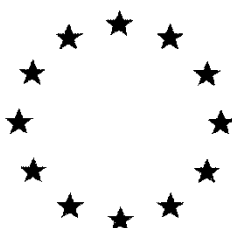


# ***European Commission***



**Draft Assessment Report prepared according to the Commission  
Regulation (EU) N° 1107/2009**

## **24-Epibrassinolide**

### **List of Endpoints**

Rapporteur Member State: Austria

Version History

When	What
2018/05	Initial DAR

## List of end points

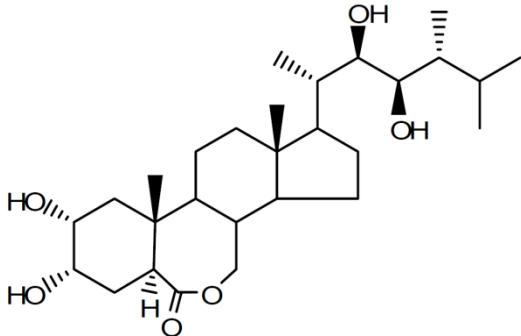
Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### 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)	24-Epibrassinolide
Function (e.g. fungicide)	Elicitor and Plant activator
Rapporteur Member State	Austria
Co-rapporteur Member State	-

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

Chemical name (IUPAC)	(22R,23R,24R)-2 $\alpha$ ,3 $\alpha$ ,22,23-tetrahydroxy-24-methyl- $\beta$ -homo-7-oxa-5-cholestan-6-one
Chemical name (CA)	-
CIPAC No	Not applicable
CAS No	78821-43-9
EC No (EINECS or ELINCS)	Not applicable
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	900 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	C <sub>28</sub> H <sub>48</sub> O <sub>6</sub>
Molar mass	480.7 g/mol
Structural formula	

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Rapporteur Member State	Month and year	Active Substance (Name)
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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Melting point (state purity)	254.6–258.2 °C (97.2% purity)
Boiling point (state purity)	No boiling could be observed up to 400 °C (97.2% purity)
Temperature of decomposition (state purity)	No decomposition could be observed up to 400 °C (97.2% purity)
Appearance (state purity)	Solid, pale white powder (97.2% purity) Solid, oyster white powder (92.3% purity)
Vapour pressure (state temperature, state purity)	No experimental determination possible. Estimated values: 1.90 x 10 <sup>-15</sup> Pa at 20 °C (97.2% purity) 8.67 x 10 <sup>-15</sup> Pa at 25 °C (97.2% purity)
Henry's law constant (state temperature)	2.40 x 10 <sup>-13</sup> Pa m <sup>3</sup> mol <sup>-1</sup> (20 °C)
Solubility in water (state temperature, state purity and pH)	3.8 mg/L at 20 °C (pH 4.5) (97.2% purity)
Solubility in organic solvents (state temperature, state purity)	At 20 °C (97.2% purity) 28.7 g/L in methanol <3.1 x 10 <sup>-3</sup> g/L in n-heptane 5.5 g/L in ethyl acetate 6.0 g/L in dichloromethane 18.0 g/L in acetone 19 x 10 <sup>-3</sup> g/L in toluene
Surface tension (state concentration and temperature, state purity)	68 mN/m at 20 °C (90 % saturated solution) (97.2% purity)
Partition coefficient (state temperature, pH and purity)	log P <sub>OW</sub> = 2.0 at 30 °C (97.2% purity) No dissociation of 24-Epibrassinolide in the range of pH 1.77 –12.51.
Dissociation constant (state purity)	pKa = . No acid or base properties were found in the range pH 1.77 –12.51. (97.2% purity)

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

(97.2% purity)  
pH 5.57:  
 $\lambda_{\max}$  (nm)       $\epsilon$  (L mol<sup>-1</sup> cm<sup>-1</sup>)  
205                  183  
215                  91  
pH 0.6:  
 $\lambda_{\max}$  (nm)       $\epsilon$  (L mol<sup>-1</sup> cm<sup>-1</sup>)  
200                  245  
pH 13.4:  
 $\lambda_{\max}$  (nm)       $\epsilon$  (L mol<sup>-1</sup> cm<sup>-1</sup>)  
219                  67

Flammability (state purity)

Not classified as flammable (92.3% purity)

Explosive properties (state purity)

No explosive properties.

Oxidising properties (state purity)

No oxidising properties.

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### Active Substance (Name)

Austria	05/2018	24-Epibrassinolide
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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

### Summary of representative uses evaluated, for which all risk assessments needed to be completed (24-Epibrassinolide) (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)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
<i>Vitis vinifera</i> VITVI (wine grapes and table grapes)	All Member states	Sunergist	F	Elicitor <i>Botryotinia fuckeliana</i> (BOTRCI) Grey mould	SL	0.099 g/L	Spraying	BBCH 15 to 85	3	7 days	1.5 - 2.5 mg a.s./hL	200 - 1000	0.05 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000
<i>Vitis vinifera</i> VITVI (wine grapes and table grapes)	All Member states	Sunergist	F	Plant activator Prevention environmental stress, quality and yield increase	SL	0.099 g/L	Spraying	BBCH 71-79	2	7 days	1.5 -2.5 mg a.s./hL	200 - 1000	0.05 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000 to 1:3000
Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, prickly lettuce LACSE), dandelion TAROF, endive CICEN, chicory CICIN	All Member states	Sunergist	F	Elicitor <i>Bremia lactucae</i> (BREMLA) Downy mildew	SL	0.099 g/L	Spraying	BBCH 10 to 41	2	7 days	1 - 2 mg a.s./hL	200 - 400	0.04 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:1000
Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, Prickly lettuce LACSE), dandelion	All Member states	Sunergist	F	Elicitor <i>Thanatephorus cucumeris</i> (RHIZSO) Bottom rot of lettuce	SL	0.099 g/L	Spraying	BBCH 10 to 41	2	7 days	1 - 2 mg a.s./hL	200 - 400	0.04 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:1000

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)		
TAROF, spinach SPQOL, witloof CICIF, chard BEAVV, lamb's lettuce VLLLO, Italian corn salad VLLER, endive CICEN															
Sugarbeet BEAVA	All Member states	Sunergist	F	Elicitor <i>Cercospora beticola</i> (CERCBE) Leaf spot of beet	SL	0.099 g/L	Spraying	BBCH 12-39	3	7 days	0.5 -2 mg a.s./hL	200-800	0.04 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000
Cucurbits 1CUCF/FFFKU e.g. Cucumber CUMSC, zucchini CUUPG, squash CUUPE, pumpkin CUUPM, melon CUMME, water melon CITLA	All Member states	Sunergist	G	Plant activator <i>Antistress</i> activity	SL	0.099 g/L	Spraying	BBCH 12 to 69	3	7 days	1.5 - 2.5 mg a.s./hL	200-1000	0.05 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000 to 1:3000
Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce) LACSA,	All Member states	Sunergist	G	Elicitor <i>Bremia lactucae</i> (BREMLA) Downy mildew	SL	0.099 g/L	Spraying	BBCH 10 to 41	2	7 days	1 - 2 mg a.s./hL	200 - 400	0.04 g/ha	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:1000

