Appendix to:

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance glyocladium catenulatum. EFSA Journal 2017;15(7):4905, 20 pp. doi:10.2903/j.efsa.2017.4905

Identity, Biological properties, Details of uses, Further information, and Proposed Classification and Labelling

Active microorganism:	*Clonostachys rosea* strain J1446 approved in regulation (EU) No 540/2011 as *Gliocladium catenulatum* strain J 1446
Function (*e.g.* control of fungi):	Fungicide (antagonistic fungus for the control of plant pathogenic fungi)
Rapporteur Member State:	Hungary
Co-rapporteur Member State:	The Netherlands
Identity of the Microbial or Viral Agent used in plant protection / Active Substance) (Regulation (EU) N° 283/2013, Annex Part B, point 1; OECD IIM Point 1)	
Name of the organism:	*Clonostachys rosea* strain J1446
Taxonomy:	Class: Fungi imperfecti Order: Moniliales Family: Moniliaceae Genus: *Clonostachys (= Gliocladium)* Species: *Clonostachys rosea* (=*Gliocladium catenulatum* =*Gliocladium roseum)* Strain: J1446
Species, subspecies, strain:	Verdera's antagonistic strain J1446 was officially identified as *Gliocladium catenulatum* by Gilman & Abbott by Centraalbureau voor Schimmelcultures in 1993 and 1996, and re-identified by Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH in 2000. Note that in Fungal Databases / Nomenclature and Species Banks of the International Mycological Association the current name for *Gliocladium catenulatum* is *Clonostachys rosea* f. *catenulata*. However, it is the Index Fungorum which represents the highest authority in the names of fungi. According to Index Fungorum, the current official name for the old name *G. roseum* is *Clonostachys rosea*, and *Gliocladium catenulatum* is listed as a synonym for *C. rosea*. So, the fungus *Gliocladium catenulatum* is the same as *Clonostachys rosea*.
Identification / detection:	*Clonostachys rosea* J1446 can easily and reliable be identified by its growth characteristics, i.e. by conventional morphological methods based on colony/stomata, conidiophore and conidia characteristics. Additionally, molecular methods and primers have been developed for the strain-level identification *Clonostachys rosea* J1446 by RAPD-PCR, RAMS and UP-PCR analysis.
Culture collection:	*Gliocladium catenulatum* strain J1446 is deposited in the German Collection of Microorganisms and Cell Cultures (DSMZ) under the accession number DSM 9212.
Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (cfu; g/kg):	The technical grade of MPCA is only a hypothetical stage in the continuous production process of end use product with *C. rosea* J1446 as active substance. The MPCA content in the representative product formulation PRESTOP

	(WP): 2 x 10^8 - 1 x 10^9 CFU/g (204 - 250 g/kg)
Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:	The technical grade of MPCA is only a hypothetical stage in the continuous production process of end use product with *C. rosea* J1446 as active substance.
Is the MPCA genetically modified; if so provide type of modification	*Clonostachys rosea* J1446 is an indigenous wild fungal strain, not genetically modified or a mutant

Biological properties of the microorganism (Regulation (EU) N° 283/2013, Annex Part B, point 2; OECD IIM Point 2)

Origin and natural occurrence,	*Clonostachys rosea* J1446 was isolated from Finnish field soil. *Clonostachys rosea / Gliocladium catenulatum* (i.e. *G. roseum*) is a common and widely distributed saprophytic fungus, common in soils all over the world. *Clonostachys spp.* and *Gliocladium* spp. are generally considered as secondary colonisers / decomposers of rotting biomass as well as known to colonise, without symptom production, apparently healthy roots, stems, pods and seeds of various plants. Wild-type and natural occurring antagonistic strains of *Clonostachys rosea* (syn. *Gliocladium roseum*) has been detected and isolated from soils (incl. different geographical and national locations), root and bark of living and dead trees, plant leaves and fruits in Europe (e.g. Denmark, Finland, Germany, France and United Kingdom), North America, Australia and New Zealand. Reports from warmer zones include Egypt, Turkey, Cyprus, Pakistan, Kenya, Swaziland, Rhodesia, Iraq, Zaire, South Africa, Nepal, India, Borneo, Central America (e.g. Jamaica, Venezuela, Guyana, Mexico and Argentina) and Hong Kong. *Gliocladium catenulatum* species have been isolated from cultivated and forest soils, willow-cottonwood lowlands, grassland, woodland, heath land, savannah, fresh water, salt marshes and arable soils from an extraordinary range of habitats in tropical, temperate, subarctic, and desert regions.
Background level:	In Denmark the presence of indigenous *C. rosea* strains were found in soil samples at a level of approximately 10^3 – $4x10^3$ CFU/g (dry weight) of soil.
Target organism(s):	Seed- and soil borne plant pathogenic fungi such as *Pythium, Rhizoctonia, Phytophthora, Fusarium* as well as foliar pathogens *Didymella* and *Botrytis.*
Mode of action:	Mode of action of *Clonostachys rosea* J1446 is based on competition for living space and nutrients or substrate i.e. root colonisation ability prior to establishment of pathogen(s), antibiosis, hyperparasitism (i.e. mycoparasitism) and production of lytic enzymes. The effect of *Clonostachys rosea* J1446 is preventive and therefore the first treatments should be made before visible or heavy disease symptoms occur in crop cultivations. When the antagonist is applied in advance, it has the time to proliferate on the actual growth niche before the actual pathogen arrives. The preventive mode of action can be seen both in rhizosphere as well as on foliar (above-soil) parts of plants.
Host specificity:	The mode of action of *Clonostachys rosea* J1446 is based on root colonisation ability and hyperparasitism with the production of lytic enzymes. The mechanisms are specifically targeted against pathogens occupying same ecological niche on plants (roots and foliage) and include pathogens such as *Pythium, Rhizoctonia, Phytophthora, Fusarium, Didymella* and *Botrytis*.
Life cycle:	Mycelium and spores of *Clonostachys rosea* J1446. Aerial mycelium forms hyaline conidiophores, which arise directly from somatic hyphae, and bear asexual spores, conidia. In favourable conditions, that is when sufficient nutrients are available spores germinate and produces new hyphae and mycelia growth. When nutrients are exhausted mycelial growth declines and spores are produced as their task

