



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. **BESLUIT**

Op 18 december 2014 is van

Bayer CropScience SA-N.V.
Energieweg 1
3641 RT MIJDRECHT

een aanvraag tot wijziging van gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Serenade SC

op basis van de werkzame stof *Bacillus subtilis* stam QST 713.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder "wettelijke grondslag" vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in paragraaf 2.2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-codering staat vermeld onder “toelatingsinformatie” in bijlage I.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 Verordening (EG) Nr. 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011, Evaluation Manual Zonaal, GD Birds & Mammals 2012 en GD Dermal Absorption 2012.

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het registration report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

Toelatingsnummer 14536N

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 5 februari 2016

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

<i>Aanvraagnummer:</i>	20146720 ZWTG
<i>Type aanvraag:</i>	Aanvraag tot wijziging van gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur
<i>Middelnaam:</i>	Serenade SC
<i>Verzenddatum aanvraag:</i>	16 december 2014
<i>Formele registratiedatum: *</i>	29 januari 2015

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2.2 Stofinformatie

Werkzame stof	Gehalte
<i>Bacillus subtilis</i> stam QST 713	1,0x10 ⁹ CFU/G

- De stof is per 1 februari 2007 geplaatst op Annex I van Richtlijn 91/414/EEG (Commission Directive 2007/6/EC, 14 februari 2007) en vervolgens goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011) met expiratiedatum 30 april 2018 (Commission Implementing Regulation (EU) No 487/2014 d.d. 12 mei 2014).

2.3 Toelatingsinformatie

<i>Toelatingsnummer:</i>	14536 N
<i>Expiratiedatum:</i>	30 april 2019
<i>Afgeleide parallel of origineel:</i>	n.v.t.
<i>Biocide, gewasbeschermingsmiddel of toevoegingsstof:</i>	Gewasbeschermingsmiddel
<i>Gebruikers:</i>	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- | | |
|---|-----|
| ▪ <i>W-codering professioneel gebruik:</i> | 2 |
| ▪ <i>Vorige w-codering professioneel gebruik:</i> | 1 |
| ▪ <i>Aflevertermijn professioneel gebruik:</i> | Nvt |
| ▪ <i>Opgebruiktermijn professioneel gebruik:</i> | nvt |

2.4 Verpakkingsinformatie

Toelatingsnummer 14536N

Aard van het preparaat :

suspensie concentraat

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Serenade SC

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram	-	
Signaalwoord	-	
Gevarenaanduidingen	-	
Voorzorgsmaatregelen	P280C	Beschermende handschoenen en beschermende kleding dragen.
Aanvullende etiketelementen	EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht		Nee
Voelbare gevaarsaanduiding verplicht		Nee

**Draft REGISTRATION REPORT
Part A**

Risk Management

Product code: Serenade SC
Active Substance: 13.96 g/L - 1.0×10^9 CFU/g
Bacillus subtilis QST 713

Central Zone

Zonal Rapporteur Member State: The Netherlands

NATIONAL ASSESSMENT THE NETHERLANDS

Applicant: Bayer CropScience
Date: January 2016

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PART A – Risk Management

1 Details of the application

This document describes the acceptable use conditions required for the registration of Serenade SC containing *Bacillus subtilis* QST 713 in several additional crops in The Netherlands. The Netherlands are the only country in which these uses are applied for.

Serenade SC is already registered in The Netherlands since September 19, 2014 (registration number 14536 N), as well as in the UK (registration number: 15625), Slovenia (registration number: U34330-3/2013/11), Belgium (registration number: 10299P/B) and in Ireland (registration number: 03847). Other products containing *B. subtilis* QST 713 as active ingredient are already registered in Slovenia, Germany, Switzerland, France, Portugal and Italy since several years (refer to table below). With the current dossier, the applicant files for extension of use of Serenade SC in The Netherlands. One of the new uses, in fruiting vegetables of Solanaceae, was also requested in the application for first product approval, but it was rejected due to insufficient efficacy data. This use is now re-applied for, together with a number of minor uses. The use in fruiting vegetables of Solanaceae was approved in zonal rapporteur member state Slovenia, as well as in concerned member state Belgium.

Country	Product name	Registration number
Ireland	Serenade ASO	03847
UK	Serenade ASO	14318 and 15625
Belgium	Serenade ASO	10299P/B
Slovenia	Serenade ASO	U34330-3/2013/11
	Serenade WP	3433-63/09/02
Germany	Serenade MAX	006388-00
Switzerland	Serenade Max	W-6678
	Serenade WPO	W-6682
France	Serenade Biofungicide	2050001
	Serenade Jardins	2110040
	Serenade MAX	2100162
Portugal	Serenade MAX	0267
Italy	Serenade MAX	12628
	Serenade NATRIA	15298

The risk assessment conclusions are based on the information, data and assessments provided in the draft Registration Report (dRR), Part B Sections 1-7 and Part C. Assessments for the safe use of Serenade SC have been made using endpoints agreed in the EU review of *B. subtilis* QST 713 and/or new studies with Serenade SC if applicable.

This document describes the specific conditions of use and labelling required for The Netherlands for the registration of Serenade SC.

Appendix 1 of this document will provide a copy of the final product authorisation in The Netherlands once approval is granted.

Appendix 2 of this document will present a copy of the approved product label for The Netherlands once approval is granted. A draft label for The Netherlands is submitted with the dRR dossier.

Appendix 3 contains the Letter of Access for the applicant for the protected data from the producer of the active ingredient *B. subtilis* QST 713 and the end-use product Serenade SC.

1.1 Application background

This application was submitted by Bayer CropScience SA-NV in December 2014.

Name	Bayer CropScience SA-NV
Address	Postbus 231 Mijdrecht 3640 AE Nederland

The application is for approval of Serenade SC, a biological fungicide and bactericide for use in strawberries, vegetables and grapes, formulated as suspension concentrate containing 1.34% (w/w) of *B. subtilis*, strain QST 713 (at least 1×10^{12} CFU/kg).

1.2 Annex I inclusion

Inclusion of *B. subtilis* QST 713 into Annex I (now list of approved active substances according to (EU) No 540/2011) entered into force in entered into force in February 2007 (Commission Directive 2007/6/EC¹). *B. subtilis* strain QST 713 was notified and defended by AgraQuest Inc., Davis, USA. The formulation Serenade SC was not the representative formulation in the dossier for Annex I inclusion of *B. subtilis* QST 713 and has not been previously evaluated according to Uniform Principles at the EU level.

The review report for *B. subtilis* QST 713 (SANCO/10184/2003 - final – 14/07/2006) is considered to provide the relevant review information or a reference to where such information can be found. The data presented in the present dossier comply with the agreed end points in the Review Report.

The Annex I Inclusion Directive for *B. subtilis* QST 713 (Commission Directive 2007/6/EC¹) provides specific provisions under Part B, which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

- For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on the active substance *B. subtilis* QST 713 (SANCO/10184/2003) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

1.3 Regulatory approach

The dossier was submitted to The Netherlands as zonal rapporteur member state for the assessment of the extension of use for Serenade SC in member states of the Central European zone. The Netherlands is the only member state involved; there are no concerned member states.

To obtain approval the new uses of Serenade SC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow extension of use of Serenade SC in The Netherlands in accordance with the above.