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)		
prickly lettuce LACSE), dandelion TAROF, endive CICEN, chicory CICIN															
Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, prickly lettuce LACSE), dandelion TAROF, spinach SPQOL, witloof CICIF, chard BEAVV, lamb's lettuce VLLLO, Italian corn salad VLLER, endive CICEN	All Member states	Sunergist	G	Elicitor <i>Thanatephorus cucumeris</i> (RHIZO) bottom rot of lettuce	SL	0.099 g/L	Spraying	BBCH 10 to 41	2	7 days	1 - 2 mg a.s./hL	200 - 400	0.04 g/ha	-	Volumes and doses will vary according to crop canopy size: Dilution rate: 1:1000

(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)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-isopropyl).**

(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

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200



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equipment used must be indicated

kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha  
(m) PHI - minimum pre-harvest interval

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

For further information, the GAP table was also displayed in the current format (as provided by the applicant):

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	All Member states	<i>Vitis vinifera</i> VITVI (wine grapes and table grapes)	F	Elicitor <i>Botryotinia fuckeliana</i> (BOTRCI) Grey mould	Spraying	BBCH 15 to 85	a) 3  b) 3	7 days	a) 0.5 L/ha b) 1.5 L/ha  a) 0.35 L/10000 m² tLWA* b)1.05 L/10000 m² tLWA*	a) 0.05 g/ha b) 0.15 g/ha  a) 0.04 g/10000 m² tLWA * b) 0.11 g/10000 m² tLWA*	200 - 1000	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000
2	All Member states	<i>Vitis vinifera</i> VITVI (wine grapes and table grapes)	F	Plant activator Prevention environmental stress, quality and yield increase	Spraying	BBCH 71-79	a) 2  b) 2	7 days	a) 0.5 L/ha b) 1.0 L/ha  a) 0.35 L/10000 m² tLWA* b) 0.7 L/10000 m² tLWA*	a) 0.05 g/ha b) 0.1 g/ha  a) 0.04 g/10000 m² tLWA * b) 0.07 g/10000 m² tLWA*	200 - 1000	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000 to 1:3000
3	All Member states	Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, prickly lettuce LACSE), dandelion TAROF, endive CICEN, chicory CICIN	Fpn	Elicitor <i>Bremia lactucae</i> (BREMLA) Downy mildew	Spraying	BBCH 10 to 41	a) 2  b) 2	7 days	a) 0.4 L/ha b) 0.8 L/ha	a) 0.04 g/ha b) 0.08 g/ha	200 - 400	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:1000
4	All Member states	Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, prickly lettuce	Fpn	Elicitor <i>Thanatephorus cucumeris</i> (RHIZSO) Bottom rot of lettuce	Spraying	BBCH 10 to 41	a) 2  b) 2	7 days	a) 0.4 L/ha b) 0.8 L/ha	a) 0.04 g/ha b) 0.08 g/ha	200 - 400	-	Volumes and doses will vary according to crop canopy size: Dilution rate: 1:1000

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or and/ situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		LACSE), dandelion TAROF, spinach SPQOL, witloof CICIF, chard BEAVV, lamb's lettuce VLLLO, Italian corn salad VLLER, endive CICEN											
5	All Member states	Sugarbeet BEAVA	F	Elicitor <i>Cercospora beticola</i> (CERCBE) Leaf spot of beet	Spraying	BBCH 12-39	a) 3  b) 3	7 days	a) 0.4 L/ha b) 1.2 L/ha	a) 0.04 g/ha b) 0.12 g/ha	200-800	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	All Member states	Cucurbits 1CUCF/FFFKU e.g. Cucumber CUMSC, zucchini CUUPG, squash CUUPE, pumpkin CUUPM, melon CUMME, water melon CITLA	Gpn	Plant activator <i>Antistress activity</i>	Spraying	BBCH 12 to 69	a) 3  b) 3	7 days	a) 0.5 L/ha b) 1.5 L/ha  a) 0.25 L/10000 m <sup>2</sup> tLWA** b) 0.75 L/10000 m <sup>2</sup> tLWA**	a) 0.05 g/ha b) 0.15 g/ha  a) 0.03 g/10000 m <sup>2</sup> tLWA** b) 0.08 g/10000 m <sup>2</sup> tLWA**	200- 1000	-	Volumes and doses will vary according to crop canopy size. Dilution rate: 1:2000 to 1:3000
2	All Member states	Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA,	Gpn	Elicitor <i>Bremia lactucae</i> (BREMLA) Downy mildew	Spraying	BBCH 10 to 41	a) 2  b) 2	7 days	a) 0.4 L/ha b) 0.8 L/ha	a) 0.04 g/ha b) 0.08 g/ha	200 - 400	-	Volumes and doses will vary according to crop canopy size. Dilution rate:

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## Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop or and/ situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		prickly lettuce LACSE), dandelion TAROF, endive CICEN, chicory CICIN											1:1000
3	All Member states	Leaf vegetables e.g. <i>Lactuca</i> sp. LACSS (Lettuce LACSA, Prickly lettuce LACSE), dandelion TAROF, spinach SPQOL, witloof CICIF, chard BEAVV, lamb's lettuce VLLLO, Italian corn salad VLLER, endive CICEN	Gpn	Elicitor <i>Thanatephorus cucumeris</i> (RHIZSO) bottom rot of lettuce	Spraying	BBCH 10 to 41	a) 2  b) 2	7 days	a) 0.4 L/ha b) 0.8 L/ha	a) 0.04 g/ha b) 0.08 g/ha	200 - 400	-	Volumes and doses will vary according to crop canopy size: Dilution rate: 1:1000

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

**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)															
Not relevant															

- (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)  
 (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)  
 (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds  
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide  
 (f) All abbreviations used must be explained  
 (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
 (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**  
 (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  
 (k) Indicate the minimum and maximum number of applications possible under practical conditions of use  
 (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha  
 (m) PHI - minimum pre-harvest interval

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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Further information, Efficacy

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

The representative formulation Sunergist (active ingredient: 24-Epibrassinolide) is an elicitor of plant's self-defence mechanisms against fungal diseases on wine and table grapes, leaf vegetables (e.g. lettuce) and sugar beet. Moreover, Sunergist is a plant activator to protect plants against abiotic stresses and to improve plant health in wine and table grapes and cucurbits.

No direct fungicidal or antagonistic effect against harmful organisms occurs.

##### **Elicitor uses:**

##### **BOTRCI on wine grapes and table grapes (VITVI):**

One GEP (South zone; EPPO Mediterranean zone) and 3 non-GEP trials (Central zone, EPPO Maritime zone) are available.

Significant effects were demonstrated in non-GEP trials only. A numerical reduction of disease incidence and severity on table and wine grapes may be expected.

##### **BREMLA and RHIZSO on lettuce (LACSA):**

Two GEP field trials (Central zone, EPPO Maritime zone) were presented.

Against RHIZSO, Sunergist significantly increased the proportion of marketable heads, compared to the untreated control. Against BREMLA no significant effect was seen. In one trial a numerical benefit was recorded, whereas in the other negligible efficacy was seen.

At least a numerical reduction of RHIZSO and BREMLA severity may be expected.

##### **CERCBE on sugar beet (BEAVA):**

A single GEP field trial (South zone, EPPO Mediterranean zone) was presented.

Sunergist at 0.1 l/ha and at 0.2 l/ha achieved a significant effect on disease severity. No significant effect was recorded for disease incidence.

