days): 1000 (conservative default)

DT<sub>50</sub> sediment (days): 1000 (conservative default)

Parameters used in FOCUSsw step 3 (if performed)

Application rate

#### GA<sub>7</sub>

Molecular weight (g/mol): 330.4

Water solubility (mg/L): 340

K<sub>FOC</sub> (mL/g): 4.0 (worst-case, pH dependent, n=4)

DT<sub>50</sub> soil (days): 2 (worst-case assumption)

DT<sub>50</sub> sediment-water system (days): 1000 (conservative default)

DT<sub>50</sub> water (days): 1000 (conservative default)

DT<sub>50</sub> sediment (days): 1000 (conservative default)

Short and long term actual and time-weighted average PEC values are not required for the risk assessment and have therefore not been calculated.

Not performed.

Crop: Apples

Crop group: pome/stone fruit (early application)

Application rate: 4 x 5 g a.s./ha, 7-day application interval

Crop interception: average crop cover

Region and season of application: South Europe, Mar-May

Crop: Pears

Crop group: pome/stone fruit (early application)

Application rate: 1 x 12 g a.s./ha

Crop interception: average crop cover

Region and season of application: South Europe, Mar-May

Crop: Pears

Crop group: pome/stone fruit (early application)

Application rate: 2 x 6 g a.s./ha, 3-day application interval

Crop interception: average crop cover

Region and season of application: South Europe, Mar-May

# GA4 and GA7

FOCUS STEP 1	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)*	
		Actual	TWA	Actual	TWA
<b>Apples</b> (4 x 5 g a.s./ha, 7-d appln interval)	0 h	8.58	-	0.343	-
<b>Pears</b> (1 x 12 g a.s./ha)	0 h	5.15	-	0.206	-
<b>Pears</b> (2 x 6 g a.s./ha, 3-d appln interval)	0 h	5.15	-	0.206	-

\* Maximum PEC<sub>SED</sub> values are reported, which do not necessarily always occur at day 0

FOCUS STEP 2	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)*	
		Actual	TWA	Actual	TWA
<b>Apples</b> (4 x 5 g a.s./ha, 7-d appln interval) Southern EU	0 h	1.66 (0.583) <sup>1</sup>	-	0.066 (0.023) <sup>1</sup>	-
<b>Pears</b> (1 x 12 g a.s./ha) Southern EU	0 h	1.40	-	0.056	-
<b>Pears</b> (2 x 6 g a.s./ha, 3-d appln interval) Southern EU	0 h	1.18 (0.700) <sup>1</sup>		0.047 (0.028) <sup>1</sup>	

\* Maximum PEC<sub>SED</sub> values are reported, which do not necessarily always occur at day 0

<sup>1</sup> values in parentheses are the corresponding PEC resulting from a single application

**Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)**

Method of calculation

Not calculated. Expert judgement based on vapour pressure and atmospheric half-life.

**PEC**

Maximum concentration

Negligible

## Ecotoxicology

### Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
<i>Colinus virginianus</i> Bobwhite quail	a.s. GA <sub>4</sub> /GA <sub>7</sub>	Acute	LD <sub>50</sub>	>2000
	Preparation	Acute	Data not submitted	No data
	Metabolite 1	Acute	Data not submitted	Not relevant
<i>Colinus virginianus</i> Bobwhite quail	a.s. GA <sub>4</sub> /GA <sub>7</sub>	Short term	NOEL	1376
	a.s.	Long-term	Data not submitted	No data*
	a.s.	Long-term	Data not submitted	Not relevant
Mammals				
<i>Rat</i>	a.s. GA <sub>4</sub> /GA <sub>7</sub>	Acute oral	LD <sub>50</sub>	>5000
Rat	GA <sub>4</sub> /GA <sub>7</sub> 10 g/L formulation (identical to Novagib)	Acute oral	LD <sub>50</sub>	>5000
	Metabolite 1	Acute	Data not submitted	Not relevant
<i>Rat</i>	a.s. GA <sub>4</sub> /GA <sub>7</sub>	Dietary Two- generation reproductive	NOAEL	300
	a.s.	Long-term [for first tier risk assessment]	Data not submitted	Not relevant
Endocrine disrupting properties (Annex Part A, points 8.1.5) [list evidence/indication on the potential for endocrine disrupting properties]				
Additional higher tier studies (Annex Part A, points 10.1.1.2): Not required.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): Additional studies to determine the effects on other terrestrial vertebrate wildlife are considered to be unnecessary.				

