



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. **BESLUIT**

Op 19 maart 2013 is van

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

een aanvraag tot toelating 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. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Slovenië.

HET COLLEGE BESLUIT

- Tot toelating van bovenstaand middel voor de volgende toepassingen:
 - Aardbei (bedekte teelt), in de bestrijding van grauwe schimmel;
 - Wortelen, in de bestrijding van loofverbruining;
 - Als kleine toepassing in aardbei (onbedekte teelt), in de bestrijding van grauwe schimmel;
 - Als kleine toepassing in druif (onbedekte teelt), in de bestrijding van grauwe schimmel;
 - Als kleine toepassing in sla, in de bestrijding van grauwe schimmel en sclerotinia.

- Tot afwijzing van bovenstaand middel voor de volgende toepassingen:
 - Vruchtgroenten van Solanaceae (bedekte teelt), in de bestrijding van grauwe schimmel;
 - Wortelen, in de bestrijding van meeldauw.

De aanleiding van dit besluit is dat bij de beoordeling van het aspect werkzaamheid is gebleken dat de werkzaamheid bij vruchtgroenten van Solanaceae (bedekte teelt) in de bestrijding van grauwe schimmel en wortelen in de bestrijding van meeldauw onvoldoende is aangetoond.

Alle bijlagen, waaronder registratierapport deel A, 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 volgens 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 worden vermeld zoals beschreven in bijlage II en in paragraaf 2.2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 en artikel 36 Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 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.

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 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 19 september 2014

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>	20130277 NLTG
<i>Type aanvraag:</i>	Zonale aanvraag tot toelating van gewasbeschermingsmiddel met Nederland als betrokken lidstaat
<i>Middelnaam:</i>	Serenade SC
<i>Verzenddatum aanvraag:</i>	15 maart 2013
<i>Formele registratiedatum: *</i>	2 april 2013
<i>Datum in behandeling name:</i>	4 februari 2014
<i>Datum compliance check:</i>	n.v.t.

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

Aangezien Serenade SC een voor Nederland nieuwe werkzame stof bevat (zie hieronder), is de zienswijzenprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 toegepast. Er zijn geen zienswijzen ontvangen binnen de daarvoor gestelde termijn.

2.2 Stofinformatie

Werkzame stof	Gehalte
<i>Bacillus subtilis stam QST 713</i>	1,0 E9CFU/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

2.4 Verpakkingsinformatie

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	

REGISTRATION REPORT
Part A

Risk Management

Product code: Serenade SC
Active Substance: 13.4 g/kg
Bacillus subtilis QST 713

Central Zone

Zonal Rapporteur Member State: Slovenia

NATIONAL ASSESSMENT THE NETHERLANDS

Applicant: Bayer CropScience
Submission date: July 2014

Table of Contents

PART A – RISK MANAGEMENT	9
1 DETAILS OF THE APPLICATION	9
1.1 APPLICATION BACKGROUND	10
1.2 ANNEX I INCLUSION	11
1.3 REGULATORY APPROACH	11
1.4 DATA PROTECTION CLAIMS	11
1.5 LETTERS OF ACCESS	11
2 DETAILS OF THE AUTHORISATION	12
2.1 PRODUCT IDENTITY	12
2.2 CLASSIFICATION AND LABELLING	12
2.2.1 CLASSIFICATION AND LABELLING UNDER REG. (EC) 1272 2008	12
2.2.2 OTHER PHRASES	12
2.3 PRODUCT USES	12
3 RISK MANAGEMENT	14
3.1 REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES	14
3.1.1 PHYSICAL AND CHEMICAL PROPERTIES	14
3.1.2 METHODS OF ANALYSIS	14
3.1.2.1 ANALYTICAL METHOD FOR THE FORMULATION	14
3.1.2.2 ANALYTICAL METHODS FOR RESIDUES	14
3.1.3 MAMMALIAN TOXICOLOGY	14

3.1.3.1	ACUTE TOXICITY	14
3.1.3.2	OPERATOR EXPOSURE.....	15
3.1.3.3	BYSTANDER EXPOSURE.....	16
3.1.3.4	WORKER EXPOSURE	16
3.1.4	RESIDUES AND CONSUMER EXPOSURE.....	16
3.1.4.1	RESIDUES	16
3.1.5	FATE AND BEHAVIOUR IN THE ENVIRONMENT	16
3.1.6	ECOTOXICOLOGY.....	18
3.1.7	EFFICACY	20
3.2	CONCLUSIONS.....	21
3.3	FURTHER INFORMATION.....	21
	APPENDIX 1 – COPY OF THE PRODUCT LABEL.....	22
	APPENDIX 2 – LIST OF DATA SUBMITTED IN SUPPORT OF THE AUTHORIZATION	24

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 The Netherlands. As intended uses and risk mitigation measures are identical in all member states of the Central Zone, Part A is more or less identical for all concerned member states.