Significant reduction of CERCBE severity may be expected.

Across uses, disease reduction at least in terms of numbers was demonstrated.

Efficacy is regarded to be sufficiently supported with data at the current level of active substance evaluation. However, for product authorisation, to demonstrate an economically relevant benefit of the application as elicitor against BOTRCI on VITVI, against BREMLA and RHIZSO on LACSA, and against CERCBE on BEAVA, further data is needed.

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#### Plant activator uses:

Prevention of environmental stress, as well as quality and yield increase is claimed for VITVI, and cucurbits.

5 non-GEP grapevine trials from the US/California (appraised to be comparable to the EPPO Maritime zone) were presented. In 3 trials Sunergist applied at dilution rates of 1:1893 to 1:3785 increased the yield. In one trial the onset of ripening was promoted, and yield was increased at the highest dilution rate, whereas in the other trials a lower bunch weight and a reduced yield was observed at the same dilution rate.

Yield was also assessed in one Maritime zone wine grape non-GEP trial and one Mediterranean zone sugar beet GEP trial. The application of Sunergist increased yield in terms of numbers.

Regarding quality parameters of the yield, in two GEP trials (one grapevine, one sugar beet) slight and statistically insignificant differences between test product treated samples, and the untreated reference samples were seen. Also in non-GEP trials no constant adverse or positive effects were recorded.

No assessments of the quality fresh fruits or vegetables (taint) were carried out.

No assessments on cucurbits were carried out.

To confirm a positive effect of Sunergist on the yield, or on the quality of yield, further data is needed for product authorisation.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Specific studies on adverse effects on field crops were not conducted.

**Crop safety** was assessed in preliminary and efficacy trials on **VITVI** in the EPPO Mediterranean zone, and the EPPO Maritime zone. No data from the EPPO South-east zone are available (EPPO North-east is not relevant for viticulture). 24-Epibrassinolide is a phytohormone. Therefore, in particular in case of perennial crops such as VITVI, the possible effect on the crop after repeated application across several years should be assessed.

Crop safety was demonstrated for field-grown **LACSA**, in the EPPO Maritime zone only. No field trials conducted in other EPPO zones (South-east, North-East) are available. Sunergist was also not assessed on **LACSA** in the green house, and was not assessed on **cucurbits** at all (Plant activator use).

**BEAVA** was assessed in a single EPPO Mediterranean zone trial. No field trials conducted in other EPPO zones (Maritime, South-east, North-East) are available.

In none of the trials crop damage was reported. However, to confirm crop safety of Sunergist at the applied doses and spray volumes for the Central zone, further data is needed for product authorisation.

**Yield** as well as **quality of yield** were assessed to address plant activator uses (see above).

The possible impact on **transformation processes** was not assessed. Sunergist is applied in all crops without a PHI, therefore residues both of the active substance as well as of the formulation on the harvested parts of the plant have to be expected. No assessments of physically processed fruits or vegetables (taint) were carried out.

No direct effect onto pure yeasts resp. malolactic bacteria during microbial fermentation is expected, however, quality parameters of grape must, and thus also of wine, may be affected. To demonstrate the neutral behavior of Sunergist on processing resp. fermentation, further product data is needed for product authorisation.

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

No specific studies regarding observations on undesirable or unintended side-effects were conducted. However, no undesirable or unintended side-effects were observed in any of the preliminary and efficacy trials conducted.

Crop safety was not sufficiently supported for all applied uses/crops. However, effects on **succeeding crops** usually are assessed for herbicides only.



## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

In particular in high growing crops spray drift onto adjacent crops is possible. To confirm crop safety of Sunergist also for **adjacent** crops, further product data are needed.

No adverse effects of Sunergist on beneficial or other non-target organisms were reported in the trials. Details on the possible effects on beneficial organisms and other non-target organisms are summarized in B.9 (Ecotoxicology).

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

Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### 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)	Technical active is analysed with HPLC-UV(DAD) after derivatisation with phenylboronic acid
Impurities in technical a.s. (analytical technique)	Impurities are analysed with HPLC-UV(DAD) after derivatisation with phenylboronic acid
Plant protection product (analytical technique)	Formulation is analysed with HPLC-UV(DAD) after derivatisation with phenylboronic acid

##### 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
Food of animal origin	Not required
Soil	Not required
Sediment	Not required
Water surface	Not required
drinking/ground	Not required
Air	Not required
Body fluids and tissues	Not required

##### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Not required
Water (analytical technique and LOQ)	Not required
Air (analytical technique and LOQ)	Not required
Body fluids and tissues (analytical technique and LOQ)	Not required

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Substance

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>:

Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

24-Epibrassinolide

None

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.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

## Section 2 Mammalian Toxicology

### 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	Rapidly absorbed and systemically bioavailable (public literature)
Toxicokinetics	Rapid distribution and excretion (public literature)
Distribution	Widespread (public literature)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Mainly via urine and faeces
Metabolism in animals	Metabolised by enzymatic degradation to bile acids (public literature)
<i>In vitro</i> metabolism	No data - not required
Toxicologically relevant compounds (animals and plants)	24-epibrassinolide
Toxicologically relevant compounds (environment)	-

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

Rat LD <sub>50</sub> oral	> 5000 mg/kg bw	
Rat LD <sub>50</sub> dermal	> 2000 mg/kg bw	
Rat LC <sub>50</sub> inhalation	> 1.08 mg/L air /4h ( <i>maximal attainable concentration</i> )	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Not sensitising	
Phototoxicity	Not required	

\*endpoint based upon preliminary study results

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 2 Mammalian Toxicology

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

Target organ / critical effect	Decreased body weight and food consumption (90 day rat)	
Relevant oral NOAEL	90-day rat: 300 mg/kg bw/d	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	No data - not required	

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

<i>In vitro</i> studies	24-Epibrassinolide was negative in the bacterial reverse mutation test (Ames) and the mammalian cell gene mutation test (HPRT). No potential for clastogenicity with and without metabolic activation in the chromosome aberration test	
<i>In vivo</i> studies	Not required	
Photomutagenicity	Not required as the value of $\epsilon > 1000$ L/mol*cm between 290-700 nm is not exceeded	
Potential for genotoxicity	24-Epibrassinolide is unlikely to be 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 - not required	
Relevant long-term NOAEL	No data - not required	
Carcinogenicity (target organ, tumour type)	No data - not required	
Relevant NOAEL for carcinogenicity	No data - not required	

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 2 Mammalian Toxicology

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

##### Reproduction toxicity

Reproduction target / critical effect	No data available. No data required.	
Relevant parental NOAEL	No data - not required	
Relevant reproductive NOAEL	No data - not required	
Relevant offspring NOAEL	No data - not required	

##### Developmental toxicity

Developmental target / critical effect	none	
Relevant maternal NOAEL	> 1000 mg/kg bw/d	
Relevant developmental NOAEL	> 1000 mg/kg bw/d	

\*endpoint based upon preliminary study results

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

Acute neurotoxicity	No data available. No data required.	
Repeated neurotoxicity	No data available. No data required.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data available. No data required.	

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

## Section 2 Mammalian Toxicology

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

Supplementary studies on the active substance	No data available. No data required.
Endocrine disrupting properties	No data available. No data required.
Studies performed on metabolites or impurities	No relevant impurities. No data required.