¹ OJ L 43, 15.02.2007

1.4 Data protection claims

All study reports that are protected are addressed in accordance with the Article 59 of Directive 1107/2009. The details on data protection claims are correctly provided in the reference lists of the Sections of Part B.

1.5 Letters of Access

Not needed. The notifier for active substance *Bacillus subtilis* QST 713 AgraQuest, Inc. is the company owned by the applicant Bayer.

2 Details of the authorisation

2.1 Product identity

Product Name	Serenade SC
Authorization Number (for re-registration)	14536 N
Function	Biological fungicide and bactericide
Applicant	Bayer CropScience
Composition	13.96 g/L <i>Bacillus subtilis</i> QST 713
Formulation type	Suspension concentrate Code:SC
Packaging	1, 5, 10 L HDPE bottle

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 1999/45/EC

The current classification and labeling can be maintained.

2.2.2 Other phrases

Mammalian toxicology

"Micro-organisms may have the potential to provoke sensitising reactions."

2.3 Product uses

Serenade SC

GAP rev. 5, date: 2015-01-07

PPP (product name/code)	Serenade SC	Formulation type:	Suspension concentrate (SC)
Active substance 1	<i>Bacillus subtilis</i> QST 713	Conc. of as 1:	13.96 g/L, 1.042 x 10 ¹² CFU/L (13.4 g/kg, 1 x 10 ¹² CFU/kg)
Active substance 2	-	Conc. of as 2:	-
Active substance	-	Conc. of as:	-
Safener	-	Conc. of safener:	-
Synergist	-	Conc. of synergist:	-

Applicant:	Bayer CropScience SA-NV	Professional use	<input checked="" type="checkbox"/>
Zone(s):	Central EU	Non professional use	<input type="checkbox"/>

Verified by MS: no

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	L product / ha	CFU/ha	Water L/ha min / max		

New uses

1	NL	Fruiting vegetables of Solanaceae (Aubergine, tomato, pepper)	G	<i>Oidium lycopersici</i>	Spray	BBCH 21-89 Jan-Dec	1-9 (5 days)	8	8.336 x 10 ¹² CFU/ha	600-3000	0	Max 72 L/ha per 12 months
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New minor uses

2	NL	Witlof (pennenteelt)	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp.	Spray	BBCH 12-49	1- 6	8	8.336 x	150-400	0	Max 48 L/ha per 12 months
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		Chicory (roots)		<i>Erysiphales</i>		Jun-Oct	(5 days)		10^{12}			CBS: 2960 ha (2014)
3	NL	Cichorei Wild chicory	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp. <i>Erysiphales</i>	Spray	BBCH 12-49 Jun-Oct	1- 6 (5 days)	8	8.336 x 10^{12}	150-400	0	Max 48 L/ha per 12 months LEI: 3200 ha (2011)
4	NL	Wouw, quinoa en sorghum (weld, quinoa, sorghum)	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp. <i>Erysiphales</i>	Spray	BBCH 12-49 Jun-Oct	1- 6 (5 days)	8	8.336 x 10^{12}	150-400	0	Max 48 L/ha per 12 months Lijst Kleine toepassingen 2.0 < 1000 ha (statistiek cijfers x 1000 geven 0 aan; allemaal max. 100-200 ha)
5	NL	Pitvruchten (pomes)	F	<i>Erwinia amylovora</i>	Spray	BBCH 51-85 April-Oct	1-9 (5 days)	8	8.336 x 10^{12}	200-1500	0	< 200-300 ha with bacterial disease problems (Erwinia) See statement DLV
6	NL	Steenvruchten (drupes)	F	<i>Pseudomonas syringae</i>	Spray	BBCH 51-85 April-Oct	1-6 (5 days)	8	8.336 x 10^{12}	200-1500	0	CBS area 2013: 990 ha CBS area 2014: 1040 ha Crop already on the label (fungicidal use)
7	NL	Steenvruchten (drupes)	G	<i>Pseudomonas syringae</i>	Spray	BBCH 51-85 April-Aug	1-6 (5 days)	8	8.336 x 10^{12}	200-1500	0	CBS area protected fruit 2013: 50 ha CBS area protected fruit 2014: 50 ha Crop already on the label (fungicidal use)
8	NL	Noten (nuts)	F	<i>Xanthomonas campestris</i> pv. <i>Juglandis</i> <i>Pseudomonas syringae</i> pv. <i>aesculi</i>	Spray	BBCH 51-85 April-Oct	1-9 (5 days)	8	8.336 x 10^{12}	200-1500	0	CBS area 2013: 60 ha CBS area 2014: 60 ha
9	NL	Vruchtgroenten van <i>Cucurbitaceae</i> met eetbare schil (Fruiting vegetables of Cucurbits with edible peel)	G	<i>Botrytis cinerea</i> <i>Sphaerotheca fuliginea</i>	Spray	BBCH 12-89 All year	1- 27 (5 days)	8	8.336 x 10^{12}	600-3000	0	9 per crop cycle, 3 cycles on a yearly basis CBS Area 2013: 620 ha CBS Area 2014: 590 ha Crop already on the label (9 applications per year)
10	NL	Vruchtgroenten van <i>Cucurbitaceae</i> met niet-eetbare schil (Fruiting vegetables of Cucurbits with non-edible peel)	G	<i>Botrytis cinerea</i> <i>Sphaerotheca fuliginea</i>	Spray	BBCH 12-89 All year	1- 27 (5 days)	8	8.336 x 10^{12}	600-3000	0	9 per crop cycle, 3 cycles on a yearly basis CBS Area 2013: 620 ha CBS Area 2014: 590 ha

												Crop already on the label (9 applications per year)
11	NL	Sluitkool (Heading cabbage)	F	<i>Xanthomonas campestris</i> pv. <i>campestris</i>	Spray	BBCH 12-49 Jun-Oct	1-6 (5 days)	8	8.336 x 10 ¹²	200-800	0	CBS area 2013: 2750 ha CBS area 2014: 2730 ha Xanthomonas is a problem specific to head cabbage , broccoli and cauliflower. Not the whole group.
12	NL	Bloemkoolachtigen (Cauliflower family)	F	<i>Xanthomonas campestris</i> pv. <i>campestris</i>	Spray	BBCH 12-49 Jun-Oct	1-6 (5 days)	8	8.336 x 10 ¹²	200-800	0	CBS area 2013: 3810 ha CBS area 2014: 3650 ha Xanthomonas is a problem specific to head cabbage , broccoli and cauliflower. Not the whole group.
13	NL	Asperges Asparagus	F	<i>Botrytis cinerea</i>	Spray	BBCH 12-49 Jun-Oct	1- 6 (5 days)	8	8.336 x 10 ¹²	500-800	0	Max 48 L/ha per 12 months CBS: 3320 ha (2014)
14	NL	Bleekselderij Stalk celery	F	<i>Septoria apicola</i>	Spray	BBCH 12-49 Apr-Oct	1- 6 (5 days)	8	8.336 x 10 ¹²	200-800	0	Max 48 L/ha per 12 months CBS: 130 ha (2014)
15	NL	Boomkwekerijgewas sen (Tree nursery crops)	F	<i>Bacterial diseases (Erwinia amylovora, Pseudomonas syringae, Xanthomonas spp.)</i>	Spray	BBCH 12-89 March-Oct	1- 9 (5 days)	8	8.336 x 10 ¹²	200-1200	0	Area sensitive to bacterial diseases: 3750 to 4250 ha. See statement ZLTO.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. Serenade SC is a light brown, opaque liquid, suspension concentrate formulation with a sourly odour. It is not explosive, oxidizing or highly flammable and it has a neat pH of 5.3, in a 1% aqueous solution it has a pH value of 5.5. No loss of efficacy is noted when Serenade SC is stored for 2 years at 20°C and for 18 weeks at 40°C in HDPE. Also, the product does not separate or crystallise at 0°C.

