ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 22 december 2016 is van

Bayer CropScience S.A.-N.V.
Postbus 231
3640 AE MIJDRECHT

een aanvraag tot toelating ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Sonata

op basis van de werkzame stof Bacillus pumilus QST 2808. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Frankrijk.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

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 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 hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 en artikel 36, derde lid, van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 16 december 2011 en HTB 1.0 (micro-organismen)

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 van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

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, 29 mei 2019

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20161009 NLTG
Type aanvraag:	aanvraag tot nationale toelating gewasbeschermingsmiddel (NL=CMS)
Middelnaam:	Sonata
Verzenddatum aanvraag:	21 december 2016
*Formele registratiedatum: **	20 januari 2017
Datum in behandeling name:	29 januari 2019
Datum compliance check:	n.v.t.

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

2.2 Stofinformatie

Werkzame stof	Gehalte
Bacillus pumilus QST 2808	$1x10^9$ CFU/g

- De stof is per 1 september 2014 goedgekeurd volgens Verordening (EC) 1107/2009 (Uitvoeringsverordening (EU) 485/2014 d.d. 12 mei 2014). De goedkeuring van deze werkzame stof expireert op 31 augustus 2024.

2.3 Toelatingsinformatie

Toelatingsnummer:	15871 N
Expiratiedatum:	31 augustus 2025
Afgeleide parallel of origineel:	Origineel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	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 Sonata

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

Pictogram	-	
Signaalwoord	-	
Gevarenaanduidingen	-	
Voorzorgsmaatregelen	SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
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:	**Sonata**
Active Substance:	***Bacillus pumilus* QST2808 1x10^9 CFU/g**

Inter Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT – THE NETHERLANDS

Applicant:	**Bayer CropScience**
Date:	**May 2019**
Evaluator	**Ctgb, NL**

OECD Statement on Confidentiality

The summaries and evaluations contained in this monograph or review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this Monograph or review report unless they have received the data on which the summaries and evaluation are based, either:

- From the owner of the data; or
- From a second party that has obtained permission from the owner of the data for this purpose or, alternatively, the applicant has received permission from the data owner that the summaries and evaluation contained in this Monograph or review report may be used in lieu of the data; or
- Following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation;

unless the period of protection of the proprietary data concerned has expired.

Applicants wishing to avail of information in this Monograph or review report should seek advice from the regulatory authority to which application is made concerning the requirements in their country.

Table of Contents

PART A – Risk Management 10
1 Details of the application 10
1.1 Application background 10
1.2 Annex I inclusion / Amendment of the Annex to Implementing Regulation (EU) 540/201110
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 Regulation 1272/2008/EC 12
2.2.2 Other phrases 12
2.3 Product uses 13
3 Risk management 17
3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles 17
3.1.1 Physical and chemical properties 17
3.1.2 Methods of analysis 18
3.1.2.1 Analytical method for the formulation 18
3.1.2.2 Analytical methods for residues 18
3.1.3.1 Acute Toxicity 18
3.1.3.2 Operator Exposure 18
3.1.3.3 Bystander Exposure 19
3.1.3.4 Worker Exposure 19
3.1.4 Residues and Consumer Exposure 19
3.1.5 Environmental fate and behaviour 19
3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) 19
3.1.5.2 Predicted Environmental Concentration in Surface water (PECsw) 20
3.1.5.3 Predicted Environmental Concentration in Air (PECair) 20
3.1.6 Ecotoxicology 20
3.1.6.1 Effects on Terrestrial Vertebrates 21

3.1.6.2 Effects on Aquatic Species....21
3.1.6.3 Effects on Bees and Other Arthropod Species....21
3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms....21
3.1.6.5 Effects on Soil Non-target Micro-organisms....22
3.1.7 Efficacy....22
3.2 Conclusions....23
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....23
Appendix 1 – Copy of the proposed product label....24
Appendix 2 – List of data submitted in support of the evaluation....27

PART A – Risk Management

1 Details of the application

This document describes the acceptable use conditions required for the registration of the Microbial Pest Control Product Sonata containing *Bacillus pumilus* QST2808 in the Netherlands.
Sonata is identical to the product BALLAD, registered in France on behalf of Dupont De Nemours for use on oilseed rape.
The specification and formulation of Sonata is identical to the one used as representative formulation in the dossier for Annex I inclusion of *B. pumilus* QST2808.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C. Assessments for the safe use of Sonata have been made using endpoints agreed in the EU review of *B. pumilus* QST2808.

This document describes the specific conditions of use and labelling required for the Netherlands for the registration of Sonata.

- Appendix 1 of this document will present a copy of the proposed label for the Netherlands.
- Appendix 2 contains data submitted in support of the evaluation.

1.1 Application background

This application was submitted by Bayer CropScience SA-NV in December 2016.

This application is for the approval of Sonata, a suspension concentrate (SC) formulation containing 13.8 g/kg or 14.35 g/L of *Bacillus pumilus* strain QST 2808, corresponding to a minimum of $1x10^9$CFU/g.

Sonata is a biological fungicide to be used mainly for control of powdery mildew on grape, strawberry, Cucurbitaceae and Solanaceae and their extrapolated minor crops.