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

Limited; new active substance, no detrimental effects on health in manufacturing personnel

### 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)		Not required	
Acute Reference Dose (ARfD)		Not required	
Acceptable Operator Exposure Level (AOEL)		Not required	
Acute Acceptable Operator Exposure Level (AAOEL)		Not required	

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

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

Representative formulation ( <i>indicate name, type e.g. EC and concentration of active substance</i> )	0.01 % Soluble Liquid 24-Epibrassinolide displays no biologically or toxicologically relevant toxicity hazard (oral, dermal, inhalation, subchronic and developmental) and toxicity after dermal absorption is considered negligible.
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<sup>3</sup> If available include also reference values for metabolites

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

### Section 2 Mammalian Toxicology

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

Operators	As no reference values (e.g. AOEL) are considered necessary, exposure assessments for operator, bystander, worker and resident are not conducted.
Workers	As no reference values (e.g. AOEL) are considered necessary, exposure assessments for operator, bystander, worker and resident are not conducted..
Bystanders and residents	As no reference values (e.g. AOEL) are considered necessary, exposure assessments for operator, bystander, worker and resident are not conducted.

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

Substance :	24-Epibrassinolide
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 classification needed according Regulation (EC) No 1272/2008
Peer review proposal <sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	No classification needed according Regulation (EC) No 1272/2008

<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.



## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 3 Residues

### Residues in or on treated products food and feed

24-Epibrassinolide is an implicit candidate for inclusion in Annex IV of Regulation (EC) 396/2005 as it fulfils criteria 3 and 4 of SANCO/11188/2013 Rev. 2, 14 September 2015. Therefore, no more information on residues in EU is necessary.

### 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)

Primary crops (Plant groups covered)	Crop groups	Crop(s)	Application(s)	DAT (days)
	Metabolism studies not relevant. Brassinosteroids, including 24-Epibrassinolide, are naturally occurring plant constituents. The concentration of Brassinosteroids in plants is regulated by a complex system of feedback pathways and Brassinosteroids are constantly synthesised, metabolised, activated and inactivated depending on the plant's needs as well as environmental cues. There is no uniform degradation pathway, but different plant and fungal species or group have their own pathways			
Rotational crops (metabolic pattern)	Crop groups	Crop(s)	PBI (days)	Comments
	Study not relevant.			
	Rotational crop and primary crop metabolism similar?	Because Brassinosteroids are ubiquitous, phylogenetically ancient phytohormones that are naturally occurring throughout the plant kingdom, studies on rotational crops is not considered necessary.		
Processed commodities (standard hydrolysis study)	Conditions			
	20 min, 90°C, pH 4	Study not relevant.		
	60 min, 100°C, pH 5			
	20 min, 120°C, pH 6			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Brassinosteroids are present in higher plants, lower plants, including algae and mosses, and present in all plant organs such as pollen, anthers, seeds, leaves, stems, roots, flowers, grains and fruits with the highest concentrations found in pollen, seeds and fruits. Furthermore, Brassinosteroids are also naturally present in other natural and processed foods such as honey (7.4 µg/kg), fruit juices (0.5 - 12 µg/kg) and wine (3 µg/kg).			

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 3 Residues

Plant residue definition for monitoring (RD-Mo)	Not relevant
Plant residue definition for risk assessment (RD-RA)	Not relevant
Conversion factor (monitoring to risk assessment)	Not relevant

### 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)

	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
<b>Animals covered</b>	Laying hen	Not relevant		
	Goat/Cow	Not relevant		
	Pig	Not relevant		
	Fish	Not relevant		
	24-Epibrassinolide has no relevant toxicity hazard towards humans, mammals or animals, including aquatic organisms. Humans, mammals and fish are constantly exposed to 24-Epibrassinolide either directly through the consumption of primary material such as plants, plant organs (e.g. natural contents in seeds, roots, and leafs 0.22 - 378 µg/kg), natural foods such as honey (7.4 µg/kg) or algae or indirectly e.g. through the consumption of herbivores.			
Time needed to reach a plateau concentration in milk and eggs (days)		Not relevant		
Animal residue definition for monitoring (RD-Mo)		Not relevant		
Animal residue definition for risk assessment (RD-RA)		Not relevant		
Conversion factor (monitoring to risk assessment)		Not relevant		
Metabolism in rat and ruminant similar (Yes/No)		Not relevant		
Fat soluble residues (Yes/No)		Not relevant		

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 3 Residues

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

<b>Confined rotational crop study</b> (Quantitative aspect)	Because Brassinosteroids are ubiquitous, phylogenetically ancient phytohormones that are naturally occurring throughout the plant kingdom, studies on rotational crops is not considered necessary.
<b>Field rotational crop study</b>	Because Brassinosteroids are ubiquitous, phylogenetically ancient phytohormones that are naturally occurring throughout the plant kingdom, studies on rotational crops is not considered necessary.



## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 3 Residues

### Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
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24-Epibrassinolide is an implicit candidate for inclusion in Annex IV of Regulation (EC) 396/2005 as it fulfils criteria 3 and 4 of SANCO/11188/2013 Rev. 2, 14 September 2015. Therefore, no more information on residues in EU is necessary.

### Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
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Brassinosteroids are present in all plant organs with the highest concentrations found in pollen, seeds and fruits and considered an obligatory plant constituent. Pollen and immature seeds show the highest contents of Brassinosteroids with a range of 0.001 – 6400 µg/kg fresh weight. Furthermore, natural concentrations of up to 7.4 µg/kg have been observed in honey.

Additionally, it is impossible to distinguish between a possible residue resulting from the use of the natural-identical active substance 24-Epibrassinolide and the similar natural substance ubiquitously present in the environment and especially in pollen.

Based on the above justification, the determination of residues in pollen and bee products are not considered necessary.

- (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 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>).

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	05/2018	24-Epibrassinolide

## Section 3 Residues

### Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
<b>Representative uses</b>				
Not relevant				
<b>MRL application</b>				
Not relevant				

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 3 Residues

### 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)

#### MRL calculations

##### Highest expected intake

(mg/kg bw/d)

(mg/kg DM for fish)

Intake >0.004 mg/kg bw

Feeding study submitted

##### Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates

Muscle

Fat

Meat<sup>(b)</sup>

Liver

Kidney

Milk<sup>(a)</sup>

Eggs

Method of calculation<sup>(c)</sup>

Ruminant	Pig/Swine	Poultry	Fish
Residue studies from livestock feeding studies are not considered relevant			

<sup>(a)</sup>: Estimated HR calculated at 1N level (**estimated mean level for milk**).

<sup>(b)</sup>: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer

**List of end points**

Rapporteur Member State	Month and year	Active Substance (Name)
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**Section 3 Residues**

factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.



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**Rapporteur Member State**

**Month and year**

**Active Substance (Name)**

**Austria**

**2018/05**

**24-Epibrassinolide**

## Section 3 Residues

### STMR calculations

**Median expected intake**

(mg/kg bw/d)

(mg/kg DM for fish)

**Representative feeding level** (mg/kg bw/d, mg/kg DM for fish) and **N rates**

Muscle

Fat

Meat<sup>(a)</sup>

Liver

Kidney

Milk

Eggs

Method of calculation<sup>(c)</sup>

**Ruminant**

**Pig/Swine**

**Poultry**

**Fish**

Residue studies from livestock feeding studies are not considered relevant

<sup>(a)</sup>:STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(b)</sup>:When the mean level is set at the LOQ, the STMR is set at the LOQ.