	is to survive the fungus over unfavourable periods and conditions.
Infectivity, dispersal and colonisation ability:	*Clonostachys rosea* J1446 is not infective. The issue remains open whether *Clonostachys rosea* J1446 produces any secondary metabolites or toxins of concern. *Clonostachys rosea (*i.e. *Gliocladium catenulatum*, *G. roseum*) is known to colonise, without symptom production, apparently healthy roots, stems, pods and seeds of various plants. Here the fungus colonises the host as a non-pathogenic parasite and in some cases the associations is even systemic. The main targets of *Clonostachys rosea* strain J1446 are seed- and soil borne pathogens *Pythium, Rhizoctonia*, *Phytophthora*, *Fusarium* as well as foliar pathogens *Didymella* and *Botrytis.* No effect against other microbes (e.g. bacteria) has been observed. *Clonostachys rosea* strain J1446 persists in plant roots, peat and rock wool for several weeks after application, but the amount of the fungus declines with time.
Relationships to known plant, animal or human pathogens:	*Clonostachys rosea* strain J1446 is not closely related to plant, animal or human pathogens
Genetic stability:	*Clonostachys rosea* strain J1446 acts against target pathogens via direct competition. The traits governing this, which are a combination of characters such as root colonisation ability prior to establishment of pathogen(s), antibiosis, hyperparasitism (i.e. mycoparasitism) and production of lytic enzymes are all under continuous, stable, polygenic genetic control, and are not controlled by only a few major genes. This means that these traits are not subject to breakdown or loss of action via mutation, which can be the case for traits controlled by one or a few major genes, and so the ability of *G. catenulatum* J1446 to control plant pathogenic fungi can be considered genetically stable. In order to ensure the genetic stability of *Clonostachys rosea* strain J1446, the microbe is stored in vials in a deep freezer (-80 ºC). Detection of potential spontaneous change in characteristics of *Clonostachys rosea* strain J1446 is based on the following criteria: 1) the morphological features and growth properties on solid medium, 2) the behaviour of the organism during the whole production process of Prestop and 3) the ability to inhibit plant pathogenic fungi *in vitro* and *in vivo*. All these characteristics are compared to that of the original strain stored at -80^{o}C. A molecular, RAPD/PCR based method with strain specific primers for distinguishing changes in the genome of *Clonostachys rosea* strain J1446 is also available.
Information on the production of relevant metabolites (especially toxins):	Data gaps for toxins/secondary metabolites No gliotoxin was detected by HPLC determinations above the LOQ of 0.05 mg/kg from *Clonostachys rosea* strain J1446 unformulated cell mass powder, culture broth samples or from mineral wool cultivation pots. The method is not fully validated. Data gap No cell toxicity was detected for *Clonostachys rosea* strain J1446 cell mass or the formulated end-product (WP) in FL-cell tests in vitro.
Resistance/ sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine:	No data available, Data gap

Summary of uses supported by available data (Regulation (EU) N° 283/2013, Annex Part B, point 3; OECD IIM Point 3)