Serenade SC is already registered in the UK (registration number: 15625) and in Ireland (registration number: 03847). With the current dossier, the applicant files for registration of Serenade SC in The Netherlands. The specification and the formulation of the product that is already registered in the UK and Ireland and the one evaluated in the presented RR dossier are the same (a.i. *B. subtilis* QST 713: 1.34% w/w; at least 1×10^{12} CFU/kg). 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).

Country	Product name	Registration number
Ireland	Serenade SC	03847
UK	Serenade SC	14318 and 15625
Slovenia	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.

Because of the number of efficacy trials only the use in strawberry (protected) for the control of *Botrytis cinerea*, the use in carrots (unprotected) for the control of *Alternaria dauci* and as a minor use in strawberries (unprotected), grapes (unprotected) and lettuce (protected and unprotected). can be authorised. The use in fruiting vegetables of Solanaceae (protected) for the control of *Botrytis cinerea* and the use in carrots (unprotected) for the control of *Erysiphe heraclei* can not be authorised.

Appendix 1 of this document will present a copy of the approved product label for The Netherlands.

Appendix 2 contains the List of data submitted in support for the authorisation.

1.1 Application background

This application was submitted by BASF SE in January 2013.

Name BASF SE
67056 Ludwigshafen
Germany

Address Crop Protection Division:
P.O. Box 120
67114 Limburgerhof
Germany

Person to contact:

Name BASF Nederland B.V.

Address BASF Nederland B.V.
Rijnpoort Building, P.O.Box 1019
Groningensingel 1
6835 EA Arnhem
The Netherlands

During the evaluation process, the applicant was changed. The Administration of the Republic of Slovenia for food safety, veterinary sector and plant protection was informed by the document received on 25 February 2013 that the responsibility and the legal succession for the application and approval for the product Serenade SC are transferred to Bayer CropScience.

It follows, that the applicant is:

Name Bayer CropScience SA-NV

Address Postbus 231
Mijdrecht
3640 AE
Nederland

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

During the registration process, the product name for the Netherlands was changed from Serenade ASO into Serenade SC.

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 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 the 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 endpoints 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 Slovenia as zonal rapporteur member state for the assessment of the application for Serenade SC in member states of the Central European zone. Concerned member states are Germany, Austria, The Netherlands, Belgium and Poland.

To obtain approval the product 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 endpoints.

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

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 the active substance *Bacillus subtilis* QST 713 AgraQuest, Inc. is the company owned by the applicant Bayer.

¹ OJ L 43, 15.02.2007

2 Details of the authorisation

2.1 Product identity

Product Name	Serenade SC
Authorisation Number (for re-registration)	The product is not yet registered in The Netherlands.
Function	Biological fungicide
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 Reg. (EC) 1272 2008

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-	-	-
Pictogram:	-	Signal word: -
H-statements:	-	-
P-statements:	P280c	Wear protective gloves and protective clothing.
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
Child-resistant fastening obligatory?		not applicable
Tactile warning of danger obligatory?		not applicable

Justification:

Pictogram:	-
H-statements:	-
P-statements:	Micro-organisms may have the potential to provoke sensitising reactions. Therefore P280c is prescribed.
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2.2 Other phrases

Mammalian toxicology

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

Efficacy

"De gewasveiligheid van Serenade SC in de wintermaanden is voor de bedekte teelt van aardbei niet onderbouwd. Voer een proefbespuiting uit voordat Serenade SC in de bedekte teelt van aardbei op grote schaal toegepast wordt."