\* No data available. As a protective worst-case, the long-term NOEL for birds has been assumed to be 100-fold lower than the NOEL for short-term toxicity. Given that the NOEL for short-term toxicity was found to equate to the highest dose rate tested in the study, this is considered to be an acceptable approach. Assumed long-term NOEL = 13.76 mg a.s./kg bw/d.

**Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)**

**Apples and pears at 12 g a.s./ha x 1**

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Screening Step (Birds)</b>					
All	Small insectivorous bird	Acute	0.562	>3651	10
All	Small insectivorous bird	Long-term	0.116	119	5
<b>Tier 1 (Birds)</b>					
Not relevant					
Higher tier (birds): <i>[in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]</i>					
Not relevant					
<b>Screening Step (Mammals)</b>					
All		Acute	1.64	3049	10
All		Long-term	0.46	652	5
<b>Tier 1 (Mammals)</b>					
Not relevant					
Higher tier (Mammals): <i>[in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]</i>					
Not relevant					
<b>Risk from bioaccumulation and food chain behaviour</b> not relevant, GA4 logPow=2.34, GA7 logPow=2.25					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	/	/	5
Earthworm-eating mammals		Long-term	/	/	5
Fish-eating birds		Long-term	/	/	5
Fish-eating mammals		Long-term	/	/	5
Higher tier : <i>[in higher tier refinement provide brief details of any refinements used]</i>					
Not relevant					
<b>Risk from consumption of contaminated water</b> K(f)oc = 0.5747 L/kg, Application rate (g a.s./ha)/relevant endpoint <50, TER calculation is not needed for birds or mammals					
<b>Scenarios</b>	<b>Indicator or focal species</b>	<b>Time scale</b>	<b>PEC<sub>dw</sub>xDWR</b>	<b>TER</b>	<b>Trigger</b>
Leaf scenario	Birds	acute	/	/	5
<b>Puddle scenario, Screening step</b>					
1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed					
2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	/	/	10
Puddle scenario	Mammals	acute	/	/	10
Puddle scenario	Birds	Long-term	/	/	5
Puddle scenario	Mammals	Long-term	/	/	5

**Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)\***

\* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Laboratory tests				
Fish				
<i>Oncorhynchus mykiss</i>	a.s. – GA47GA7	Acute 96 hr (semi-static)	Mortality, LC <sub>50</sub>	>100 mg a.s./L <sub>(nom)</sub>
<i>Oncorhynchus mykiss</i>	Preparation Novagib	Acute 96 hr (static)	Mortality, LC <sub>50</sub>	>9700 mg prep./L (>100 mg a.s./L <sub>(nom)</sub> )
	a.s.	Chronic (static, or semi-static or flow- through)	Data not submitted	No data, read across from GA3
	Metabolite 1	96 hr (static, or semi- static or flow- through)	Data not submitted	Not relevant
Aquatic invertebrates				
<i>Daphnia magna</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	48 h (static,)	Mortality, EC <sub>50</sub>	> 100 mg a.s./L <sub>(nom)</sub>
<i>Daphnia magna</i>	Preparation Novagib	48 h (static,)	Mortality, EC <sub>50</sub>	> 9700 mg prep./L (> 100mg a.s./L <sub>(nom)</sub> )
<i>Daphnia magna</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	21 d (semi- static)	Reproduction, NOEC	3 mg a.s./L <sub>(nom)</sub>
	Metabolite 1	48 h (static, or semi- static or flow- through)	Data not submitted	Not relevant
Algae				
<i>Pseudokirchneriella subcapitata</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	72 h (static)	Growth rate: E <sub>r</sub> C <sub>50</sub> (NOEC)  Biomass: E <sub>b</sub> C <sub>50</sub> (NOEC)	> 100 mg a.s./L <sub>(nom)</sub>  > 100 mg a.s./L <sub>(nom)</sub>
<i>Navicula pelliculosa</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	72h (static)	E <sub>r</sub> C <sub>50</sub>	> 91.35 mg a.s./L <sub>(nom)</sub>



Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
<i>Desmodemus subspicatus</i>	Preparation - Novagib	72h (static)	E <sub>r</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>50</sub>	6080mg prep./L (60mg a.s./L <sub>(nom)</sub> ) 6384 mg prep/L (63 mg a.s./L <sub>(nom)</sub> )
	Metabolite 1	72 h (static, or semi- static or flow- through)	Data not submitted	Not relevant
Higher plant				
<i>Lemna minor</i>	Preparation - Novagib	7 day (semi- static)	Fronds number, biomass, growth rate, E <sub>r</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>50</sub>	>100 mg prep./L (>0.96 mg a.s./L <sub>(nom)</sub> )  >100 mg prep./L (>0.96 mg a.s./L <sub>(nom)</sub> )
<i>Myriophyllum spicatum</i>	Preparation - Novagib	14 day (semi static)	E <sub>r</sub> C <sub>50</sub>  E <sub>y</sub> C <sub>50</sub>	<100 mg prep./L (<0.95 mg a.s./L <sub>(nom)</sub> )*  <100 mg prep./L (<0.95 mg a.s./L <sub>(nom)</sub> )*
	Metabolite 1	14 d (static, or semi- static or flow- through)	Data not submitted	Not relevant
Further testing on aquatic organisms				
<i>Not required</i>				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3)				
<i>[list evidence/indication on the potential for endocrine disrupting properties]</i>				

<sup>1</sup> (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

\* the study is not sufficient to address the risk to aquatic macrophytes, data gap has been concluded

**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

	Active substance
logP <sub>O/W</sub>	GA <sub>4</sub> logPow=2.34 GA <sub>7</sub> logPow=2.25
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	Not relevant
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	Not relevant
Annex VI Trigger for the bioconcentration factor	Not relevant
Clearance time (days) (CT <sub>50</sub> )	Not relevant
(CT <sub>90</sub> )	Not relevant
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not relevant

\* based on total <sup>14</sup>C or on specific compounds

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)**

**FOCUS<sub>sw</sub> step 1-3 - TERs for gibberellins GA<sub>4</sub>/GA<sub>7</sub>– Apples and pears at 12 g a.s./ha x 1**

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Higher plant
		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Desmodesmus subspicatus</i>	<i>Lemna minor</i>	<i>Myriophyllum spicatum</i>
		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>	NOEC
		>100000 µg/L	11000 µg/L	>100000 µg/L	3000 µg/L	60000 µg/L	>960 µg/L	<950µg/L
<b>FOCUS Step 1</b>	8.58	>11655	1282	>11655	350	6993	>112	<b>&lt;111</b>
<b>FOCUS Step 2</b>								
North Europe								
South Europe	1.66	>60241	6627	>60241	1807	36145	>578	<b>&lt;572</b>
<b>FOCUS Step 3*</b>								
D3 / ditch								
D4 / pond								
D4 / stream								
D5 / pond								
D5 / stream								
R1 / pond								
R1 / stream								
R2 / stream								
R3 / stream								
R4 / stream								
Trigger**		100	10	100	10	10	10	10

\*[Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 1-2 should be included in step 3.]

\*\*[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

Values in **bold** indicate unacceptable risk.

**FOCUS<sub>sw</sub> step 4 - TERs [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]**

*[Fate experts should also be asked to review this table to check if it is in line with their assessments]*

**Organisms** *Indicate species:*

**Toxicity endpoint:** x.xx µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)	PEC <sub>sw</sub> (x.xx µg/L)	TER	Trigger
<b>FOCUS Step 4*</b>					
D3 / ditch					
D4 / pond					
D4 / stream					
D5 / pond					
D5 / stream					
R1 / pond					
R1 / stream					
R2 / stream					
R3 / stream					
R4 / stream					

\*[Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 3 should be included in step 4].

**Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)\***

\* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>Apis mellifera</i>	a.s. – GA4/GA7	Acute oral 48h	Oral toxicity (LD <sub>50</sub> )	>87 µg a.s./bee
	preparation		Data not submitted	Not relevant
<i>Apis mellifera</i>	a.s. – GA4/GA7	Acute contact 48h	Contact toxicity (LD <sub>50</sub> )	>100 µg a.s./bee
	preparation		Data not submitted	Not relevant
<i>Apis mellifera</i>	a.s. – GA4/GA7	Chronic oral 10 days	10 d-LDD <sub>50</sub> 10 d -LC <sub>50</sub>	>5.644 µg a.s./bee/day >150 mg a.s./kg diet
	preparation		Data not submitted	Not relevant
<i>Apis mellifera</i>	a.s. – GA4/GA7	Larval single exposure	NOEClarvae	>100 µg a.s./larva
	preparation		Data not submitted	Not relevant
	a.s.,	Sub-lethal effects (behavioural and reproductive)	Data not submitted	Not relevant
	preparation		Data not submitted	Not relevant

Potential for accumulative toxicity: *no*

Semi-field test (Cage and tunnel test)

*Not required*

Field tests

*Not required*

**Risk assessment** for – Apples and pears at 12 g a.s./ha x 1

Species	Test substance	Risk quotient	HQ	Trigger
<i>Apis mellifera</i>	a.s., preparation	HQacute contact	<0.12	50
	a.s., preparation	HQacute oral	<0.14	50

**Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)**

**Laboratory tests with standard sensitive species**

Species	Test Substance	Exposure system	End point	Toxicity
<i>Typhlodromus pyri</i> (protonymphs)	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	Laboratory test glass plates 2D	Mortality, LR <sub>50</sub>	>40 g a.s./ha
<i>Aphidius rhopalosiphi</i> (adults)	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	Laboratory test glass plates 2D	Mortality, LR <sub>50</sub>	>40 g a.s./ha
<i>Typhlodromus pyri</i> (protonymphs)	Preparation Novagib	Laboratory test glass plates 2D	Mortality, LR <sub>50</sub>	>80 L product/ha (> 800 g a.s./ha)
	Additional species			
Not required				

**First tier risk assessment** for – Apples and pears at 5g a.s./ha x 4 (for in-field), 12g a.s./ha x 1 (for off-field)

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
GA <sub>4</sub> /GA <sub>7</sub>	<i>Typhlodromus pyri</i>	>40	<0.338	<0.047	2
GA <sub>4</sub> /GA <sub>7</sub>	<i>Aphidius rhopalosiphi</i>	>40	<0.338	<0.047	2

<sup>1</sup>indicate distance assumed to calculate the drift rate

**Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)**

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity
<b>Earthworms</b>					
<i>Eisenia fetida</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>		Acute 14 days	LC <sub>50</sub> LC <sub>50corr</sub>	>1250 mg a.s./kg d.w.soil >625 mg a.s./kg d.w. soil
<i>Eisenia fetida</i>	Preparation Novagib		Acute 14 days	LC <sub>50</sub> LC <sub>50corr</sub>	>96 mg a.s./kg d.w. soil >48 mg a.s./kg d.w. soil
	a.s.		Chronic	No data submitted	Read across from GA3
	metabolite 1			No data submitted	Not relevant
<b>Other soil macroorganisms</b>					

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity
<i>Folsomia candida</i>	a.s.			No data submitted	Not relevant
	preparation			No data submitted	Not relevant
	metabolite 1			No data submitted	Not relevant
<i>Hypoaspis aculeifer</i>	a.s.			No data submitted	Not relevant
	preparation			No data submitted	Not relevant
	metabolite 1			No data submitted	Not relevant