<sup>(c)</sup>:The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 3 Residues

### Conversion Factors (CF) for monitoring to risk assessment

Not relevant

### Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies <sup>(a)</sup>	Processing Factor (PF)		Conversion Factor (CF <sub>P</sub> ) for RA <sup>(b)</sup>
		Individual values	Median PF	
Not relevant				

<sup>(a)</sup>: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

<sup>(b)</sup>: When the residue definition for risk assessment differs from the residue definition for monitoring

### 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

In the absence of any significant evidence for toxicity, or adverse effects in animal studies it was neither possible nor necessary to establish an ADI

Not relevant

Not relevant

Not relevant

Not relevant

Not relevant

#### ARfD

IESTI (% ARfD), according to EFSA PRIMo

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

Factors included in IESTI and NESTI

In the absence of any significant evidence for toxicity, or adverse effects in animal studies it was neither possible nor necessary to establish an ARfD

Not relevant

Not relevant

Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 3 Residues

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

Code <sup>(a)</sup>	Commodity/Group	MRL/Import tolerance <sup>(b)</sup> ( mg/kg) and Comments
<b>Plant commodities</b>		
<p>24-Epibrassinolide has a very low toxicity profile and is ubiquitous distributed in the plant kingdom (please see Table CA 6.2.1-01) and therefore fulfils criterion 3 of SANCO/11188/2013 Rev. 2 of 14 September 2015: <i>The compound has no identified hazardous properties</i>. In addition, criterion 4 of SANCO/11188/2013 Rev. 2 of 14 September 2015: <i>Natural exposure is higher than the one linked to the use as PPP</i>, is met. Therefore, no more information on residues in registered uses in EU is necessary.</p> <p>Therefore, 24-Epibrassinolide is considered a candidate for the inclusion in Annex IV of Regulation 396/2005.</p> <p>The setting of MRLs are therefore not considered necessary.</p>		

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (\*) after the figure.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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	Natural occurring ubiquitous substance; not relevant
Non-extractable residues after 100 days	Natural occurring ubiquitous substance; not relevant
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Natural occurring ubiquitous substance; not relevant

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

Mineralisation after 100 days	Natural occurring ubiquitous substance; not relevant
Non-extractable residues after 100 days	Natural occurring ubiquitous substance; not relevant
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Natural occurring ubiquitous substance; not relevant

##### 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)	Natural occurring ubiquitous substance; not relevant
Mineralisation at study end	Natural occurring ubiquitous substance; not relevant
Non-extractable residues at study end	Natural occurring ubiquitous substance; not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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	Characteristics	pH value	Organic matter (g/kg)	Cation exchange capacity (cmol/kg)	Degradation rate, d <sup>-1</sup>	Half-life, d	Normalised half-life <sup>b</sup> , d
Jiangxi red soil (Luvisols)	Loamy clay	5.29	9.94	10.60	0.016	43.3	69.55
Henan fluvo-aquic soil (Cambisols)	Loam	9.17	16.90	8.46	0.042	16.5	26.50
Northeast China black soil (Chernozems and Phaeozems)	Clay	8.45	28.70	29.80	0.050	13.8	22.17
Geometric mean (if not pH dependent)					-	21.44	34.44
pH dependence,					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

#### 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 <a href="#">xxx</a>							
Soil type	X <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. (X <sup>2</sup> )	Method of calculation
Not relevant								

<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

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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).	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
Not relevant.								

<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 xxx								
Soil type	Location	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
Not relevant.									

<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)

Not relevant

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

Not relevant

Not relevant

Kinetic formation fraction (f. f. k<sub>f</sub> / k<sub>dp</sub>) of transformation products, arithmetic mean

Not relevant

Not relevant

\* 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

Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 4 Environmental Fate

**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	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. (X <sup>2</sup> )	Method of calculation
Not relevant						

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

b) Normalised using a Q10 of 2.58

**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. (X <sup>2</sup> )	Method of calculation
Not relevant								

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

b) 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	pH <sup>a</sup>	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d) calculated at ??°N	St. (X <sup>2</sup> )	Method of calculation
Not relevant.					

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

**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>d</sub> <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>F</sub> <sub>oc</sub> (mL/g)	1/n
Not relevant.							

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

<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
Not relevant.							

<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

Not relevant

Not relevant

### 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

Not relevant

Not relevant

### 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

A lysimeter study is an optional higher tier study. In view of the ubiquitous natural occurrence, the rapid degradation and the low leaching potential of 24-Epibrassinolide, a study is not considered necessary.



## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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 5: 24.1 d at 25 °C  
pH 5: 20.9 d at 50 °C

pH 7: 19.6 d at 25 °C  
pH 7: 16.3 d at 50 °C

pH 9: 16.4 d at 25 °C  
pH 9: 13.6 d 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 %

Photolysis is not expected to contribute significantly to the degradation of 24-Epibrassinolide due to the low light absorbance of the active substance at a wavelength of 295 nm.

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

Not relevant

#### 'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)

A substance can be considered "readily biodegradable" according to REGULATION (EC) No 1272/2008 "if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period."

~~As was shown in the hydrolytic degradation study, half-life of Brassinolide was 24.1 days at pH 5 at 25 °C. Together with biological degradation through readily uptake of 24-Epibrassinolide by algae (Mekhalfi *et al.*, 2012) and plants, it can be concluded that the degradability in water will be at a level >70 % within a 28-day period. It is therefore concluded that 24-Epibrassinolide is readily biodegradable and a study is not considered necessary.~~

Not enough data is available to prove that >70 % of 24-epibrassinolide would be metabolised within a 28-day period based on the half-life value for 24-Epibrassinolide of 24.1 days at pH 5 at 25 °C. The substance is not readily biodegradable.

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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 <sub>a)</sub>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. (χ <sup>2</sup> )	Method of calculation
				At study temp	Normalised to x °C <sup>c)</sup>		At study temp	Normalised to x °C <sup>c)</sup>		
Not relevant										

<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).