2.3 Product uses

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		
1	NL	Strawberries	G	<i>Botrytis cinerea</i>	Spray	BBCH 60-89 Jan-dec	1- 6 (5 days)	8	8.336 x 10 ¹² CFU/ha	400-1000	-	Max 48 L/ha/ per 12 months
2	NL	Fruiting vegetables of Solanaceae (Aubergine, tomaat, paprika)	G	<i>Botrytis cinerea</i> ,	Spray	BBCH 21-89 Jan-dec	1-6 (5 days)	8	8.336 x 10 ¹² CFU/ha	500-1000	-	Max 48 L/ha per 12 months
3	NL	Carrots	F	<i>Alternaria dauci</i> <i>Erysiphe heraclei</i>	Spray	BBCH 41-49 Jun-nov	1-6 (5 days)	8	8.336 x 10 ¹² CFU/ha	200-500	-	Max 48 L/ha per 12 months
Minor uses												
1	NL	Strawberries	F	<i>Botrytis cinerea</i>	Spray	BBCH 60-89 Apr-Oct	1- 6 (5 days)	8	8.336 x 10 ¹² CFU/ha	400-1000	-	Max 48 L/ha per 12 months
2	NL	Grapes	F	<i>Botrytis cinerea</i>	Spray	BBCH 68-89 Apr-Nov	1-9 (5 days)	8	8.336 x 10 ¹² CFU/ha	500-1000	-	Max 48 L/ha per 12 months
3	NL	Lettuce	G	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i> ,	Spray	BBCH 13-49 Jan-Dec	1-6 (5 days)	8	8.336 x 10 ¹² CFU/ha	300-1000	-	Max 48 L/ha per 12 months
4	NL	Lettuce	F	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i> ,	Spray	BBCH 13-49 March-october	1-6 (5 days)	8	8.336 x 10 ¹² CFU/ha	250-500	-	Max 48 L/ha per 12 months

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

The majority of studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a light brown, opaque liquid, suspension concentrate formulation with a sourly odour. It is not explosive and has no oxidising properties. In a 1% aqueous solution, it has a pH value of 4.96. The data indicate that Serenade SC is not stable when stored at high temperature (40°C for 8 weeks) and does not separate or crystallise at 0°C. The shelf life study proves a stability of at least 2 years when Serenade SC is stored at 20°C in its original HDPE container.

The physical, chemical and technical characteristics of Serenade SC are acceptable for a suspension concentrate [SC] formulation.

Some parameters (suspensibility, persistent foaming) were not done on the prescribed concentrations. Flash point and auto-flammability were not determined.

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 developed 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. *Bacillus subtilis* strain QST713 is listed in Annex IV of Regulation 396/2005 by the Regulation 839/2008 – hence it is exempt from having MRL.

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	Dose level]	Findings	Classification
Acute oral toxicity	Rat	5000 mg/kg bw corresponding to at least 5×10^9 CFU QST 713/kg bw	LD ₅₀ > 5000 mg/kg bw	Not applicable

Parameter [Reference]	Species	Dose level[Findings	Classification
Acute percutaneous toxicity	Rat	2000 mg/kg bw corresponding to at least 2×10^9 CFU QST 713/kg bw	LD ₅₀ > 2000 mg/kg bw	Not applicable
Acute inhalation toxicity	Rat	1.45 mg/L corresponding to at least 1.45×10^6 CFU QST 713/L	No adverse effects LC ₅₀ > 1.45 mg/L	Not applicable
Skin irritation	Rabbit	500 mg/animal corresponding to at least 0.5×10^9 CFU QST 713/animal	Non-irritating	Not applicable
Eye irritation	Rabbit	0.1 mL/animal	Non-irritating	Not applicable
Skin sensitisation	Guinea pig	100% Serenade AS	Non-sensitising	Not applicable

Serenade SC containing *B. subtilis* strain QST 713 as active substance was not a sensitiser in the modified Buehler method in Guinea pigs. However, in accordance with the PRAPeR Expert Meeting on micro-organisms in June 2009 the following labelling is proposed:

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

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 generally not carried out. However estimations of operator exposure were done in the core registration report and compared to a virtual reference value of potential pathogenicity (VRPP) of 107 CFU/day. The virtual reference value of potential pathogenicity (VRPP) proposed by the applicant was obtained considering the minimum dose reported for potentially pathogenic *Bacillus* spp. (other than *Bacillus cereus*) involved in food borne illness, which is 10^6 CFU/g according to the Opinion of the Scientific EFSA Panel on Biological Hazards on *Bacillus cereus* and other *Bacillus* spp. in food stuffs (EFSA Journal 2005, 175).