<sup>1</sup>To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

#### Higher tier testing (e.g. modelling or field studies)

Nitrogen transformation	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	28 day, aerobic	< 15% effect at day 28 at 0.13 mg a.s./kg d.w.soil
	metabolite 1	No data submitted	Not relevant

#### Toxicity/exposure ratios for soil organisms

Apples and pears at 5 g a.s./ha x 4

Test organism	Test substance	Time scale	Soil PEC <sub>initial</sub>	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	a.s. – GA <sub>4</sub> /GA <sub>7</sub>	Acute	0.0133	>46993	5
<i>Eisenia fetida</i>	Preparation Novagib	Acute	0.0133	>3609	5
<i>Eisenia fetida</i>	a.s. – GA <sub>3</sub>	Chronic	0.0133	9398	5

<sup>1</sup>indicate which PEC soil was used (e.g. plateau PEC)

#### Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER<sub>50</sub> tests should be provided

#### Laboratory dose response tests

Species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	PER <sub>off-field</sub> (g/ha) <sup>2</sup>	TER	Trigger
10 species, including <i>Lactuca sativa</i> (lettuce)	a.s. – GA <sub>4</sub> /GA <sub>7</sub>		>222 g a.s./ha	1.89	>117	5

Species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	PER <sub>off-field</sub> (g/ha) <sup>2</sup>	TER	Trigger
10 species, including <i>Lactuca sativa</i> (Lettuce)	Preparation Novagib	34.8 g a.s./ha		1.89	18.4	5
Extended laboratory studies: <i>not required</i> Semi-field and field test: <i>not required</i>						

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

### Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	3 h EC <sub>50</sub> > 100 mg a.s./L

### Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. <i>No data available</i> Available monitoring data concerning effect of the PPP. <i>No data available</i>
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### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

Compartment	
soil	Gibberellins GA <sub>4</sub> and GA <sub>7</sub>
water	Gibberellins GA <sub>4</sub> and GA <sub>7</sub>
sediment	Gibberellins GA <sub>4</sub> and GA <sub>7</sub>
groundwater	Gibberellins GA <sub>4</sub> and GA <sub>7</sub>

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent



**Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)**

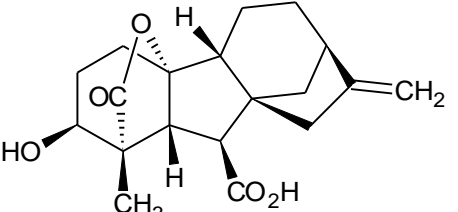
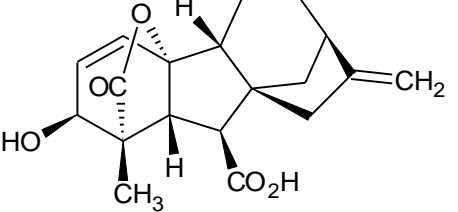
Substance	Gibberellins GA <sub>4</sub> /GA <sub>7</sub>
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>9</sup> :	Aquatic Acute 1, H400 Aquatic Chronic 3, H412
Peer review proposal <sup>10</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	

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<sup>9</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, 1-1355.

<sup>10</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

**Used compounds code(s)**

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula	
Gibberrellin, GA4/GA7, GA4/GA7, GA4/7	<p>GA<sub>4</sub>: (3<i>S</i>,3<i>aR</i>,4<i>S</i>,4<i>aR</i>,7<i>R</i>,9<i>aR</i>,9<i>bR</i>,12<i>S</i>)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4<i>a</i>,7-methano-3,9<i>b</i>-propanoazuleno[1,2-<i>b</i>]furan-4-carboxylic acid</p> <p>GA<sub>7</sub>: (3<i>S</i>,3<i>aR</i>,4<i>S</i>,4<i>aR</i>,7<i>R</i>,9<i>aR</i>,9<i>bR</i>,12<i>S</i>)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4<i>a</i>,7-methano-9<i>b</i>,3-propenoazuleno[1,2-<i>b</i>]furan-4-carboxylic acid</p>	GA4	
		GA7	

\* The compound code / trivial name in bold is the name used in the list of endpoints.