Metabolite X	Max in total system x % after n days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed <sub>a)</sub>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)		St. (X <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)		St. (X <sup>2</sup> )	Method of calculation
				At study temp	Normalised to x °C <sup>c)</sup>		At study temp	Normalised to x °C <sup>c)</sup>		
Not relevant										

<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 x % after n d. (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Not relevant					

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> water	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. (χ <sup>2</sup> )	Method of calculation
Not relevant										

<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 X	Distribution. Max in total system x % after n days, kinetic formation fraction (k <sub>f</sub> /k <sub>dp</sub> ):									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> water	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. (χ <sup>2</sup> )	Method of calculation
Not relevant										

<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)
Not relevant					

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

Direct photolysis in air

Not relevant

Photochemical oxidative degradation in air

Not relevant

Volatilisation

Not relevant

Not relevant

Metabolites

Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

#### 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:	None
Surface water:	None
Sediment:	None
Ground water:	None
Air:	None

#### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

#### Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

No monitoring data available

Surface water (indicate location and type of study)

No monitoring data available

Ground water (indicate location and type of study)

No monitoring data available

Air (indicate location and type of study)

No monitoring data available

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

Parent

Method of calculation

DT<sub>50</sub> (d): 69.55 days (pH 5.29)  
Kinetics: first-order kinetics  
Field or Lab: representative worst case from lab study normalised to 20 °C

Application data

Crop: Vine  
Depth of soil layer: 5 cm  
Soil bulk density: 1.5 g/cm<sup>3</sup>  
% plant interception: No crop interception  
Number of applications: 3  
Interval (d): 7  
Application rate(s): 0.05 g a.s./ha

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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### Section 4 Environmental Fate

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.000067	-	0.000187	-
Short term 24h	0.000066	0.000066	0.000185	0.000186
2d	0.000065	0.000066	0.000183	0.000185
4d	0.000064	0.000065	0.000180	0.000183
Long term 7d	0.000062	0.000064	0.000174	0.000180
28d	0.000050	0.000058	0.000141	0.000163
50d	0.000041	0.000053	0.000114	0.000147
100d	0.000025	0.000042	0.000069	0.000118
Plateau concentration	Not relevant			

Metabolite I	Not relevant			
Method of calculation				
Application data	Not relevant			
PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	Not relevant			
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	-			

### 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)	Not relevant
Application rate	Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 4 Environmental Fate

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

Model /Crop	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Met I	Met II	Met III
	Chateaudun	Not relevant			
	Hamburg				
	Jokioinen				
	Kremsmunster				
	Okehampton				
	Piacenza				
	Porto				
	Sevilla				
	Thiva				

Model /Crop	Scenario	Metabolite (µg/L)			
		Met IV	Met V	Met VI	Met VII
	Chateaudun	Not relevant			
	Hamburg				
	Jokioinen				
	Kremsmunster				
	Okehampton				
	Piacenza				
	Porto				
	Sevilla				
	Thiva				

### 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)	Not relevant		
Metabolite X	1 <sup>st</sup> year	2 <sup>nd</sup> year	3 <sup>rd</sup> year
Annual average (µg/L)	Not relevant		

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

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

Parent	Version control no. of FOCUS calculator:
Parameters used in FOCUSsw step 1 and 2	K <sub>OC</sub> /K <sub>OM</sub> (mL/g): 0 (worst case) / 10000 (worst case) DT <sub>50</sub> soil (d): 69.55 days (Lab, maximum value, normalised). DT <sub>50</sub> water/sediment system (d): 1000 (worst case) DT <sub>50</sub> water (d): 31.48 (pH 7, normalised to 20 °C) DT <sub>50</sub> sediment (d): 1000 Crop interception (%): no interception
Parameters used in FOCUSsw step 3 (if performed)	Not performed as Step 1 and Step 2 estimate resulted in safe uses.
Application rate	Crop and growth stage: Vines (BBCH 15-85) Number of applications: 3 Interval (d): 7 Application rate(s): 0.05 g a.s./ha Application window: late spray drift selected

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Koc 0	0 h	<b>0.0540</b>		0.0000	
Koc 10000	0 h	0.0075		0.3488	

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

	Scenario FOCUS Step 2	Time period	Calculated Concentrations in the water body (multiple application)		Calculated Concentrations in the water body (respective single application pattern)	
			Max. PEC <sub>sw</sub> [µg/L]	Max. PEC <sub>sed</sub> [µg/kg]	Max. PEC <sub>sw</sub> [µg/L]	Max. PEC <sub>sed</sub> [µg/kg]
Koc 0	Northern Europe	March-May (early application)	0.0100	0.000	0.0036	0.000
		June-Sept (late application)	0.0117	0.000	0.0044	0.000
	Southern Europe	March-May (early application)	0.0190	0.000	0.0068	0.000
		June-Sept (late application)	0.0162	0.000	0.0060	0.000
Koc 10000	Northern Europe	March-May (early application)	0.0007	0.0711	0.0004	0.0254
		June-Sept (late application)	0.0014	0.0857	0.0013	0.0315
	Southern Europe	March-May (early application)	0.0014	0.1337	0.0005	0.0477
		June-Sept (late application)	0.0014	0.1170	0.0013	0.0426

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
	body		Actual	TWA	Actual	TWA
Not relevant.						

Metabolite

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Parameters used in FOCUS<sub>sw</sub> step 3 (if  
performed)

Application rate

Main routes of entry

Not relevant

Not relevant

Not relevant

Not relevant



## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 4 Environmental Fate

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Not relevant					

FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Not relevant					

FOCUS STEP 3 Scenario	Water	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
	body		Actual	TWA	Actual	TWA
Not relevant						

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

Method of calculation

Not relevant

### PEC

Maximum concentration

Not relevant

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

## Section 5 Ecotoxicology

### 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				
Rat, considered adequate for bridging to birds	24-Epibrassinolide (TGAI)	Acute, oral	LD <sub>50</sub>	> 500 <sup>1</sup> mg a.s./kg bw/d
Rat, considered adequate for bridging to birds	Sunergist (0.01% 24-Epibrassinolide SL)	Acute, oral	LD <sub>50</sub>	> 500 <sup>1</sup> mg prod./kg bw/d (equivalent to > 0.05 <sup>1</sup> mg a.s./kg bw/d)
Rat, considered adequate for bridging to birds	24-Epibrassinolide (TGAI)	Long-term	NOEL	> 100 <sup>1</sup> mg a.s./kg bw/d
Mammals				
Rat	24-Epibrassinolide (TGAI)	Acute, oral	LD <sub>50</sub>	> 5000 mg a.s./kg bw/d
Rat	Sunergist (0.01% 24-Epibrassinolide SL)	Acute, oral	LD <sub>50</sub>	> 5000 mg prod./kg bw/d (equivalent to > 0.5 mg a.s./kg bw/d)
Rat	24-Epibrassinolide (TGAI)	Long-term	NOEL	> 1000 mg a.s./kg bw/d
Endocrine disrupting properties (Annex Part A, points 8.1.5): No evidence for endocrine disruption properties				
Additional higher tier studies (Annex Part A, points 10.1.1.2): No data, not relevant				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No data, not relevant				

<sup>1</sup> Endpoints of rat studies were used as surrogate for birds and divided by a factor of 10 for a worst case assumption