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, based on the possible sensitising properties of micro-organisms operators must wear suitable protective clothing (coveralls), and suitable protective gloves when handling the concentrate or applying the product, and the sentence “Micro-organisms may have the potential to provoke sensitising 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. Inhalation exposure is not relevant for cultivation work in the field and for the greenhouse applications is expected to be only a small fraction of the operator exposure during spraying.

3.1.4 Residues and Consumer Exposure

No PHI is specified.

MRLs

Bacillus subtilis strain QST 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. *B. subtilis* is naturally present in our environment and has been found to be non-pathogenic and non-infective. In addition, the unfavourable environmental conditions prevailing on the leaf surface and the dependence of *B. subtilis* on organic matter supply are restricting its growth. Therefore, *B. subtilis* strain QST 713 does not present a risk for consumers..

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.

The dose rate for all uses is 8.336×10^{12} CFU/ha. For indoor uses, exposure of soil organisms is not relevant and no PECsoil is calculated. For field uses the calculation bases on a maximum application rate of 8 L Serenade SC/ha, assuming as a worst case that no degradation occurs between applications related to the top 5 cm of soil. The highest number of application is 9 for grapes. This results in an accumulated application rate of 7.5×10^{13} CFU/ha. In terms of CFU, this is equivalent to 1×10^8 CFU/kg dry weight soil.

No PECgw is calculated for *B. subtilis*. 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 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 (PECsw)

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.

For glasshouse use there is no agreed methodology to determine the PECsw for glasshouse uses with micro-organisms. For field uses the highest predicted initial concentration of Serenade SC in 30 cm depth in surface waters is 1.85×10^5 CFU/L (downward spray) and 2.16×10^6 CFU/L (grapes, sideward spray).

3.1.5.3 Predicted Environmental Concentration in Air (PECAir)

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 relevant to consider in assessing the fate in air. 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.

3.1.6 Ecotoxicology

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 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 in carrots is 4.17×10^{10} CFU/L tank mix suspension.

Daily dose birds:

The application liquid contains - 4.2×10^{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 = $(4.2 \times 10^{10} \times 0.00270) / 0.010 = 1.1 \times 10^{10}$ CFU/kg bw/d. To this value a dilution factor of 5 can be applied (EPPO, 1994), which result in an exposure density of 2.2×10^9 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 4.2×10^{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 = $(4.2 \times 10^{10} \times 0.00157) / 0.010 = 6.6 \times 10^9$ CFU/kg bw/d. To this value a dilution factor of 5 can be applied (EPPO, 1994), which result in an exposure density of 1.3×10^9 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 based on predicted concentrations in surface water from exposure via drift calculated in accordance with the national procedure, Section 5 and reported in 3.1.5.2. For glasshouse use there is no agreed methodology to determine the PEC_{sw} for glasshouse uses with micro-organisms.

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

Use	PIEC (CFU/L)	TER _{it} (trigger 10) Daphnid (NOEC 1.5×10^8)	TER _{it} (trigger 10) Fish (NOEC 1.72×10^9)	TER _{it} (trigger 10) Algae (NOEC $> 3.3 \times 10^8$)
Carrots (F)	1.85×10^5	811	9297	<1784
lettuce (F)	1.85×10^5	811	9297	<1784

Strawberries (F)	1.85 10 ⁵	811	9297	<1784
Grapes (F)	2.16 10 ⁶	69.4	796	<153

Glasshouse uses are covered by field uses

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.

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; 2.78×10^7 CFU/mL and 4.17×10^7 CFU/mL respectively. Hence, the LC₅₀ value is 4.3 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.

In the core assessment a derived LR50 is reported. The use of an LR50 the same way as for chemicals is not scientifically justified for micro organisms. Furthermore, this rate is not provided in relevant units for micro organisms (CFU) and therefore hard to compare.