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
Fruiting vegetables	EU	PRESTOP	G	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Soil incorporation	Before sowing BBCH 00	4	21	100-250	20000-50000	**23-58** **($1*10^{14}$-$2.5*10^{14}$ cfu/ha)** minimum ($2*10^{13}$-$5*10^{13}$ cfu/ha)	n.r	200–500 g product /m^3. Using 0.5% product suspension. 500 m^3/ha (5cm soil depth) 1-5 crop cycles/year
							Soil drench / Drip irrigation	From transplanting BBCH 15-89	4	21	8-10	1600-2000	**1.8-2.3** **($8*10^{12}$-$1*10^{13}$ cfu/ha)** minimum ($1.6*10^{12}$-$2*10^{12}$	n.r	200 - 250 g product / 1 000 plants. Estimated plant density: 4 plants/m^2.
				Foliar pathogens e.g. *Botrytis* and *Didymella*			Foliar spray	From transplanting BBCH 15-89	4	21	1-10	200-2000	**0.23-2.3** **($1*10^{12}$-$1*10^{13}$ cfu/ha)** minimum ($2*10^{11}$-$2*10^{12}$ cfu/ha)	n.r	0.1 – 1 g product / m^2. Using 0.5% product suspension.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
Seedlings	EU	PRESTOP	G	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Soil incorporation	Before sowing BBCH 00	1	-	100-250	20000-50000	**23-58** **($1*10^{14}$-$2.5*10^{14}$ cfu/ha)** minimum ($1*10^{13}$-$5*10^{13}$ cfu/ha)	n.r	200–500 g product /m^3 500 m^3/ha (5cm soil depth) 1-5 crop cycles/year
							Soil spray / Soil drench / Drip irrigation	After emergence BBCH 09-13	3	21	50-100	10000-20000	**12-23** **($5*10^{13}$-$1*10^{14}$ cfu/ha)** minimum ($1*10^{13}$-$2*10^{13}$ cfu/ha)	n.r	5 – 10 g product / m^2. Using 0.5% product suspension.
Strawberry	EU	PRESTOP	G / F	*Botrytis* sp.	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	foliar spraying	At flowering BBCH 60-73	2	21	1-10	200-2000	**0.23-2.3** **($1*10^{12}$-$1*10^{13}$ cfu/ha)** minimum ($2*10^{11}$-$2*10^{12}$	n.r	0.1 – 1 g product / m^2. Using 0.5% product suspension.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
Ornamentals - Pot plants, cut flowers	EU	PRESTOP	G	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Soil incorporation	Before sowing BBCH 00	1	-	100 – 250	20000-50000	**23-58** **($1*10^{14}$-$2.5*10^{14}$ cfu/ha)** minimum ($2*10^{13}$-$5*10^{13}$ cfu/ha)	n.r	200–500 g product /m^3 500 m^3/ha (5cm soil depth) 1-5 crop cycles/year
							Soil drench / Drip irrigation	From potting / transplanting BBCH 13-65	4	21	12 – 22.5	2400-4500	**2.8-5.2** **($1.2*10^{13}$-$2.25*10^{13}$ cfu/ha)** minimum ($2.4*10^{12}$-$4.5*10^{12}$ cfu/ha)	n.r	200 - 250 g product / 1 000 plants. Estimated plant density: 6 - 9 plants/m^2. Using 0.5% product suspension.
							Spraying (soil)	From potting / transplanting BBCH 13-65	4	21	100 – 250	20000-50000	**23-58** **($1*10^{14}$-$2.5*10^{14}$ cfu/ha)** minimum ($2*10^{13}$-$5*10^{13}$ cfu/ha)	n.r	200 - 500 g product / 1 000 plants when root ball size is 1 L. Using 0.5% product suspension.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
				Foliar pathogens e.g. *Botrytis* and *Didymella*			Foliar spray	From transplanting BBCH 15-89	4	21	1-10	200-2000	**0.23-2.3 ($1*10^{12}$-$1*10^{13}$ cfu/ha)** minimum ($2*10^{11}$-$2*10^{12}$ cfu/ha)	n.r	0.1 – 1 g product / m^2. Using 0.5% product suspension.
Ornamentals – Cuttings and bulbs	EU	PRESTOP	G	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Dipping of rooted cuttings and bulbs	Before potting / planting BBCH 10-15	1	-	15-25	--	**3.5-5.8 ($1.5*10^{13}$-$2.5*10^{13}$ cfu/ha)** minimum ($3*10^{12}$-$5*10^{12}$ cfu/ha)	n.r	Using 0.5% product solution. Estimation: 50-60 plants/m^2 and 25-50 mg product/cutting.
Seeds	EU	PRESTOP	G/F	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Dry seed treatment	Before sowing BBCH 00	1	-	0.25-6.25	--	**0.058-1.44 ($2.5*10^{11}$-$6.25*10^{12}$ cfu/ha)** minimum ($5*10^{10}$-$1.25*10^{12}$ cfu/ha)	n.r	5 – 25 g product / kg seeds. Estimated seed density: 50 – 250 kg seeds / ha.
Grapewine	EU	PRESTOP	F	Grey mould *(Botrytis cinerea)*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Foliar spray	End of flowering to grape harvest BBCH 67-89	1-4	6	1-5	200-1000	**0.23-1.2 ($1*10^{12}$-$5*10^{12}$ cfu/ha)** minimum ($2*10^{11}$-$1*10^{12}$ cfu/ha)	n.r	