## List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Austria	2018/05	24-Epibrassinolide

### Section 5 Ecotoxicology

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

##### Grapes (field use) at 3 x 0.05 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Active substance - Screening Step (Birds)</b>					
All	Small omnivorous bird	Acute	0.00762	> 65617 <sup>1</sup>	10
All	Small omnivorous bird	Long-term	0.00389	25707 <sup>1</sup>	5
<b>Formulated product - Screening Step (Birds)</b>					
All	Small omnivorous bird	Acute	0.00762	> 6.56 <sup>1</sup>	10
<b>Formulated product – Tier 1 (Birds)</b>					
BBCH 10 - 19	Small insectivorous bird “Redstart”	Acute	0.00219	> 23 <sup>1</sup>	10
BBCH ≥ 20	Small insectivorous bird “Redstart”	Acute	0.00206	> 24 <sup>1</sup>	10
BBCH 10 - 19	Small granivorous bird “Finch”	Acute	0.00118	> 42 <sup>1</sup>	10
BBCH 20 - 39	Small granivorous bird “Finch”	Acute	0.00099	> 50 <sup>1</sup>	10
BBCH ≥ 40	Small granivorous bird “Finch”	Acute	0.00059	> 84 <sup>1</sup>	10
Ripening	Frugivorous bird “Thrush”	Acute	0.00231	> 22 <sup>1</sup>	10
BBCH 10 - 19	Small omnivorous bird “lark”	Acute	0.00115	> 43 <sup>1</sup>	10
BBCH 20 - 39	Small omnivorous bird “lark”	Acute	0.00096	> 52 <sup>1</sup>	10
BBCH ≥ 40	Small omnivorous bird “lark”	Acute	0.00058	> 87 <sup>1</sup>	10
<b>Active substance - Screening Step (Mammals) – covering lettuce (Shortcut Value of grapes = SV of lettuce)</b>					
All	Small herbivorous mammal	Acute	0.0109	> 458716	10
All	Small herbivorous mammal	Long-term	0.00723	138313	5
<b>Formulated product - Screening Step (Mammals) – covering lettuce (Shortcut Value of grapes = SV of lettuce)</b>					
All	Small herbivorous mammal	Acute	0.0109	> 46	10
<b>Risk from bioaccumulation and food chain behaviour</b> Not relevant, as Log Pow is ≤ 3					
<b>Risk from consumption of contaminated water</b>					

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**Leaf scenario:** not relevant for grapes

### Puddle scenario, Screening step:

Not considered necessary, Koc is 0 (thus < 500 L/kg). The ratio between effective application rate and endpoint is below the trigger for less sorptive substances (< 50):

Birds, acute:  $0.05 / > 500^1 = < 0.0001$

Birds, long-term:  $0.05 / 100^1 = 0.0005$

Mammals, acute:  $0.05 / > 5000 = < 0.00001$

Mammals, long-term:  $0.05 / 1000 = 0.00005$

<sup>1</sup> Endpoints of rat studies were used as surrogate for birds and divided by a factor of 10 for a worst case assumption

## Sugar beet (field use) at 3 x 0.04 g a.s./ha (also covering lettuce with 2 x 0.04 g a.s./ha)

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Active substance - Screening Step (Birds)</b>					
All	Small omnivorous bird	Acute	0.01016	> 49213 <sup>1</sup>	10
All	Small omnivorous bird	Long-term	0.00518	19305 <sup>1</sup>	5
<b>Formulated product - Screening Step (Birds)</b>					
All	Small omnivorous bird	Acute	0.01016	> 4.92 <sup>1</sup>	10
<b>Formulated product – Tier 1 (Birds)</b>					
Early (BBCH 10 – 19)	Small omnivorous bird “lark”	Acute	0.00154	> 33	10
Late (BBCH 30 – 49)	Small granivorous bird “Finch”	Acute	0.00158	> 32	10
BBCH 10 - 19	Small insectivorous bird “wagtail”	Acute	0.00070	> 72	10
BBCH 20 - 49	Small insectivorous bird “wagtail”	Acute	0.00049	> 101	10
BBCH 10 - 19	Small insectivorous bird “wagtail”	Acute	0.00070	> 72	10
BBCH 20 - 49	Small insectivorous bird “wagtail”	Acute	0.00161	> 31	10
<b>Active substance - Screening Step (Mammals) – covered by grapes (Shortcut Value of grape &gt; SV of sugar beet)</b>					
All	Small herbivorous mammal	Acute	0.0109 <sup>2</sup>	> 458716 <sup>2</sup>	10
All	Small herbivorous mammal	Long-term	0.00723 <sup>2</sup>	138313 <sup>2</sup>	5
<b>Formulated product - Screening Step (Mammals) – covered by grapes (Shortcut Value of grape &gt; SV of sugar beet)</b>					
All	Small herbivorous mammal	Acute	0.0109 <sup>2</sup>	> 46 <sup>2</sup>	10
<b>Risk from bioaccumulation and food chain behaviour</b>					
Not relevant, as Log Pow is ≤ 3					

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Risk from consumption of contaminated water</b>					
Scenarios	Indicator or focal species	Time scale	PEC <sub>pool</sub> x DWR	TER	Trigger
Leaf scenario (for lettuce)	Birds	Acute	0.0184	> 27174 <sup>1</sup>	10
<b>Puddle scenario, Screening step:</b> Covered by the assessment of grapes.					

<sup>1</sup> Endpoints of rat studies were used as surrogate for birds and divided by a factor of 10 for a worst case assumption

<sup>2</sup> The risk assessment of grapes covers the assessment of sugar beet. The DDD of grape is considered worst case since it has a higher application rate the Shortcut Value of grapes is higher then the SV of lettuce

## Cucurbits (glass house use) at 3 x 0.05 g a.s./ha

In uses in glass houses no exposure to birds and mammals is considered, therefore no risk assessment is necessary.

## 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 has been amended to 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>Danio rerio</i> (Zebrafish)	24-Epibrassinolide	Acute, 96 hr (static)	Mortality, LC <sub>50</sub>	> 5.0 mg a.s./L <sub>(nom)</sub>
	Preparation	Acute	Mortality, LC <sub>50</sub>	No data
	24-Epibrassinolide	Chronic	NOEC	No data
Aquatic invertebrates				
<i>Daphnia magna</i>	24-Epibrassinolide	Acute, 48 hr (static)	Mortality, EC <sub>50</sub>	> 2.86 mg a.s./L <sub>(mm)</sub>
	Preparation	Acute	Mortality, EC <sub>50</sub>	No data
	24-Epibrassinolide	Chronic	NOEC	No data

## List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Sediment-dwelling organisms: No data				
Algae: No data				
Higher plant: No data				
Further testing on aquatic organisms: Not necessary				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3): No evidence for endocrine disruption properties				

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

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

Not necessary, as logPow = 2.0 (thus < 3).

## 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 1-2 – PEC/RAC ratios for 24-Epibrassinolide, use in cucurbits at 3 x 0.05 g a.s./ha (covering all other uses due to maximum worst case PECs)

Group		Fish		Invertebrates		Algae	Macrophyts
		Acute	Chronic	Acute	Chronic		
Test species		<i>Danio rerio</i>	No data	<i>D. magna</i>	No data	No data	No data
Endpoint [µg a.s./L]		LC <sub>50</sub> > 5000	-	EC <sub>50</sub> > 2680	-	-	-
AF		100	-	100	-	-	-
RAC [µg a.s./L]		50.00	-	26.8	-	-	-
FOCUS Scenario	PEC <sub>SW</sub> [µg a.s./L]						
Step 1							
	0.0514	< 0.0010	-	< 0.0018	-	-	-
Step 2							
	0.0232	< 0.0005	-	< 0.0008	-	-	-

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### 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., 24-Epibrassinolide	Acute (48 h)	Oral toxicity (LD <sub>50</sub> )	> 92.2 µg a.s./bee (actual consumed dose)
<i>Apis mellifera</i>	a.s., 24-Epibrassinolide	Acute (48 h)	Contact toxicity (LD <sub>50</sub> )	> 10 µg a.s./bee (solubility limit)
	a.s.	Chronic	10 d-LC50	No data
	a.s.	Bee brood development	NOEC larvae	No data
	a.s.	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	No data