In conclusion, the physical, chemical and technical properties of Serenade SC indicate that no particular problems are to be expected when it is used as recommended.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Method for the determination of *Bacillus subtilis* in formulation Serenade SC using CFU count of *Bacillus subtilis* was development and validated. The method is considered appropriate and sufficiently validated.

3.1.2.2 Analytical methods for residues

The nature of Serenade SC and its active ingredient *B. subtilis* QST 713 are not adequately described and assessed by applying the term ‘residue’, or by quantifying ‘residues’, since this definition commonly implies a toxicological concern of the residual deposit of a plant protection product, which is not attributable to both, the product and the active ingredient.

In particular, strain QST 713 shows no harmful effects on men and domestic animals, without regard to the fact that the intake of sprayed deposits of active ingredient can be excluded.

Basically, determination of the active agent implies its isolation from media as soil or water. Respective methods for cultivation and differentiation of *Bacillus* spp. available in the published literature have been evaluated during the EU review and were considered adequate. For strain specific methods and growth criteria, please refer to Point IIIM 5.1.3 and the reports cited in Part C Point IIIM 1.7.2.3.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Table 3.1.3-1: Acute toxicological data obtained with Serenade SC and Serenade AS

Parameter [Reference]	Species	Result [mg/kg or mg/m ³ or effect]	Classification
Acute oral toxicity	Rat	5000 mg/kg bw corresponding to at least 5 x 10 ⁹ CFU QST 713/kg bw	Not applicable
Acute percutaneous toxicity	Rat	2000 mg/kg bw corresponding to at least 2 x 10 ⁹ CFU QST 713/kg bw	Not applicable

Parameter [Reference]	Species	Result [mg/kg or mg/m ³ or effect]	Classification
Acute inhalation toxicity	rat	1.45 mg/L corresponding to at least 1.45×10^6 CFU QST 713/L	Not applicable
Skin irritation	Rabbit	500 mg/animal corresponding to at least 0.5×10^9 CFU QST 713/animal	Not applicable
Eye irritation	Rabbit	0.1 mL/animal	Not applicable
Skin sensitization	Guinea pig	100% Serenade AS	Not applicable

3.1.3.2 Operator Exposure

All submitted toxicological studies and supplemental information on *Bacillus subtilis* including Serenade SC prove that these are non-toxic and non-infectious to mammals, have no irritating potential to the skin and eye and impose no health risk for operators, bystanders, residents or workers. Since no hazard identification can be made for any clearly adverse effect of *Bacillus subtilis*, a formal dose-response assessment is not necessary. However estimations of operator exposure were done and compared to a virtual reference value of potential pathogenicity (VRPP) of $10E7$ CFU/day. Thus, even if *B. subtilis* QST 713 would be a potentially pathogenic strain the exposure would be below a dose that may cause diarrheal effects in humans even though the risk assessment is based on the very conservative approach that 100% of the inhaled spores are ingested. Therefore, and considering the excellent safety report of *B. subtilis* QST 713 and *B. subtilis*-based products in general, which are used for more than 20 years without any reports on adverse effects in humans, no risk for operators from possible exposure to Serenade SC exists.

Nevertheless, operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate or applying the product, and the sentence “*Bacillus subtilis* QST 713 may have the potential to provoke sensitizing reactions.” should be mentioned on the label.

3.1.3.3 Bystander Exposure

During spraying operations there should be no bystanders present in the greenhouse. No exposure to bystanders is therefore expected. For residents living near greenhouses, the exposure is expected to be only a small fraction of operator exposure during spraying and thus negligible.

For the field application the bystander exposure will be a small fraction of the operator exposure. *Bacillus subtilis* was found to be non-toxic and non-infectious to mammals. They have been used for more than 20 years without any reports on adverse effects in humans. Therefore, no risk for bystanders is expected during spraying of Serenade SC.

3.1.3.4 Worker Exposure

Worker exposure is considered negligible because dermal exposure is not relevant for *B. subtilis*, since intact skin is an effective barrier, and inhalation exposure is not relevant for cultivation work.

For sections from 3.1.3.2 to 3.1.3.4: Generally no assessment of exposure as no Reference values established for microorganisms. In some cases, if monitoring data are available, a comparison is done with acute toxicity data.

The absence of toxicity, infectivity and pathogenicity of the microorganism must be demonstrated in the DAR. If the microorganism produces a toxin, then an evaluation must be done like for chemical pesticides.

3.1.4 Residues and Consumer Exposure

No PHI is specified.

MRLs

Bacillus subtilis strain QSR 713 is listed in Annex IV of Regulation 396/2005 by the Regulation 839/2008 – hence it is exempt from having MRL.

No additional data were submitted or needed.

3.1.4.1 Residues

See point 3.1.4.

3.1.4.2 Consumer exposure

See point 3.1.4.

3.1.5 Fate and behaviour in the Environment

The environmental fate and behaviour of Serenade SC was not evaluated as part of the EU review of *Bacillus Subtilis*. However, environmental fate and behaviour data on Serenade SC is not relevant as it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment. It is possible to extrapolate from data obtained with the active substance and all relevant data were assessed in the EU review. *Bacillus subtilis* is a member of the natural micro-flora in soils and occurs without geographical restriction in almost any environmental niche, including the direct human environment. Following an application of Serenade SC, survival of the endospores of *Bacillus subtilis* in soil is very likely for a period of a few months during which time a natural breakdown begins and gradually reduces the numbers of spores remaining. In a dry state endospores can remain viable for several years, vegetative cells, however, are far more rapidly degraded. Due to its ubiquitous distribution in soil and the absence of growth, *B. subtilis* cells and spores introduced into soils are not expected to exceed the natural level permanently.

Based on a negligible amount of *B. subtilis* spores reaching groundwater habitats and the absence of active growth it is thus concluded that no threat of contamination of groundwater exists following applications of Serenade SC according to GAP. Persistence of *B. subtilis* in soil is restricted to viable spores which are metabolically inactive. Thus, production of new metabolites upon reaching the soil environment can be excluded. Moreover, *B. subtilis* QST 713 does not produce metabolites of toxicological concern and no such substances are contained in the end-use product. Therefore, contamination with metabolites is not of relevance for the evaluation of Serenade SC.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil)

Following an application of Serenade SC, survival of the endospores of *Bacillus subtilis* in soil is very likely for a period of a few months during which time a natural breakdown begins and gradually reduces the numbers of spores remaining. In dry state endospores can remain viable for several years, vegetative cells however are far more rapidly degraded.