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
Wheat	EU	PRESTOP	F	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Drench	At / after sowing BBCH 00	1-5	21	5	1000	**1.2 ($5*10^{12}$ cfu/ha)** minimum ($1*10^{12}$ cfu/ha)	n.r	
							Seed treatment	Before planting BBCH 00	1	-	1.4-1.8	--	**0.32-0.41 ($1.4*10^{12}$-$1.8*10^{12}$ cfu/ha)** minimum ($2.8*10^{11}$-$3.6*10^{11}$ cfu/ha)	n.r	
				Fusarium sp.			Foliar spraying	At flowering stage BBCH 61-69	1	-	2	150-400	**0.46 ($2*10^{12}$ cfu/ha)** minimum ($4*10^{11}$ fu/ha)	n.r	
Corn (maize)	EU	PRESTOP	F	Seed borne and soil borne fungi, such as *Rhizoctonia*, *Pythium;* damping off	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Drench	At / after sowing BBCH 00	1-5	21	5	200-1000	**1.2 ($5*10^{12}$ cfu/ha)** minimum ($1*10^{12}$ cfu/ha)	n.r	

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
							Seed treatment	Before planting BBCH 00	1	-	1-14	--	**0.23-3.22 (1 *10^{12}-1.4*10^{13} cfu/ha)** minimum (2*10^{11}-2.8*10^{12} cfu/ha)	n.r	Target use is to have 1E6 – 1E7 cfu/seed. Seed density: 100000 – 140000 seeds / ha (maize).
Fruiting vegetables (e.g. cucumber, melons, tomato, pepper)	EU	PRESTOP	F	Foliar pathogens e.g. *Botrytis* and *Didymella*	WP	230 g/kg (2*10^{8} - 1*10^{9} CFU/g)	Foliar spraying	Before / at transplanting BBCH 10-15	1	-	0.6	120	**0.14 (6*10^{11}- cfu/ha)** minimum (1.2*10^{11} cfu/ha)	n.r	Using 0,5% product solution.
							Foliar spraying	After / from transplanting BBCH 13-65	1 – 4	21	2 – 3	400-600	**0.46-0.69 (2*10^{12}-3*10^{12} cfu/ha)** minimum (4*10^{11}-6*10^{11} cfu/ha)	n.r	Using 0,5% product solution.
Leaf vegetables	EU	PRESTOP	F	Foliar pathogens e.g. *Botrytis* and *Didymella*	WP	230 g/kg (2*10^{8} - 1*10^{9} CFU/g)	Foliar spraying	After emergence BBCH 09-19	1 – 3	21	2 – 3	400-600	**0.46-0.69 (2*10^{12}-3*10^{12} cfu/ha)** minimum (4*10^{11}-6*10^{11} cfu/ha)	n.r	Using 0,5% product solution.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
			G	Seed borne and soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*			Hydroponic	From transplanting BBCH 13-49	1	-	3 – 6	600-1200	**0.69-1.4 ($3*10^{12}$-$6*10^{12}$ cfu/ha)** minimum ($6*10^{11}$-$1.2*10^{12}$ cfu/ha)	n.r	Application dose: 25 g product / 1000 plants. Plant density: 12-24 plants/m^2.
Onion	EU	PRESTOP	F	Seed borne and soil borne fungi, such as *Fusarium*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Spraying of sets/bulbs	At planting BBCH 00	1	-	3–3.5	600-700	**0.69-0.8 ($3*10^{12}$-$3.5*10^{12}$ cfu/ha)** minimum ($6*10^{11}$-$7*10^{11}$ cfu/ha)	n.r	Using 0,5% product solution.
Potato	EU	PRESTOP	F	Seed borne and soil borne fungi, such as *Rhizoctonia* and *Helminthosporium*	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Spraying of tubers	Before planting BBCH 00	1	-	0.75-1.5	150-300	**0.18-0.35 ($7.5*10^{11}$-$1.5*10^{12}$ cfu/ha)** minimum ($1.5*10^{11}$ - $3*10^{11}$ cfu/ha)	n.r	Using 0,5% product solution. Calculations according to water volumes.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
							Soaking (for 15 minutes)	Before planting BBCH 00	1	-	0.7	140	**0.16 ($7*10^{11}$ cfu/ha)** minimum ($1.4*10^{11}$ cfu/ha)	n.r	Using 0,5% product solution. Estimated seed weight per ha = 1900 kg/ha. Estimated application dose for tubers = 75 ml/kg potato.
Leek	EU	PRESTOP	G/F	Seed borne and soil borne fungi, e.g. *Fusarium*, *Rhizoctonia*, *Phytophtora* and *Pythium*	WP	230 g/kg ($2*10^{8}$ - $1*10^{9}$ CFU/g)	Drench	At seedling stage/before transplanting BBCH 09-15	1 – 2	21	50 – 100	5000-10000	**12-23 ($5*10^{13}$-$1*10^{14}$ cfu/ha)** minimum ($1*10^{13}$-$5*10^{13}$ cfu/ha)	n.r	
							Foliar spraying	At (trans)planting BBCH 13-19	1	-	3 – 3.5	600-700	**0.69-0.8 ($3*10^{12}$-$3.5*10^{12}$ cfu/ha)** minimum ($6*10^{11}$-$7*10^{11}$ cfu/ha)	n.r	Leek seedlings are sprayed just before or at transplanting stage. Using 0,5% product solution.