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 *Nasonia 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 200 L. The concentration of *B. subtilis* in the spray solution will be 4.168×10^{10} CFU/L and the LC₅₀ value is at least 21.6 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 PECsoil as calculated in section 3.1.5.1 is 1×10^8 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 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

For the Netherlands the following is applied for:

- Strawberry (protected): 8 l product/ha for the control of *Botrytis cinerea*
- Fruiting vegetables of Solanaceae (protected): 8 l/ha for the control of *Botrytis cinerea*
- Carrots (unprotected): 8 l product/ha for the control of *Alternaria dauci* and *Erysiphe heraclei*.

For the most important part of the efficacy assessment we refer to the Core Part B7 from Slovenia and further to the national addendum from the Netherlands.

Because of the number of efficacy trials only the use in strawberry (protected) for the control of *Botrytis cinerea* and the use in carrots (unprotected) for the control of *Alternaria dauci* can be authorised.

The use in fruiting vegetables of Solanaceae (protected) for the control of *Botrytis cinerea* and the use in carrots (unprotected) for the control of *Erysiphe heraclei* can not be authorised.

For the use in strawberry (protected) no phytotoxicity trials were conducted under ‘worse case’ situations (winter period, low light), so phytotoxicity in winter cannot be excluded. Therefore the following warning sentence should be put on the label:

“De gewasveiligheid van Serenade SC in de wintermaanden is voor de bedekte teelt van aardbei niet onderbouwd. Voer een proefbespuiting uit voordat Serenade SC in de bedekte teelt van aardbei op grote schaal toegepast wordt.”

Further the use of Serenade SC in strawberries (unprotected), grapes (unprotected) and lettuce (protected and unprotected) 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.

3.2 Conclusions

The assessment conducted for Serenade SC for the use in strawberry (protected), carrots (unprotected), of the control of *Alternaria dauci* and as a minor use in strawberries (unprotected), grapes (unprotected) and lettuce (protected and unprotected) 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:

- Strawberry (protected): for the control of *Botrytis cinerea*
- Carrots (unprotected): of the control of *Alternaria dauci*.
- As a minor use in strawberries (unprotected), grapes (unprotected) and lettuce (protected and unprotected).

An authorisation can not be granted for the following uses:

- Fruiting vegetables of Solanaceae (protected): for the control of *Botrytis cinerea*
- Carrots (unprotected): for the control of *Erysiphe heraclei*.

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 label

Toegestaan is uitsluitend het professionele gebruik als schimmelbestrijdingsmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden.

Toepassings-gebied	Te bestrijden organisme	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
Wortelen	Loofverbruining ²	8 L/ha	6	5 dagen

¹ *Botrytis cinerea*

² *Alternaria dauci*

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

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen
Aardbei (onbedekte teelt)	Grauwe schimmel ¹	8 L/ha	6	5 dagen

Toepassings- gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen
Druif (onbedekte teelt)	Grauwe schimmel ¹	8 L/ha	9	5 dagen
Sla (<i>Lactuca</i> spp.)	Grauwe schimmel ¹ Sclerotinia ²	8 L/ha	6	5 dagen

¹ *Botrytis cinerea*² *Sclerotinia sclerotiorum*

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.

Micro-organismen kunnen mogelijk sensibiliserende reacties veroorzaken.

De gewasveiligheid van Serenade SC in de wintermaanden is voor de bedekte teelt van aardbei niet onderbouwd. Voer een proefbespuiting uit voordat Serenade SC in de bedekte teelt van aardbei op grote schaal toegepast wordt.

Appendix 2 – List of data submitted in support of the authorisation

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	Data protection granted Y/N	Study used Y/N	Owner¹
KIIIM 2.1/01	2007a	PHYSICO-CHEMICAL PROPERTIES OF THE FORMULATION SERENADE ASO BEFORE AND AFTER ACCELERATED STORAGE AT 40 °C FOR 8 WEEKS eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCAS GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 2.2/02	2011	REPORT AMENDMENT NO. 1 TO STUDY 2071148/01 PHYSICO-CHEMICAL PROPERTIES OF THE FORMULATION SERENADE ASO OVER 2 YEARS AT 20 °C eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCTY GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 2.2/03	2008	POURABILITY OF THE FORMULATION SERENADE ASO AFTER ACCELERATED STORAGE eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. S08-00905-PCRB GLP: yes Published: no	yes	Y	Y	Bayer CropScience