For indoor uses, according to the PEC calculation the expected initial concentration in soil is 66.69 mg Serenade SC/kg dry weight soil (0.89 mg *B. subtilis*/kg dry weight soil). In terms of CFU, this is equivalent to 0.6068×10^8 CFU/kg dry weight soil. For field uses, according to the PEC calculation the expected initial concentration in soil is 100.03 mg Serenade SC/kg dry weight soil (1.34 mg *B. subtilis*/kg dry weight soil). In terms of CFU, this is equivalent to 1.0003×10^8 CFU/kg dry weight soil. For the use in glasshouses no PECsoil is calculated. For glasshouse uses a risk for soil organisms is considered less relevant² and no PECsoil is required.

Bacillus subtilis endospores are reported to as having longevity in groundwater. However, *B. subtilis* is not regarded as an autochthonous inhabitant of aquatic environments and does not find optimal conditions for growth, e.g. waters are poor in organic C. Therefore, proliferation in ground water is not likely to occur.

An evaluation of the probable spread of *B. subtilis* into the soil or to associated environments is of minor concern, because dispersal of *B. subtilis* would lack any hazardous effects. Considering the unfavourable conditions in the groundwater, the overall low surface load at the site of application and the natural distribution of *B. subtilis*, as an integral part of the soil-microflora, no detrimental concern is attributable to field applications of the *B. subtilis* containing product Serenade SC.

3.1.5.2 Predicted Environmental Concentration in Surface water (PEC_{sw})

B. subtilis is not regarded as an autochthonous inhabitant of aquatic environments and does not find optimal conditions for growth, e.g. waters are poor in organic C. Therefore, proliferation is not likely to occur. Bacterial cells and especially endospores may survive, but will be subject to natural competition in the diverse micro-flora and to natural physical and chemical degradation in natural waters. It may be stated that *B. subtilis* is inactivated in water under natural conditions, including water.

The highest predicted initial concentration of Serenade SC in 30 cm deep surface waters is 3.1×10^6 CFU/L (use in pomes and nuts).

3.1.5.3 Predicted Environmental Concentration in Air (PEC_{air})

Endospores are suitable for aerial distribution as they are easily blown about by wind. Therefore, under conditions of use drift spacious transport may occur. Multiplication of *B. subtilis* in the air, aerosols or clouds can be excluded due to lack of organic matter supply and lack of mineral matrix to adhere to. Furthermore, unlike chemical products, evaporation and volatility of bacteria is not expected to be a factor to consider in assessing the fate in air. Hence volatilisation from plant surfaces and from soil can be excluded. An investigation of photochemical-oxidative degradation in air is of no relevance in view of the volatility characteristics of the bacteria. In addition, during distribution of vegetative cells of *B. subtilis* in air they are exposed to several environmental stress factors (desiccation, UV-radiation, temperature). Therefore survival of vegetative cells in air is limited.

Implications for labelling resulting from environmental fate assessment: None.

3.1.6 Ecotoxicology (indoor uses)

Effects on Terrestrial Vertebrates

Effects on birds and mammals for SERENADE SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. However further data on SERENADE SC is not relevant as active substance data on toxicity to birds is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for SERENADE SC with the proposed

² EFSA guidance protected crops

use pattern are provided in Part B and are considered adequate. For glasshouse uses exposure to birds and mammals is not relevant.

In field uses exposure via food items can take place. The toxicity endpoint for birds is a 5 day LD50 of $> 10^{11}$ CFU/kg b.w./day. For mammals the toxicity endpoint is LD50 $> 2.5 \times 10^{10}$ CFU/kg b.w. The highest concentration in the spray liquid for field use 5.56×10^{10} CFU/L tank mix suspension.

Daily dose birds:

The application liquid contains 5.6×10^{10} CFU/L. The daily water intake of a 10 g bird: 2.70×10^{-3} L/d (conc. Spray liquid x daily water intake) / body weight = $(5.6 \times 10^{10} \times 0.00270) / 0.010 = 1.5 \times 10^{10}$ CFU/kg bw/d. To this value a dilution factor of 5 can be applied (EPPO, 1994), which results in an exposure density of 3.0×10^9 CFU/kg bw/d. The LD50 is $> 10^{11}$ spores (CFU)/kg b.w. /d. (more than 10 times higher than exposure via water uptake). This would mean that if birds would consume the spray liquid as their daily water intake they would not be at risk.

Daily dose mammals:

The application liquid contains 5.6×10^{10} CFU/L. The daily water intake of a 10 g mammal: 1.57×10^{-3} L/d. (conc. Spray liquid x daily water intake) / body weight = $(5.6 \times 10^{10} \times 0.00157) / 0.010 = 8.7 \times 10^9$ CFU/kg bw/d. To this value a dilution factor of 5 can be applied (EPPO, 1994), which results in an exposure density of 1.7×10^9 CFU/kg bw/d. The acute oral LD50 is $> 2.5 \times 10^{10}$ CFU/kg bw (more than 10 times higher than exposure via water uptake). This would mean that if mammals would consume the spray liquid as their daily water intake they would not be at risk.

The field use of Serenade SC in accordance with the proposed GAP fulfils the criteria laid down in the Uniform Principles with regard to the risk to birds and mammals. The risk to birds and mammals is considered low.

Effects on Aquatic Species

Effects on aquatic organisms of SERENADE SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. Therefore all relevant data are provided in part B and are considered adequate. The risk to aquatic organisms is assessed in the Core Assessment, Section 6, based on predicted concentrations in surface water from exposure via drift calculated in accordance with the national procedure reported in the Core Assessment, Section 5. For glasshouse use there is no agreed methodology to determine the PEC_{sw} for glasshouse uses with microorganisms. Glasshouse uses are covered by field uses.

TER values for active substance *Bacillus subtilis* QST 713, field uses

Use	PIEC (CFU/L)	TER _{LT} (trigger 10)		
		Daphnid (NOEC 1.5×10^8)	Fish (NOEC 1.72×10^9)	Algae (NOEC $> 3.3 \times 10^8$)
Grapes (F)	2.16×10^6	69.4	796	>153
Pome fruits, nuts	3.1×10^6	48.4	554.8	>106.5

For the Netherlands different spray drift values than presented in the core assessment would be applicable. For products based on micro-organisms no National Addendum is required. Nevertheless, national drift values are based on national climatologic circumstances and would therefore be more

appropriate. In this case the uses in the Netherlands are covered by the exposure calculated in the core. The use of SERENADE SC in accordance with the proposed GAP fulfils the criteria laid down in the Uniform Principles with regard to aquatic organisms. The risk to aquatic organisms' is considered low.

Effects on Bees and Other Arthropod Species

Effects on bees and other non-target arthropods of SERENADE SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. Therefore all relevant data and assessments are provided in part B and are considered adequate.

Effects on bees and other non-target arthropods of Serenade SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. In a study assessing the dietary toxicity and pathogenicity of *B. subtilis* on the honey bee, *Apis mellifera*, a 5-day LC₅₀ value was determined to be 1.8×10^8 CFU/mL diet. According to the GAP of Serenade SC the highest concentration of *B. subtilis* in the tank mix suspension is calculated for application in glasshouses in lettuce and for field use in carrots; 5.56×10^7 CFU/mL respectively. Hence, the LC₅₀ value is 3.2 times higher than the maximum concentration of *B. subtilis* in the tank mix suspension, indicating that application of Serenade SC does not pose risk to honey bees.