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					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
							Dipping rooted plants	Before transplanting BBCH 10-15	1	-	1	-	**0.23 ($1*10^{12}$ cfu/ha)** minimum ($2*10^{11}$ cfu/ha)	n.r	Roots of nursery plants are treated by dipping them into 0.5% product solution just before transplanting.
Strawberry	EU	PRESTOP	F	Seed borne and soil borne fungi, e.g. *Fusarium*, *Phytophtora* and *Pythium*	WP	230 g/kg ($2*10^{8}$ - $1*10^{9}$ CFU/g)	Spraying or Drench / drip irrigation	At/from transplanting BBCH 10-19	2	28	5 – 15	1000-3000	**1.2-3.5 ($5*10^{12}$-$1.5*10^{13}$ cfu/ha)** minimum ($1*10^{12}$-$3*10^{12}$ cfu/ha)	n.r	200-300 g product / 1000 plants. Estimated plant density: 25000 – 50000 plants/ha.
			G					At/from transplanting BBCH 10-19	2	28	10 – 27	2000-5400	**2.3-6.2 ($1*10^{13}$-$2.7*10^{13}$ cfu/ha)** minimum ($2*10^{12}$-$5.4*10^{12}$ cfu/ha)	n.r	200-300 g product / 1000 plants. Estimated plant density: 50000 – 90000 plants/ha.
Raspberry	EU	PRESTOP	F	Foliar fungi e.g. *Botrytis* and *Didymella*	WP	230 g/kg ($2*10^{8}$ - $1*10^{9}$ CFU/g)	Spraying (foliar)	At/from transplanting BBCH 10-73	5	21	3	200-1200	**0.69 ($3*10^{12}$ cfu/ha)** minimum ($6*10^{11}$ cfu/ha)	n.r	

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
			G/F	Soil borne fungi, such as *Fusarium*, *Pythium* and *Phytophtora*			Spraying (soil) or drench /drip irrigation	At/from transplanting BBCH 10-73	2	28	1 – 3.3	200-1200	**0.23- 0.76 ($1*10^{12}$- $3.3*10^{12}$ cfu/ha)** minimum ($2*10^{11}$- $6.6*10^{11}$ cfu/ha)	n.r	200-300 g product / 1000 plants. Estimated plant density: 5000 plants/ha (field) and 11000 plants/ha (tunnel).
Blueberry	EU	PRESTOP	F	Foliar fungi e.g. *Botrytis* and *Didymella*	WP	230 g/kg ($2*10^{8}$ - $1*10^{9}$ CFU/g)	Spraying	At/from transplanting BBCH 10-73	5	21	3	200-1200	**0.69 ($3*10^{12}$ cfu/ha)** minimum ($6*10^{11}$ cfu/ha)	n.r	
				Soil borne fungi, such as *Fusarium* and *Phytophtora*			Drench / drip irrigation	At/from transplanting BBCH 10-73	5	21	3 – 5	200-1200	**0.69- 1.2 ($3*10^{12}$- $5*10^{12}$ cfu/ha)** minimum ($6*10^{11}$- $1*10^{12}$ cfu/ha)	n.r	
Ornamentals (roses)	EU	PRESTOP	G	Grey mould *(Botrytis cinerea)*	WP	230 g/kg ($2*10^{8}$ - $1*10^{9}$ CFU/g)	Foliar ULV spray	From transplanting BBCH 10-69	1 – 12	7	2.5	150-800	**0.58 ($2.5*10^{121}$ cfu/ha)** minimum ($5*10^{11}$ cfu/ha)	n.r	

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as * (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg FP/ha min max	water L/ha min max	kg as/ha min max		
Turfs (golf courses, amenity areas)	EU	PRESTOP	F	Seed and soil borne fungi or diseases such as Anthracnose, Fairy rings, Kikuyu patch, *Pythium*, *Rhizoctonia*, Take-all patch, snow moulds	WP	230 g/kg ($2*10^8$ - $1*10^9$ CFU/g)	Spraying	During the summer season BBCH 09-99	1 – 6	28	1 – 2	200-600	**0.23- 0.46 ($1*10^{12}$-$2*10^{12}$ cfu/ha)** minimum ($2*10^{11}$-$4*10^{11}$ cfu/ha)	n.r	
							Seed treatment	Before sowing BBCH 00	1	-	1.25		**0.29 ($1.25*10^{12}$ cfu/ha)** minimum ($2.5*10^{11}$ cfu/ha)	n.r	Application dose: 5 g product / kg seed. Estimated seed density: 250 kg (seed) / ha.