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	Data protection granted Y/N	Study used Y/N	Owner ¹
KIIIM 2.2/04	2007b	STORAGE STABILITY OF THE FORMULATION SERENADE ASO AT 0 °C FOR 7 DAYS eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCCS GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 2.3.4/01	2007c	VISCOSITY OF SERENADE ASO eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCVC GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 2.3.4/02	2007d	SURFACE TENSION OF SERENADE ASO eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCST GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 2.4.7/01	2008	POURABILITY OF SUSPENSION CONCENTRATES Stillmeadow, Inc., Sugar Land, Texas, USA AgraQuest, Inc. Report-no. 12401-08 GLP/GEP: no Published: no	yes	Y	Y	Bayer CropScience

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	Data protection granted Y/N	Study used Y/N	Owner ¹
KIIM 2.4.7/02	2008	POURABILITY OF THE FORMULATION SERENADE ASO AFTER ACCELERATED STORAGE eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. S08-00905-PCRB GLP: yes Published: no Submitted in: KIIM 2.2/03	yes	Y	Y	Bayer CropScience
KIIM 2.4.7/03	2011	REPORT AMENDMENT NO. 1 TO STUDY 2071148/01 PHYSICO-CHEMICAL PROPERTIES OF THE FORMULATION SERENADE ASO OVER 2 YEARS AT 20 °C eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCTY GLP: yes Published: no Submitted in: KIIM 2.2/02	yes	Y	Y	Bayer CropScience
KIIM 2.5/01	2007e	RELATIVE DENSITY OF SERENADE ASO eurofins-GAB GmbH, Niefern-Öschelbronn, Germany AgraQuest, Inc. Report-no. 20071148/01-PCRD GLP: yes Published: no	yes	Y	Y	Bayer CropScience

INDOOR USE

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.1	2004a	Italy-2004-Trial n.9 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no. NA GEP: no Published: no	Yes	Yes	Bayer CropScience
IIIM 6.1.1	2004b	Italy-2004-Trial n.10 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no. NA GEP: no Published: no	Yes	Yes	Bayer CropScience
IIIM 6.1.1	2004c	Italy-2004-Trial n.11 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no.NA GEP: no Published: no	Yes	Yes	Bayer CropScience
IIIM 6.1	2011	Bekämpfung Von Grauschimmel an Erdbeeren DEV-F-2011-DE-S50-K-02.0-DE-DMN-001 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.3	2010	Development of Serenade Max Against <i>Botrytis cinerea</i> in Strawberry. DEV-F-2010-IT-S50-B-01.0-IT-IT0-035 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Development of Serenade ASO Against <i>Botrytis cinerea</i> in Strawberry. Serenade Spray Programs - Botrci, (+ Powdery Mildew) DEV-F-2010-PL-S50-A-01.1-PL-AGR-001 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Registration of Serenade ASO Against Botrci (and Sphrsp If Observed) in Strawberry DEV-F-2011-PL-S50-A-03.1-PL-PLD-002 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Registration of Serenade ASO Against Botrci (and Sphrsp If Observed) in Strawberry DEV-F-2011-PL-S50-A-03.1-PL-PLD-001 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.3	2010	Feasibility Serenade ASO Against Botrci + Sphrma in Strawberries DEV-F-2010-UK-S50-A-02.0-UK-UK4-J07 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2010	Feasibility Serenade ASO Against Botrci + Sphrma in Strawberries DEV-F-2010-UK-S50-A-02.0-UK-UK4-J08 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Feasibility Serenade ASO Against Botrci + Sphrma in Strawberries DEV-F-2011-UK-S50-A-01.0-UK-UK4-J74 BASF DocID 2013/1043066 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2010	Development of Serenade Max Against Botrci in Tomato. DEV-F-2010-IT-V52-B-01.0-IT-IT2-015 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Efficacy Trial of Serenade in Tomatoes DEV-F-2011-NL-V51-A-03.0-NL-NL5-514 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.3	2010	Development of Serenade ASO Against Botrytis cinerea Ans Sclerotinia in Peper - in Door Application. Serenade Registration - Sclesc (+ Assessments For Botrci) DEV-F-2010-PL-V53-A-01.1-PL-AGR-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2010	Development of Serenade ASO Against Botrytis cinerea and Alternaria Solani in Tomatoes. Serenade Registration - Alteso & Botrci DEV-F-2010-PL-V52-A-01.1-PL-AGR-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2010	Development of Serenade ASO Against Botrytis cinerea and Alternaria Solani in Tomatoes. DEV-F-2010-PL-V52-A-01.1-PL-PLS-ZP1 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLD-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.3	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLS-RYB BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.3	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLS-ZP1 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.4.2	2011	Study of unintentional effects of the compound Serenade max on roduction and quality of musts and wines Vinification trial Serenade MAX BASF DocID 2011/1288313 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