In a 30-day field study with Serenade and free-living honey bees no adverse effects were observed at an application rate 6×1.12 kg *Bacillus subtilis* /ha with a 5-day interval. In comparison, the maximum single application rate of Serenade SC is 8 L/ha, corresponding to 0.112 kg *Bacillus subtilis*/ha. Assuming a worst case of nine applications, and considering no degradation of bacteria on leaf and fruit surfaces and on flowers, the amount of *B. subtilis* would result in 1.008 kg/ha. The highest accumulated application rate of Serenade SC is far below the amount of Serenade Biofungicide Wettable Powder (6.72 kg *B. subtilis*/ha) that was used in the field study. For 27 applications the exposure would be 3.02 kg *Bacillus subtilis*/ha. This is over a factor 2 lower than the that was tested in the field study.

The studies on dietary toxicity are considered the most relevant to investigate potential infectivity and pathogenicity towards non-target arthropods. Studies assessing the dietary toxicity and pathogenicity of *B. subtilis* on the non-target arthropods, *Hippodamia convergens*, *Chrysoperla carnea* and *Nasoni vitripennis* were conducted. The LC₅₀ value was determined to be $>9 \times 10^{11}$ CFU/L diet. According to the GAP directed use of Serenade SC the concentration of *B. subtilis* in the spray solution is calculated. For application in lettuce in glasshouses per hectare 8 L Serenade SC, corresponding to 8.336×10^{12} CFU, are used, suspended in a water volume of 300 L. Assuming 300 L as worst case, the concentration of *B. subtilis* in the spray solution will be 2.78×10^{10} CFU/L. Hence, the LC₅₀ value is at least 32 times higher than the maximum concentration. For field uses the highest spray solution concentration can be expected for application in carrots, 8.336×10^{12} CFU are suspended in a water volume of 150 L. The concentration of *B. subtilis* in the spray solution will be 5.56×10^{10} CFU/L and the LC₅₀ value is at least 16 times higher than the maximum concentration.

The use of SERENADE SC in accordance with the proposed GAP fulfils the criteria laid down in the Uniform Principles with regard to the risk to bees and other non-target arthropods. The risk to bees and other non-target arthropods is considered low.

Effects on Earthworms and Other Soil Macro-organisms

Effects on earthworms and other soil macro-organisms of SERENADE SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. The acute toxicity of *B. subtilis* to earthworms was tested to be $>5.07 \times 10^9$ CFU/kg dw soil. For glasshouse uses the exposure to soil organisms is not considered relevant. For field uses a maximum PEC_{soil} as calculated in section 3.1.5.1 is 3×10^8 CFU kg dw soil. Furthermore, *Bacillus subtilis* is a member of the natural micro-flora in soils and occurs without geographical restriction in almost any environmental niche. The risk to earthworms and other soil macro-organisms is considered low.

Effects on organic matter breakdown

The use of SERENADE SC in accordance with the proposed GAP fulfils the criteria laid down in the Uniform Principles with regard to the risk to soil organic matter breakdown processes. The risk to soil organic matter breakdown processes is considered low.

Effects on Soil Non-target Micro-organisms

Effects on soil non-target micro-organisms of Serenade SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713. For glasshouse uses the exposure to soil organisms is not considered relevant. For field uses, based on the available information from open literature evaluated in the EU review, no negative effects on soil micro flora are to be expected. The use of Serenade SC in accordance with the proposed GAP fulfils the criteria laid down in the Uniform Principles with regard to the risk to soil microbial processes. The risk to soil microbial processes is considered low.

Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

Effects on non-target plants of Serenade SC were not evaluated as part of the EU review of *Bacillus subtilis* QST 713 neither it was considered in the core assessment. Based on the fact that *Bacillus subtilis* is a natural occurring organism ubiquitous in nature. As in public literature vegetative growth is reported to decline fast if nutrient sources decline the species does not seem to compete well for limited resources and *B. subtilis* populations will be subject to competition in the natural micro-flora. No further studies are considered necessary at this stage.

3.1.7 Efficacy

This evaluation concerns an extension of the authorisation of Serenade SC for the control of powdery mildew in fruiting vegetables of Solanaceae (protected crops) in the Netherlands.

Further the use of Serenade SC in chicory roots, wild chicory, weld, quinoa, sorghum, pome fruit, stone fruit, tree nuts, fruiting vegetables with edible peel, fruiting vegetables with non-edible peel head cabbage, flowering brassica, asparagus, stalk celery and tree nursery crops are applied for as minor use (according to article 51 EG 1107/200). No efficacy and phytotoxicity data are required for these minor uses. Therefore these uses can also be authorised.

No results of preliminary tests performed in laboratory or growth chamber were provided in the core dossier. It was indicated that development work in laboratory and field, have indicated that *Bacillus subtilis* QST 713 is effective against several fungal plant pathogens on many crops.

No specific minimum effective dose trials were provided. In one effectiveness trial two dose rates of Serenade were tested (5 L/ha (0.6N) and 8 L/ha (N)). The effectiveness of the 0.6N dose rate in the last assessment (34 days after application) was slightly lower (78% versus 92%). In all other assessments no differences in effectiveness between both tested dose rate were found.

Serenade SC gave a good control of powdery mildew (*Oidium lycopersici*) on tomato. The number of trials is limited to five and trials were only conducted in tomato.

Based on the good and consistent results of Serenade SC in tomato in the evaluated trials, development work in laboratory and field, and the fact that *Bacillus subtilis* QST 713 is known to be effective against several fungal pathogens on various crops, it can be concluded that Serenade SC will be effective against powdery mildew in fruiting vegetables of Solanaceae crops.

Phytotoxicity was evaluated based upon the results of phytotoxicity assessments performed in all effectiveness trials performed indoor on tomato and in four specific phytotoxicity trails in aubergine and tomato during low light conditions.

In the phytotoxicity trials, in aubergine some minor visible residues were observed, but the percentage of visible residues was well acceptable for practice, even when the double dose was applied.

In tomato, no visible residues were observed, both at single as at double dose rate.

In both tomato and aubergine, no phytotoxicity symptoms were observed. As assessments were conducted until 3 weeks after the last application, it is not expected that any delayed effects would show up.

In the efficacy trials no phytotoxicity or spray deposit was observed.

Based on phytotoxicity and efficacy tests, extrapolation possibilities and expert judgement the following uses were evaluated according to general principles and can be claimed: application in fruiting vegetables of Solanaceae crops (aubergine, tomato and pepper).

No data were provided on impact of Serenade SC on succeeding or adjacent crops. These aspects are considered not relevant for the claimed uses because claimed crops are grown indoors on artificial growing medium.