*) The concentration of the a.s. is based on the nominal value of 230 g/kg. The range is 204-250 g/kg.

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions
n.r not relevant
CFU Colony Forming Unit
ULV Ultra Low Volume

Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

with regard to physical/chemical data:	No classification
with regard to toxicological data:	'Micro-organisms may have the potential to provoke sensitising reactions'
with regard to fate and behaviour:	No classification
with regard to ecotoxicological data:	No classification

Methods of analysis (Regulation (EU) N° 283/2013, Annex Part B, point 4 and Regulation (EU) N° 284/2013, Annex Part B, point 5)

Analytical methods for the microorganism (MA 4.1 & MP 5.1; OECD IIM 4.3 & IIIM 5.1)

Manufactured microorganism (principle of method):	Standard dilution-plate counting methods or Most Probable Number (MPN) methods are used to determine the amount of viable *Gliocladium catenulatum* J1446 within samples.
Impurities and contaminating microorganisms in manufactured material (principle of method):	Contaminating microbes are observed in routine viability analyses during the quality control of production batches. Standard dilution-plate counting methods or Most Probable Number (MPN) methods are used to detect contamination at various stages of the manufacturing process.
Microbial Pest Control Product (principle of method):	Specified viability and microbiological purity are the main quality criteria for the end-product: - viability is checked using standard dilution-plate counting methods or Most Probable Number (MPN) methods. - storage stability is determined by analysing viability after storage at different temperatures - short-term storage stability at 28°C after 1 week and 1 month, and long-term storage stability at 4°C at regular intervals during 1 year. Further information is needed. Data gap - contaminating microbials present in samples taken at various stages of production are detected and quantified by using standard dilution-plate counting methods or MPN methods. Colonies appearing on the quality control agar plates are identified based on gross morphology of the colonies and with standard taxonomic identification methods. - pathogenic contaminating microbes present in end-product are analysed by an independent laboratory annually from random batches according to the OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products (Series on Pesticides, No. 65, 12 October 2011).

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (MA 4.2 & MP 5.2; OECD IIM 4.5 & IIIM 5.2)

of the active microorganism (principle of method):	No residue definition/MRL is set or expected, therefore no methods are required.
of relevant metabolites (principle of method):	Open for toxins/secondary metabolites

Impact on Human and Animal Health (Regulation (EU) N° 283/2013, Annex Part B, point 5 and Regulation (EU) N° 284/2013, Annex Part B, point 7)

Medical data: (including medical surveillance on manufacturing plant personnel) (MA 5.1.1; OECD IIM 5.1)	There is no direct observation suggesting that exposure to *Clonostachys rosea* strain J1446 could be related to harmful effects in humans. There is no information suggesting the occurrence of poisoning incidents which could be related to an exposure to *Clonostachys rosea* strain J1446. No harmful effects to people involved in research with the strain *Colostachys rosea* J1446 since 1991, or to employees in the production plant since 1995, have been observed or reported.
Sensitisation: (MA 5.2.1 & MP 7.2.3; OECD IIM 5.2 & IIIM 7.1.6)	Equivocal results in a Buehler test. Warning phrase: "*Clonostachys rosea* J1446 may have the potential to provoke sensitising reactions".
Acute oral infectivity, toxicity and pathogenicity: (MA 5.2.2.1 & MP 7.1.1; OECD IIM 5.3.2 & IIIM 7.1.1)	No evidence of toxicity or infectivity/pathogenicity to rats following a single oral administration of 2 x 10^9 CFU/kg body weight of viable *Clonostachys rosea* cell mass.
Acute intratracheal/inhalation infectivity, toxicity and pathogenicity: (MA 5.2.2.2 & MP 7.1.2; OECD IIM 5.3.3 & IIIM 7.1.3)	No evidence of toxicity, infectivity/pathogenicity to rats following a single intratracheal administration of 6.60 - 7.98 x 10^7 CFU/kg body weight of viable *Clonostachys rosea* cell mass.
Acute intravenous/intraperitoneal infectivity: (MA 5.2.2.3; OECD IIM 5.3.4)	No evidence of infectivity to rats following a single intra-peritoneal administration of 4.2. x 10^8 CFU/kg body weight of viable *Clonostachys rosea* cell mass.
Genotoxicity: (MA 5.2.3; OECD IIM 5.3.5)	Negative Ames test with crude extract and gliotoxin. The active microorganism is not likely to have genotoxic potential.
Cell culture study: (MA 5.2.4; OECD IIM 5.3.6)	*Clonostachys rosea* strain J1446 is not likely to cause cell transformation.
Information on short-term toxicity and pathogenicity: (MA 5.2.5; OECD IIM 5.3.7)	*Clonostachys rosea* strain J1446 is not likely to show short term toxicity.
Dermal toxicity: (MP 7.1.3; OECD IIIM 7.1.2)	PRESTOP WP: Rat LD_{50} > 2000 mg/ kg bw; no mortality, no signs of toxicity, pathogenicity and infectivity.
Specific toxicity, pathogenicity and infectivity: (MA 5.3; OECD IIM 5.5)	No data, not required
Genotoxicity – *in vivo* studies in germ cells: (MA 5.5; OECD IIM 5.5.3)	No data, not required