Potential for accumulative toxicity: no

Semi-field test (Cage and tunnel test):

No data, not necessary

Field tests :

No data, not necessary

### Risk assessment for 24-Epibrassinolide – use in grapes at 3 x 0.05 g a.s./ha (covering all other uses)

Terrestrial Ecotoxicology GD (SANCO/10329/2002)				
Species	Test substance	Risk quotient	HQ	Trigger
<i>Apis mellifera</i>	a.s., 24-Epibrassinolide	HQ <sub>oral</sub>	< 0.0005	50
<i>Apis mellifera</i>	a.s., 24-Epibrassinolide	HQ <sub>contact</sub>	< 0.005	50
EFSA Bee GD (2013)				
Species	Test substance	Risk quotient	HQ/ETR	Trigger
<i>Apis mellifera</i>	a.s., 24-Epibrassinolide	HQ <sub>contact</sub>	< 0.005	85
<i>Apis mellifera</i>	a.s., 24-Epibrassinolide	ETR <sub>acute adult oral</sub>	< 0.000006	0.2

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### Section 5 Ecotoxicology

#### 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	End point	Toxicity
<i>Aphidius rhopalosiphi</i>	Sunergist (0.01% 24-Epibrassinolide SL)	Mortality, LR <sub>50</sub>  Reproduction, ER <sub>50</sub>	> 7000 mL product/ha (equivalent to > 0.69 g a.s./ha)  > 7000 mL product/ha (equivalent to > 0.69 g a.s./ha)
<i>Typhlodromus pyri</i>	Sunergist (0.01% 24-Epibrassinolide SL)	Mortality, LR <sub>50</sub>  Reproduction, ER <sub>50</sub>	2831.9 mL product/ha (equivalent to 0.28 g a.s./ha)  n.d.
Additional species: No additional studies submitted, not necessary.			

n.d. ... not determined

#### First tier risk assessment for 24-Epibrassinolide - use in grapes at 3 x 0.05 g a.s./ha (covering all other uses)

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in-field	HQ off-field <sup>1</sup>	Trigger
Preparation, Sunergist (0.01% 24-Epibrassinolide SL)	<i>Aphidius rhopalosiphi</i>	> 0.69 g a.s./ha	< 0.17	< 0.06	2
Preparation, Sunergist (0.01% 24-Epibrassinolide SL)	<i>Typhlodromus pyri</i>	0.28 g a.s./ha	0.41	0.14	2

<sup>1</sup>drift factor 0.069, worst case use in grape

#### Extended laboratory tests, aged residue tests

No data, not necessary
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Semi-field tests: No data, not necessary
Field studies: No data, not necessary
Additional specific test: No data, not necessary



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#### 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
Earthworms					
	a.s.	-	Chronic	-	No data
Other soil macroorganisms					
	a.s.	-	-	-	No data

<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): No data available

#### Toxicity/exposure ratios for soil organisms

In public literature a natural occurrence in soil and a fast uptake of Brassinosteroids by plants via roots are reported. Further the soil degradation (DT<sub>50</sub> 69.55 d) and the low predicted worst case environmental concentration in soil (PEC<sub>soil</sub> = 0.2 µg/kg soil,) support that no adverse effects from the use of 24-Epibrassinolide and the representative formulation Sunergist (24-Epibrassinolide 0.01% SL) according to the proposed GAP are expected on soil organisms (earthworms and other soil macroorganisms). Therefore an acceptable risk is concluded and no further risk assessment is required.

Nitrogen transformation	a.s.	No data	No studies were submitted to address the effects of the active substance or the formulated product on soil nitrogen transformation. However public literature and PEC <sub>soil</sub> calculations support that the natural exposure to 24-Epibrassinolide can be considered to be higher than the exposure following an application of the active substance in the form of a plant protection product. Therefore it is concluded that the risk to soil nitrogen transformation posed by the application of Sunergist (24-Epibrassinolide 0.01% SL) following the proposed GAP can be considered acceptable and no further risk assessment is required.
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#### 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

No data available

##### Laboratory dose response tests

No laboratory studies were submitted by the notifier to address the effects of the active substance on terrestrial non-target plants, but public literature studies support that brassinosteroids are commonly found in plant tissue and no negative effects are reported. It was reported that treatment of crop plants with brassinosteroids, including 24-Epibrassinolide increased crop health and yield. Furthermore in efficacy trials with the product Sunergist no effects on phytotoxicity and vegetative vigour were found in grapes (with application rates up to 0.8 L product/ha in 600-800 L water), in lettuce (with application

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rates up to 0.8 L product/ha in 400 L water) and in sugar beet (with application rates up to 0.2 L product/ha in 200 L water).

Therefore it is concluded that waiving the effect studies on terrestrial non-target plants can be considered acceptable and negative effects on non-target plants induced by 24-Epibrassinolide and the representative formulation Sunergist (24-Epibrassinolide 0.01% SL) following the proposed GAP are considered unlikely.

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

No effect studies were submitted by the notifier to address the effects on biological methods for sewage treatment. No data was presented by the applicant regarding natural background concentrations of 24-Epibrassinolide in sewage or sewage sludge. However taking into account that brassinosteroids naturally occur in plant matter and the environment the waiver is considered acceptable. Further it is reported in public literature study that microorganisms in general are capable to metabolise 24-Epibrassinolide. This provides together with low predicted environmental concentrations evidence that adverse effects to sewage sludge induced by 24-Epibrassinolide are considered unlikely. The data requirement was sufficiently addressed and no further risk assessment is necessary.

Test type/organism	End point
Activated sludge	No data available
<i>Pseudomonas sp.</i>	No data available

### 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.  
No data, not necessary

Available monitoring data concerning effect of the PPP.  
No data, not necessary

### 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	A residue definition is not needed <sup>2</sup>
water	A residue definition is not needed <sup>2</sup>
sediment	A residue definition is not needed <sup>2</sup>
groundwater	A residue definition is not needed <sup>2</sup>

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

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<sup>2</sup> 24-Epibrassinolide is considered to occur naturally in all compartments of the environment. It is not possible to distinguish between the residues arising from the use of 24-Epibrassinolide as a plant protection product and its natural presence in environmental compartments.

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

Substance	24-Epibrassinolide
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>6</sup> :	No entry into Annex VI or ATPs.
Peer review proposal <sup>7</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	H413 The effect studies of the active substance on algae and macrophyts were waived, however both aquatic plants are considered to be potentially susceptible organisms (due to possible effects on growth under static exposure laboratory conditions). Since such potential effects are considered unlikely but can't be fully excluded it is proposed to classify 24-Epibrassinolide according to Regulation (EU) 286/2011 within the "safety net" as hazard class "aquatic chronic 4 (H413)" since no studies are presented and the active substance is considered as not readily biodegradable.

<sup>6</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.

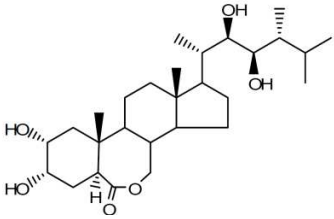
<sup>7</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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## Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
<b>24-Epibrassinolide</b>	(22R,23R,24R)-2 $\alpha$ ,3 $\alpha$ ,22,23-tetrahydroxy-24-methyl- $\beta$ -homo-7-oxa-5-cholestan-6-one	

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