3.2 Conclusions

The assessment conducted for Serenade SC for the use in fruiting vegetables of *Solanaceae*, chicory (roots), wild chicory, weld, quinoa, sorghum, fruiting vegetables of Cucurbits with edible and non-edible peel, asparagus, stalk celery, pomes, drupes, nuts, heading cabbage, cauliflower family and tree nursery crops was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted for the following uses:

- Fruiting vegetables of Solanaceae (protected): for the control of *Oidium licopersici*
- Chicory (roots), wild chicory, weld, quinoa, sorghum (unprotected): for the control of *Sclerotinia sclerotiorum*, *Alternaria spp.* and *Erysiphales*
- Fruiting vegetables of Cucubitaceae: for the control of *Botrytis cinerea* and *Sphaerotheca Fuliginea*
- Asparagus: for the control of *Botrytis cinerea*
- Stalk celery: for the control of *Septoria apicola*
- Pomes: for the control of *Erwinia amylovora*
- Drupes: for the control of: *Pseudomonas syringae*
- Nuts: for the control of *Xanthomonas campestris* pv. *Juglandis* and *Pseudomonas syringae* pv. *Aesculi*
- Heading cabbage: for the control of *Xanthomonas campestris* pv. *Campestris*
- Cauliflower family: for the control of *Xanthomonas campestris* pv. *Campestris*
- Tree nursery crops: for the control of *Erwinia amylovora*, *Pseudomonas syringae* and *Xanthomonas* spp.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

None.

Appendix 1 – Copy of the product authorisation

Appendix 2 – Copy of the product label

Wettelijk Gebruiksvoorschrift

Het middel is uitsluitend toegelaten als schimmelbestrijdingsmiddel en bacteriebestrijdingsmiddel voor het professionele gebruik door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1, Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Werkzaamheid getoetst op	Dosering * middel per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen
Aardbei (bedekte teelt)	Grauwe schimmel ¹	8 L/ha	6	5 dagen
Vruchtgroenten van <i>Solanaceae</i>	Echte meeldauw ²	8 L/ha	9	5 dagen
Wortelen	Loofverbruining ³	8 L/ha	6	5 dagen

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.

¹ *Botrytis cinerea*

² *Oidium lycopersici*

³ *Alternaria dauci*

Het gebruik in onderstaande teelten is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Werkzaamheid aannemelijk tegen	Dosering* middel per toepassing	Maximaal aantal toepassingen per 12 maanden of per teeltcyclus	Minimum interval tussen toepassingen in dagen
Peulvruchten	Grauwe Schimmel ¹ Sclerotinia ⁴	8 L/ha	6 per 12 maanden	5 dagen
Oliehoudende zaden	Grauwe Schimmel ¹ Sclerotinia ⁴	8 L/ha	6 per 12 maanden	5 dagen
Vezelgewassen	Grauwe Schimmel ¹ Sclerotinia ⁴ Echte meeldauw ⁵	8 L/ha	6 per 12 maanden	5 dagen
Witlof (pennenteelt)	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Cichorei	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen

Quinoa	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Wouw	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Sorghum	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Pitvruchten	Bacterievuur ⁷	8 L/ha	9 per 12 maanden	5 dagen
Steenvruchten	Grauwe Schimmel ¹ Monilia ^{8,9} Pseudomonas ¹⁰	8 L/ha	6 per 12 maanden	5 dagen
Aardbei (bedekte teelt)	Echte meeldauw ¹¹	8 L/ha	6 per 12 maanden	5 dagen
Aardbei (onbedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹¹	8 L/ha	6 per 12 maanden	5 dagen
Bessen	Grauwe schimmel ¹ Echte meeldauw ¹²	8 L/ha	9 per 12 maanden	5 dagen
Druif	Grauwe schimmel ¹ Echte meeldauw ¹³	8 L/ha	9 per 12 maanden	5 dagen
Braam- en framboosachtigen (<i>Rubus</i> spp.)	Grauwe schimmel ¹ Echte meeldauw ¹⁴	8 L/ha	9 per 12 maanden	5 dagen
Noten	Bacterieziekten ^{15,16}	8 L/ha	9 per 12 maanden	5 dagen
Bladgroenten	Grauwe schimmel ¹ Sclerotinia ⁴	8 L/ha	6 per 12 maanden	5 dagen
Boon met peul	Grauwe Schimmel ¹ Sclerotinia ⁴ Echte meeldauw ⁵	8 L/ha	6 per 12 maanden	5 dagen
Erwt met peul (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴	8 L/ha	6 per 12 maanden	5 dagen
Vruchtgroenten van <i>Cucurbitaceae</i> met eetbare schil (bedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per teeltcyclus	5 dagen
Augurk (onbedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per 12 maanden	5 dagen
Courgette (onbedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per 12 maanden	5 dagen
Vruchtgroenten van <i>Cucurbitaceae</i> met niet-eetbare schil (bedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per teeltcyclus	5 dagen
Pompoen-achtigen (onbedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per 12 maanden	5 dagen
Meloen (onbedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per 12 maanden	5 dagen
Vruchtgroenten van <i>Malvaceae</i> (bedekte teelt)	Grauwe schimmel ¹ Echte meeldauw ¹⁷	8 L/ha	9 per 12 maanden	5 dagen
Sluitkool	Xanthomonas ¹⁹	8 L/ha	6 per 12 maanden	5 dagen

			maanden	
Bloemkool (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Spikkelziekte ¹⁸	8 L/ha	9 per 12 maanden	5 dagen
Bloemkoolachtigen (onbedekte teelt)	Xanthomonas ¹⁹	8 L/ha	6 per 12 maanden	5 dagen
Chinese kool (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Spikkelziekte ¹⁸	8 L/ha	9 per 12 maanden	5 dagen
Koolrabi	Sclerotinia ⁴	8 L/ha	6 per 12 maanden	5 dagen
Radijs-achtigen	Sclerotinia ⁴ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Wortelgewassen (<i>Umbelliferae</i>) m.u.v. wortelen	Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Knolraap, koolraap, aardpeer, Japanse aardappel, zoete aardappel, rode biet, knolselderij, schorseneer, mierikswortel en yam	Sclerotinia ⁴ Alternaria ⁶	8 L/ha	6 per 12 maanden	5 dagen
Bosui (bedekte teelt)	Botrytis- bladvlekkenziekte ²⁰	8 L/ha	9 per 12 maanden	5 dagen
Asperge (onbedekte teelt)	Grauwe schimmel ¹	8 L/ha	6 per 12 maanden	5 dagen
Bleekselderij (onbedekte teelt)	Septoria ²¹	8 L/ha	6 per 12 maanden	5 dagen
Asperge (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶	8 L/ha	9 per 12 maanden	5 dagen
Bleekselderij (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶	8 L/ha	9 per 12 maanden	5 dagen
Rabarber (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶	8 L/ha	9 per 12 maanden	5 dagen
Knolvenkel (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶	8 L/ha	9 per 12 maanden	5 dagen
Prei	Alternaria ²²	8 L/ha	9 per 12 maanden	5 dagen
Kruidenteelt (vers of gedroogd)	Grauwe schimmel ¹ Sclerotinia ⁴ Echte meeldauw ⁵ Alternaria ⁶	8 L/ha	9 per 12 maanden	5 dagen
Bolbloemen en knolbloemen (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴	8 L/ha	9 per 12 maanden	5 dagen
Rozen (bedekte teelt)	Echte meeldauw ⁵	8 L/ha	25 per 12 maanden	5 dagen
Bloemisterijgewassen (onbedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴	8 L/ha	9 per 12 maanden	5 dagen

	Alternaria ⁶ Echte meeldauw ^{5,23}			
Boomkwekerijgewassen (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶ Echte meeldauw ^{5,23} Bacterieziekten ^{7,10,24}	8 L/ha	9 per 12 maanden	5 dagen
Boomkwekerijgewassen (onbedekte teelt)	Bacterieziekten ^{7,10,24}	8 L/ha	9 per 12 maanden	5 dagen
Vaste plantenteelt	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶ Echte meeldauw ^{5,23}	8 L/ha	9 per 12 maanden	5 dagen
Bloemenzaadteelt	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶ Echte meeldauw ⁵	8 L/ha	9 per 12 maanden	5 dagen
Veredeling en zaadteelt (bedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶ Echte meeldauw ⁵	8 L/ha	9 per 12 maanden	5 dagen
Veredelingsteelt en basiszaadproductie van akkerbouw-, groente-, en fruitgewassen, kruiden en sierteeltgewassen (onbedekte teelt)	Grauwe schimmel ¹ Sclerotinia ⁴ Alternaria ⁶ Echte meeldauw ⁵	8 L/ha	9 per 12 maanden	5 dagen

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.