Reference values

AOEL:	*Clonostachys rosea* strain J1446 is concluded as not toxic, pathogenic or infective. AOEL is not required.
ADI:	*Clonostachys rosea* strain J1446 is concluded as not toxic, pathogenic or infective. ADI is not required.
ARfD:	*Clonostachys rosea* strain J1446 is concluded as not toxic, pathogenic or infective. ARfD is not required.

Exposure (operator, workers, bystander, consumer): (MA 6.1 & MP 7.3, 8.0; OECD IIM 5.6 & IIIM 7.2, 7.3)	Not required for *Clonostachys rosea* strain J1446. Data gap for potential exposure of workers and residents to secondary metabolites / toxins.

Residues (Regulation (EU) N° 283/2013, Annex Part B, point 6 and Regulation (EU) N° 284/2013, Annex Part B, point 8; OECD IIM Point 6 & IIIM Point 8)

Viable residues:	Not relevant considering the nature of the fungus i.e. *Clonostachys rosea* J1446 is a common fungus in natural environments. Furthermore a risk to consumers is not expected from for viable cell forming units relating to the proposed use of *Clonostachys rosea* strain J1446 neither a residue definition nor an MRL are considered necessary.
Non-viable residues:	Data gap. Because of the uncertainties related to the potential production of toxins/secondary metabolites, an inclusion in Annex IV of Regulation (EC) No 396/2005 can therefore not be recommended.

Fate and Behaviour in the Environment (Regulation (EU) N° 283/2013, Annex Part B, point 7 and Regulation (EU) N° 284/2013, Annex Part B, point 9; OECD IIM Point 7 & IIIM Point 9)

Persistence and multiplication (competitiveness) in soil, water and air:	*Gliocladium* species naturally occur worldwide in soil and decaying organic matter. Background level of *Gliocladium catenulatum* in Europe (Finland) has been estimated to be some hundreds colony forming units (CFU)/g and in soil layers with active root growth 1,000 – 10,000 CFU/g. Antagonistic strains of *Clonostachys rosea* (syn. *Gliocladium roseum*) were found in at a level of approximately $1x10^3$ – $4x10^3$ CFU/g (dry weight) in soil samples isolated in Denmark. The optimum temperature for the growth of the species *Gliocladium catenulatum* is 25-28°C. The optimum pH of species *Gliocladium catenulatum* is 5.6, but the fungus can grow within the pH range of 3.0-8.2. Based on literature data germination, propagation and survival depend on the isolate used and the nutrient supply. With insufficient nutrient supply, conidia added to soil do not proliferate but rather stays constant for some time (10-20 days) and then declines in soils. No study on persistence and multiplication in soil was conducted. On peat the numbers of *Clonostachys rosea* strain J1446 decreased to a large extent (by 94-98%) or to below the detection limit within 8-9 weeks; however, it was effective against diseases four weeks after the treatment. *C. rosea* is not able to proliferate in water, although it can remain viable quite a long time based on a laboratory trial (duration 7 months, temperatures 8 and 22°C) with different water samples that had limited nutrients available (seawater, lake water, tap water and distilled water). No study on viability/population dynamics in natural water/sediment systems under both dark and illuminated conditions was performed. Based on greenhouse trials, when suspension of *C. rosea* strain J1446 is used it is expected to be spread to the nearby surroundings at the time of treatment, but not after the treatment has been completed.
Mobility:	Based on literature data vertical growth in the soil is expected to occur downward to a few cm. *C. rosea* strain J1446 is not expected to spread in soil to a large extent and as a typical filamentous fungus is not likely to leach from soil to groundwater.