OUTDOOR USE

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
-------------	------	---	-------------------------	------------	-------

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM 6.1.1	2004a	Italy-2004-Trial n.9 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no. NA GEP: no Published: no	Yes	yes	Bayer CropScience
IIIM 6.1.1	2004b	Italy-2004-Trial n.10 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no. NA GEP: no Published: no	Yes	yes	Bayer CropScience
IIIM 6.1.1	2004c	Italy-2004-Trial n.11 Bio-Intrachem Italia Via Calcinaro 2085 – Int. 7, 47023 Cesena, FC, Italy AgraQuest, Inc., 1540 Drew Avenue, Davis, CA 95618, U.S.A Report-no.NA GEP: no Published: no	Yes	yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Feasibility Bas 700 F Solo Against Sclerotinia and Rhizoctonia in Lettuce DEV-F-2010-BE-V53-A-01.0-BE-BE0-001 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade ASO Against <i>Botrytis cinerea</i> , Rhiso and Sclesc in Lettuce Serenade Registration - Sclesc (+ Assessments For Botrci, Rhizoc) DEV-F-2010-PL-V53-B-01.1-PL-AGR-001 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade ASO Against <i>Botrytis cinerea</i> , Rhiso and Sclesc in Lettuce. DEV-F-2010-PL-V53-B-01.1-PL-PLS-ZP1 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Sclesc + Botrci + Rhizso in Lettuce Open Field / indoor DEV-F-2011-BE-V52-A-03.0-BE-BE5-004 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Sclesc + Botrci + Rhizso in Lettuce Open Field DEV-F-2011-PL-V52-A-03.1-PL-PLD-001 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Sclesc + Botrci + Rhizso in Lettuce Open Field DEV-F-2011-PL-V52-A-03.1-PL-PLD-002 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Sclesc + Botrci + Rhizso in Lettuce Open Field DEV-F-2011-PL-V52-A-03.1-PL-PLS-DP1 BASF DocID 2013/1043067 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade Max Against Botrci in Tomato. DEV-F-2010-IT-V52-B-01.0-IT-IT2-015 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Efficacy Trial of Serenade in Tomatoes DEV-F-2011-NL-V51-A-03.0-NL-NL5-514 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade ASO Against <i>Botrytis cinerea</i> Ans Sclerotinia in Peper - in Door Application. Serenade Registration - Sclesc (+ Assessments For Botrci) DEV-F-2010-PL-V53-A-01.1-PL-AGR-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade ASO Against <i>Botrytis cinerea</i> and Alternaria Solani in Tomatoes. Serenade Registration - Alteso & Botrci DEV-F-2010-PL-V52-A-01.1-PL-AGR-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Development of Serenade ASO Against <i>Botrytis cinerea</i> and Alternaria Solani in Tomatoes. DEV-F-2010-PL-V52-A-01.1-PL-PLS-ZP1 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLD-001 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLS-RYB BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration of Serenade ASO Against Alteso + Botrci in Tomatoes [Field] DEV-F-2011-PL-V51-A-04.1-PL-PLS-ZP1 BASF DocID 2013/1043069 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2008	Crop Tolerance and Efficacy of Serenade and Sonata in Smart Spray Programs Against Plasmopara Viticola on Grapes. DEV-F-2008-ZX-W71-V-03.0-DE-VTV-009 BASF DocID 2013/1043070 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2009	Efficacy of Serenade Max Against Uncine DEV-F-2009-ZX-W53-V-03.0-DE-VTV-025 BASF DocID 2013/1043070 BASF GEP Unpublished	Yes	yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2010	Crop Tolerance and Efficacy of BCAs in Smart Spray Programs Against <i>Botrytis cinerea</i> on Grapes DEV-F-2010-ZX-W91-V-03.0-DE-VTV-012 BASF DocID 2013/1043070 BASF Not GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Crop Tolerance and Efficacy of BCAs in Smart Spray Programs Against <i>Botrytis cinerea</i> on Grapes DEV-F-2010-ZX-W91-V-03.0-DE-VTV-035 BASF DocID 2013/1043070 BASF Not GEP Unpublished	Yes	yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2012	Development of Serenade Max against <i>Botrytis cinerea</i> on grapes DEV-F-2010-PT-W21-A-01.0-PT-PTC-383 BASF DocID 2013/1043070 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2009	Feasibility Serenade Max Against <i>Sclerotinia</i> and <i>Alternaria</i> in Carrots DEV-F-2009-NL-V50-B-01.0-NL-NL2-239 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3	2010	Testing Efficacy AF Serenade ASO Against Alternaria in Carrots DEV-F-2010-DK-727-A-01.0-DK-DK1-002 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Feasibility Serenade Max Against Sclerotinia and Alternaria in Carrots DEV-F-2010-UK-V50-A-01.0-UK-UK3-G23 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2010	Feasibility Serenade Max Against Sclerotinia and Alternaria in Carrots DEV-F-2010-UK-V50-A-01.0-UK-UK3-N24 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Registration Serenade ASO Against Alteda, Sclesc and Eryshe in Carrots DEV-F-2011-DE-V50-B-02.0-DE-D04-001 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience

Annex point	Year	Title Source Company, Report No. GLP or GEP status Published or Unpublished	Data protection granted	Study used	Owner
IIIM6.1.3 IIIM6.2.1	2011	Feasibility Serenade ASO Against Sclerotinia, Alternaria and Mildew in Carrots DEV-F-2011-UK-V50-A-01.0-UK-UK3-G22 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	yes	Bayer CropScience
IIIM6.1.3 IIIM6.2.1	2011	Feasibility Serenade ASO Against Sclerotinia, Alternaria and Mildew in Carrots DEV-F-2011-UK-V50-A-01.0-UK-UK4-J49 BASF DocID 2013/1043068 BASF GEP Unpublished	Yes	Yes	Bayer CropScience
IIIM 6.1.4.2	2011	Study of unintentional effects of the compound Serenade max on roduction and quality of musts and wines Vinification trial Serenade MAX BASF DocID 2011/1288313 BASF GEP Unpublished	Yes	yes	Bayer CropScience

Annex point/reference number	Year	Title Testing Facility Source (where different from owner) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Data protection granted Y/N	Study used Y/N	Owner
KIIIM 7.1.1/01	2000	ACUTE ORAL TOXICITY STUDY IN ALBINO RATS WITH SERENADE AS. AgraQuest, Inc. Report-no. 012770-1 GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 7.1.2/01	2008	ACUTE DERMAL TOXICITY STUDY OF SERENADE ASO IN RATS (AMENDMENT NO. 1 TO FINAL REPORT) AgraQuest, Inc. Report-no. 21360 GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 7.1.3/01	2001	AN ACUTE IN-NOSE ONLY INHALATION TOXICITY STUDY IN RATS WITH SERENADE AS AgraQuest, Inc. Report-no. 3474.2 GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 7.1.4/01	2008a	ACUTE DERMAL IRRITATION/CORROSION TEST (PATCH TEST) OF SERENADE ASO IN RABBITS (AMENDMENT NO. 1 TO FINAL REPORT) AgraQuest, Inc. Report-no. 21361 GLP: yes Published: no	yes	Y	Y	Bayer CropScience

KIIIM 7.1.5/01	2008b	ACUTE EYE IRRITATION/CORROSION OF SERENADE ASO IN RABBITS (AMENDMENT NO. 1 TO FINAL REPORT) AgraQuest, Inc. Report-no. 21362 GLP: yes Published: no	yes	Y	Y	Bayer CropScience
KIIIM 7.1.6/01	2001	DERMAL SENSITIZATION STUDY (CLOSED-PATCH REPEATED INSULT) IN GUINEA PIGS WITH SERENADE AS AgraQuest, Inc. Report-no. 012774-1 GLP: yes Published: no	yes	Y	Y	Bayer CropScience