¹ *Botrytis cinerea*

⁴ *Sclerotinia sclerotiorum*

⁵ *Erysiphaceae*

⁶ *Alternaria* spp

⁷ *Erwinia amylovora*

⁸ *Monilia laxa*

⁹ *Monilia fructigena*

¹⁰ *Pseudomonas syringae*

¹¹ *Sphaerotheca macularis*

¹² *Sphaerotheca mors-uvae*

¹³ *Uncinula necator*

¹⁴ *Sphaerotheca aphani*

¹⁵ *Xanthomonas Campestris* pv. *juglandis*

¹⁶ *Pseudomonas syringae* pv. *aesculi*

¹⁷ *Sphaerotheca fuliginea*

¹⁸ *Alternaria brassicae*

¹⁹ *Xanthomonas campestris* pv. *campestris*

²⁰ *Botrytis squamosa*

²¹ *Septoria* spp.

²² *Alternaria porri*

²³ *Sphaerotheca pannosa*

²⁴ *Xanthomonas* spp.

Overige toepassingsvoorwaarden

Voor de toepassing in aardbei dient een spuitvolume van 400-1000 l/ha te worden gehanteerd.

Voor de toepassing in sla (onbedekte teelt) dient een spuitvolume van 250-500 l/ha te worden gehanteerd.

Voor de toepassing in sla (bedekte teelt) dient een spuitvolume van 300-1000 l/ha te worden gehanteerd.

Voor de toepassing in wortelen dient een spuitvolume van 200-500 l/ha te worden gehanteerd.

Voor de toepassing in druiven dient een spuitvolume van 500-1000 l/ha te worden gehanteerd.

In de bedekte teelt van aardbei mag Serenade SC maximaal 6 maal per 12 maanden toegepast worden.

Micro-organismen kunnen mogelijk sensibiliserende reacties veroorzaken.

Appendix 3 – Letter of Access (copy)

The original document is submitted with the dossier.

Appendix 4 – Reference list (data relied on for national authorisation)

dRR Annex point/ referen ce numbe r	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec tion claimed yes/no	Study relied on Y/N	Dataprotectio n granted Y/N	Owner
KIIM 2.2/05	2015	Cold stability of Bacillus subtilis QST713 SC (Serenade ASO) Bayer CropScience AG Study ID. FM0265(ACR17)N01	yes	Y	Y	BCS
KIIM 2.3.1/01	2015	Safety relevant data of Bacillus subtilis QST713 SC (Serenade ASO) Bayer Technology Services GmbH Report-no. M-525556-01-1 GLP: yes Published: no	yes	Y	Y	BCS
KIIM 2.3.2/02	2015	Safety relevant data of Bacillus subtilis QST713 sc (Serenade ASO) Bayer Technology Services GmbH Report-no. M-525556-01-1 GLP: yes Published: no	yes	Y	Y	BCS
KIIM 2.4/05	2015	Physical, chemical and technical properties of Bacillus subtilis QST713 SC Bayer CropScience AG Report no. FM0265(PCF00)G01 GLP: yes Published: no	yes	Y	Y	BCS

dRR Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Study relied on Y/N	Data protection granted Y/N	Owner
KIIM 4.1/03	1900	TECHNICAL SPECIFICATION MECHANICAL DRAWING P00197 - AgraQuest, Inc. Report-no. not stated GLP/GEP: no Published: no	yes	N	N	QST
KIIM 4.7/01	2013	BASF SAFETY DATA SHEET: SERENADE ASO - BASF AG Report-no. 394711/SDS_CPA_EU/EN GLP/GEP: no Published: no	yes	N	N	BAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Data protection granted? Y/N	Studies relied on? Y/N
6.1-6.2	2013	FD13NLDV02X008 Determine the efficacy of different fungicides against oidium in tomato	Y	BCS	Y	Y
6.1-6.2	2013	FD13NLDV03X007 Determine the efficacy of different fungicides against oidium in tomato	Y	BCS	Y	Y

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Data protection granted? Y/N	Studies relied on? Y/N
6.1-6.2	2013	FD13NLDV03X009 Determine the efficacy of different fungicides against oidium and botrytis in tomato	Y	BCS	Y	Y
6.1-6.2	2013	FD14NLDV03X024 Determine the efficacy of different fungicides against oidium in tomato	Y	BCS	Y	Y
6.1-6.2	2013	FD14NLDV03X023 Determine the efficacy of different fungicides against oidium in tomato	Y	BCS	Y	Y

Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Study relied on Y/N	Data protection granted Y/N	Owner
KIIM 9/01	1982	FATE IN MODEL ECOSYSTEMS OF MICROBIAL SPECIES OF POTENTIAL USE IN GENETIC ENGINEERING not applicable Appl Environ Microbiol, 44, 708-714 Report-no. not applicable GLP/GEP: no Published: yes	no	Y	N	-

Ecotox

Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Data protection granted Y/N	Study relied on Y/N	Owner
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Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Data protection granted Y/N	Study relied on Y/N	Owner
IIIM 10.4	2000	QST 713 TP: TOXICITY TO THE PREDATORY MITE, TYPHLODROMUS PYRI SCHEUTEN (ACARI, PHYTOSEIIDAE) IN THE LABORATORY ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany Bayer CropScience Report-no. 99431/01-NLTp Edition-no: M-473491-01-2 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.1	2004	SUB-ACUTE (4-WEEK) INHALATION TOXICITY STUDY, INCLUDING AN 8-WEEK RECOVERY STUDY, WITH SERENADE BIOFUNGICIDE IN RATS Bayer CropScience Report-no. 010.44225, 5435 Edition-no: M-474026-02-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.4	2001	BACILLUS SUBTILIS STRAIN QST 713: A DIETARY PATHOGENICITY AND TOXICITY STUDY WITH THE PARASITIC HYMENOPTERAN (NASONIA VITRIPENNIS) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489-107B Edition-no: M-473490-01-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.6	1989	INTRODUCTION TO PLANT PATHOLOGY AND MICROBIAL ECOLOGY - Biological control of microbial plant pathogens, Cambridge University Press, Cambridge, 1-40 Report-no. not applicable GLP/GEP: no Published: yes	no	N	Y	-
IIIM 10.6	1991	ON THE SAFETY OF BACILLUS SUBTILIS AND B. AMYLOLIQUEFACIENS: A REVIEW not applicable Appl Microbiol Biotechnol, 36, 1-4 Report-no. not applicable GLP/GEP: no Published: yes	no	N	Y	-
IIIM 10.2	2000	TESTING OF TOXIC EFFECTS OF QST 713 TP ON THE SINGLE CELL GREEN ALGA SCENEDESMUS SUBSPICATUS ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany Bayer CropScience Report-no. 99431/01-AASs Edition-no: M-473469-01-1 GLP: yes Published: no	yes	Y	Y	BCS

Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Data protection granted Y/N	Study relied on Y/N	Owner
IIIM 10.2	2001a	QST 713 TECHNICAL : A FIVE CONCENTRATION TOXICITY AND PATHOGENICITY TEST WITH THE RAINBOW TROUT (ONCORHYNCHUS MYKISS) Bayer CropScience Report-no. 489A-108 Edition-no: M-473492-01-1 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.2	2001b	QST 713 TECHNICAL - A 21-DAY LIFE CYCLE TOXICITY AND PATHOGENICITY TEST WITH THE CLADOCERAN (DAPHNIA MAGNA) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489A-107A Edition-no: M-473458-02-1 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.2	1998a	BACILLUS SUBTILIS: A FIVE-CONCENTRATION TOXICITY AND PATHOGENICITY TEST WITH THE RAINBOW TROUT (ONCORHYNCHUS MYKISS) Bayer CropScience. Report-no. 489A-101 Edition-no: M-473642-01-1 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.2	1998b	BACILLUS SUBTILIS: A 48-HOUR STATIC ACUTE TOXICITY TEST WITH THE CLADOCERAN (DAPHNIA MAGNA) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489A-103 Edition-no: M-473465-01-1 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.2	1998c	BACILLUS SUBTILIS: A 21-DAY-CYCLE TOXICITY AND PATHOGENICITY TEST WITH THE CLADOCERAN (DAPHNIA MAGNA) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489A-102B Edition-no: M-473638-02-1 GLP: yes Published: no	yes	Y	Y	BCS

Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Data protection granted Y/N	Study relied on Y/N	Owner
IIIM 10.1	1998	BACILLUS SUBTILIS: AN AVIAN ORAL PATHOGENICITY AND TOXICITY STUDY IN THE NORTHERN BOBWHITE Bayer CropScience Report-no. 489-101 Edition-no: M-473475-01-3 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.1	1998	TOXICITY / PATHOGENICITY TESTING OF QST 713 FOLLOWING ACUTE ORAL CHALLENGE IN RATS Bayer CropScience Report-no. L08726 SN4 Edition-no: M-474035-01-2 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.3	1998a	BACILLUS SUBTILIS: A DIETARY PATHOGENICITY AND TOXICITY STUDY WITH THE HONEY BEE (APIS MELLIFERA) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489-102C Edition-no: M-473639-01-2 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.4	1998b	BACILLUS SUBTILIS: A DIETARY PATHOGENICITY AND TOXICITY STUDY WITH THE LADYBIRD BEETLE (HIPPODAMIA CONVERGENS) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489-103B Edition-no: M-473489-01-2 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.4	1998c	BACILLUS SUBTILIS: A DIETARY PATHOGENICITY AND TOXICITY STUDY WITH GREEN LACEWING LARVAE (CHRYSOPERLA CARNEA) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489-104 Edition-no: M-473488-01-2 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.4	1998d	BACILLUS SUBTILIS: A DIETARY PATHOGENICITY AND TOXICITY STUDY WITH THE PARASITY HYMENOPTERA (NASONIA VITRIPENNIS) Wildlife International, Ltd., Easton, Maryland, USA Bayer CropScience Report-no. 489-105A Edition-no:473640-01-2 GLP: yes Published: no	yes	Y	N	BCS

Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec- tion claimed yes/no	Data protect ion grante d Y/N	Study relied on Y/N	Owner
IIIM 10.4	2000a	EFFECTS OF SERENADE WP ON PREDATORY MITES (TYPHLODROMUS PYRI) UNDER TYPICAL VINE CULTURE CONDITIONS ON GRAPE VINES, GERMANY 2000 Staatliche Lehr- und Forschungsanstalt, Neustadt/Weinstraße Bayer CropScience Report-no. GAB01 Edition-no: M-486909-01-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.4	2000b	EFFECTS OF SERENADE WP ON PREDATORY MITES (TYPHLODROMUS PYRI) UNDER TYPICAL VINE CULTURE CONDITIONS ON GRAPE VINES, GERMANY 2000 Staatliche Lehr- und Forschungsanstalt, Neustadt/Weinstraße Bayer CropScience Report-no. GAB02 Edition-no: 486910-01-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.3	2004	SAFETY OF THE BACILLUS SUBTILIS-BASED BIOFUNGICIDE, SERENADE®, TO THE HONEYBEE, APIS MELLIFERA L. AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, USA Bayer CropScience Report-no. not applicable Edition-no: M-486885-01-1 GLP/GEP: no Published: no	yes	Y	N	BCS
IIIM 10.3	2003	EVALUATION OF THE DIETARY EFFECT(S) OF QST713 TECHNICAL POWDER ON LARVAL HONEYBEE DEVELOPMENT (APIS MELLIFERA L.) - VOLUME 3 OF 3 California Agricultural Research, Inc., 4141 N. 93630 Kerman Bayer CropScience Report-no. CAR 158-03 Edition-no: M-473477-01-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.2	2001	QST 713 TECHNICAL POWDER - INFECTIVITY AND PATHOGENICITY TO GRASS SHRIMP (PALAEMONETES PUGIO) DURING A 30-DAY STATIC RENEWAL TEST Springborn Bionomics, Inc., Wareham, USA Bayer CropScience Report-no. 13759.6101 Edition-no: 473476-01-1 GLP: yes Published: no	yes	Y	N	BCS

Annex point	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Data protection granted Y/N	Study relied on Y/N	Owner
IIIM 10.1	1998	ACUTE ORAL EXPOSURE TOXICITY STUDY IN RATS WITH QST 713 WP Bayer CropScience Report-no. 0402XA54.001 Edition-no: M-474041-01-1 GLP: yes Published: no	yes	Y	N	BCS
IIIM 10.3	2000	HONEY BEE FIELD STUDY OF SERENADE BIOFUNGICIDE WETTABLE POWDER IN ALFALFA The Bee Group, Washington State University, Prosser, USA Bayer CropScience Report-no. 00-001 Edition-no: M-473494-01-1 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.4	2000	QST 713 TP: ACUTE TOXICITY TO THE APHID PARASITOID APHIDIUS RHOPALOSIPHI (HYMENOPTERA BRACONIDAE) ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany Bayer CropScience Report-no. 99431/01-NLAp Edition-no: M-473472-01-2 GLP: yes Published: no	yes	Y	Y	BCS
IIIM 10.5	2002	ACUTE TOXICITY OF QST 713 WP (SERENADE WP) ON EARTHWORMS EISENIA FETIDA USING AN ARTIFICIAL SOIL TEST ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany Bayer CropScience Report-no. 20011062/01-NLEf Edition-no: M-486916-01-1 GLP: yes Published: no	yes	Y	Y	BCS