Effects on non-target organisms (Regulation (EU) N° 283/2013, Annex Part B, point 8 and Regulation (EU) N° 284/2013, Annex Part B, point 10; OECD IIM Point 8 & IIIM Point 10)

Effects on birds and other terrestrial vertebrates (MA 8.1 & MP 10.1; OECD IIM 8.1 & IIIM 10.1)

Dosage	Test substance	Category (*e.g.* insectivorous bird) and species	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
1.4 x 10^6 CFU/g body weight per day	*Clonostachys rosea* cell mass	Northern bobwhite (*Colinus virginianus)*	5 d dosing and 25 d observation periods	No mortalities. No signs of toxicity.
> 2000 mg/kg b.w.	*Gliocladium (J1446)* preparation (WP)	Rat	14 d	No mortalities.

Effects on aquatic organisms (MA 8.2 & 10.2; OECD IIM 8.2, 8.3& IIIM 10.2)

Group	Test substance	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests			
Fish species			
Oncorhynchus mykiss	*Clonostachys rosea* cell mass	30 d	30 d LC_{50}: 5.58 x 10^6 – 2.08 x 10^7 CFU/L NOEC (based on signs of toxicity and tissue contamination): 9.76 x 10^5 CFU/L
Invertebrate species:			
Daphnia magna	*Clonostachys rosea* cell mass	21 d	NOEC (based on reproduction): 2.8 mg test item/L corresponding to 3.0 x 10^4 CFU/L (mm)* The high doses of MPCA caused heavy parent mortality and effects on reproduction and growth; but obvious signs of neither infectivity nor pathogenicity were recorded.

*: the study followed an EPA/FIFRA test guideline. Relatively high control mortality and relatively low reproduction rate was observed in the control, which would have questioned the validity of the results if the test have followed the pertinent OECD test guideline.

Effects on algae: (species, growth, growth rate, capacity to recover) (MA 8.2.3 & MP 10.2; OECD IIM 8.4 & IIIM 10.2)	No data
Effects on aquatic plants (species, growth, growth rate, capacity to recover)(MA 8.2.4 & MP 10.2; OECD IIM 8.5 & IIIM 10.2)	No data

Effects on bees (MA 8.3 & MP 10.3; OECD IIM 8.7 & IIIM 10.3)

Species	Test Substance	Route/timescale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
laboratory test			

Apis mellifera	*Clonostachys rosea* cell mass	oral 10 d	No reliable endpoint is available. *Clonostachys* was neither infective nor pathogenic to bees.

Effects on terrestrial arthropods other than bees (MA 8.4 & MP 10.4; OECD IIM 8.8 & IIIM 10.4)

Species	Stage	Test Substance	Dose kg MPCA/ha (nominal)	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
laboratory test				
Nasonia vitripennis	adult	*Clonostachys rosea* cell mass	52, 520 and 5200 ppm (3.6×10^4, 3.6×10^5, 3.6×10^6 CFU/L)	No significant effects on the survival of adults up to 520 ppm. 8 day NOEC 520 ppm (3.6×10^5 CFU/mL) *C. rosea* cell mass
Hippodamia convergens	adult		52, 520 and 5200 ppm (3.6×10^4, 3.6×10^5, 3.6×10^6 CFU/L)	No toxicity or pathogenicity at any concentration tested 16 day LC_{50} value >5200 ppm (3.6×10^6 CFU/mL) *C. rosea* cell mass 16 day NOEC 5200 ppm (3.6×10^6 CFU/mL) *C. rosea* cell mass
Chrysoperla carnea	newly hatched larvae		52, 520 and 5200 ppm (3.6×10^4, 3.6×10^5, 3.6×10^6 CFU/L)	No significant effects on the survival and development of larvae. 12 day LC_{50} value >5200 ppm (3.6×10^6 CFU/mL) *C. rosea* cell mass 12 day NOEC 5200 ppm (3.6×10^6 CFU/mL) *C. rosea* cell mass

Effects on other terrestrial invertebrates (MA 8.5 & MP 10.5; OECD IIM 8.9.1 and IIM 8.9.2 & IIIM 10.5)

Toxicity, infectivity and pathogenicity: (endpoint, value or other description of effects)	An acute earthworm toxicity study has been carried out with the technical active substance of *Clonostachys rosea*. 14 d LC_{50}: > 1250 mg/kg soil d.w. (8.8×10^8 CFU/kg soil d.w.) NOEC (infection): 1250 mg/kg soil d.w. (8.8×10^8 CFU/kg soil d.w.)

Effects on soil microorganisms (MA 8.6 & MP 10.6; OECD IIM 8.10 & IIIM 10.6)

3.3×10^8 CFU/kg peat (8 x the highest outdoor application): *Clonostachys rosea* J1446 biofungicide did not clearly affect the number of soil microbes at this application rate (study duration: 61 days).
3×10^9 CFU/kg peat (75 x the highest outdoor application): the concentration of other fungi was slightly higher in the untreated peat as compared to *Clonostachys* treated peat practically throughout the whole study, however, this difference was not seen at the end of the test (study duration: 27 weeks).

Additional studies (MA 8.7 & MP 10.7; OECD IIM 8.11 & IIIM 10.7)

Not required