1.2 Annex I inclusion / Amendment of the Annex to Implementing Regulation (EU) 540/2011

This MPCP is the representative formulation of the IIM/IIIM dossier submitted on 3 December 2010 by AgraQuest Inc., now Bayer CropScience, for the inclusion of the MPCA Bacillus pumilus QST2808 in the Annex I of Directive 91/414/EEC. The completeness of this dossier has been recognized on 26 April 2011 by Commission decision 2011/253/EU. The Rapporteur Member State, the Netherlands, delivered a Draft Assessment Report to EFSA on 8 May 2012. The conclusion of the EU peer review of the pesticide risk assessment of the active substance *Bacillus pumilus* QST2808 were published by EFSA in 2013 (EFSA Journal (2013) 11(8):3346). The Review Report was finalised on 20 March 2014 (SANCO/12800/2013 rev 2).

Bacillus pumilus QST2808 was approved as an active substance in accordance with Regulation (EC) N°1107/2009 of the European Parliament and of the Council: Commission Implementing Regulation (EU) N°485/2014 of 12 May 2014, entry into force 1st September 2014.

The Annex to Implementing Regulation (EU) N°540/2011 relative to *Bacillus pumilus* QST2808 provides some specific provisions under Part B which need to be considered:

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 *Bacillus pumilus* QST2808 and in particular Appendices I and II thereof, as finalized in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.

In the overall assessment, Member States shall pay particular attention to the protection of operators and workers, taking into account that *Bacillus pumilus* QST2808 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.
Specific provisions under Part B include the request for confirmatory information to be submitted to the Commission, the Member States and the Authority by 31 August 2016:

a) The identification of the aminosugar produced by *Bacillus pumilus* QST2808
b) The analytical data for the content of that aminosugar in the production batches

The data were submitted on July 2016.

The Review Report (SANCO/12800/2013 rev 2) and EFSA Scientific Report (EFSA Journal 2013;11(8) :3346) for *B. pumilus* QST2808 are considered to provide the relevant scientific information for the review of the product.
The active substance data is relied upon in the risk assessment of the formulation Sonata.

1.3 Regulatory approach

The dossier is submitted to France as zonal rapporteur member state in order to allow the first authorization of this product/use in Member States of the Southern and Inter European zone. Concerned member states are France, Bulgaria, Croatia, Greece, Italy, Portugal and Spain (Southern zone); and Czech Republic, Hungary, Ireland, Netherlands, Romania, Slovenia, Slovakia and United Kingdom (Interzone).
Sonata is identical to the product BALLAD, registered in France on behalf of Dupont De Nemours for use on oilseed rape.

1.4 Data protection claims

All study reports that are protected are addressed in accordance with the Article 59 of the Regulation 1107/2009. The details on data protection claims are correctly provided in the reference lists of the Sections of Part B.
The reference lists included in the dossier defines the list of studies and reports, submitted with the application, for which a claim for data protection was made. This claim for protection was made as the studies and reports were submitted and used as the basis for approval for the first time in France. Based on Article 59 of Regulation 1107/2009 Bayer CropScience S.A.-N.V claims 10 years protection for these studies and reports. The authority confirms that these studies and reports are protected for 10 years from the date of authorisation of the product and thus cannot be used for the benefit of another applicant. As this is the first product registered in the Netherlands with this active substance also the active substance data will receive from this point on 10 years of data protection (as indicated in the Bacillus pumilus QST 2808_DAR_02_volume 2 April 2012).

1.5 Letters of Access

Not needed. The notifier for active substance *Bacillus pumilus* QST2808 Agraquest Inc. is a company owned by the applicant Bayer.

2 Details of the authorisation

2.1 Product identity

Product Name	Sonata
Function	Biological fungicide
Applicant	Bayer CropScience SA-NV
Composition	*Bacillus pumilus* QST2808: 13.8 g/kg or 14.35 g/L, corresponding to a minimum of $1x10^{12}$CFU/kg
Formulation type	Suspension concentrate [Code: SC]
Packaging	HDPE: 5L and 10L

2.2 Classification and labelling

2.2.1 Classification and labelling under Regulation 1272/2008/EC

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	-	Signal word:	-
H-statements:	-		
P-statements:	-		
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	-
Other:	-

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

2.2.2 Other phrases

Other safety/precautionary phrases: contains *Bacillus pumilus* QST 2808: Micro-organisms may have the potential to provoke sensitising reactions.

2.3 Product uses

Use No.	Member State(s)	Crop and/ or situation (a)	F G or I (b)	Pests or Group of pests controlled (c)	Application					Application rate per treatment		
					Method kind (f-h)	Timing /growth stage & season (j)	Number per 12 months (k)		Min. interval between applications (days)	L product / ha min max	water L/ha min / max	CFU/ha - a.s. g/ha min / max
							Min.	Max.				
1	NL	Fruiting vegetables of Solanaceae	G	*Leivellula taurica* (LEVETA) *Oidium neolycopersici* (OIDINL)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200 - 1500	$1x10^{13}$ CFU/ha 143.5 g/ha
2	NL	Ornamental crops (cutflowers and potplants)	G	Powdery mildew *Erysiphe spp* (ERYSSP) *Sphaerotheca spp* (SPHRSP) *Oidium spp.* (OIDISP) *Microsphaera spp* (MCRSSP)	Spray	BBCG 15 – 85 Jan-Dec	1	7	5	10	500 - 4000	$1x10^{13}$ CFU/ha 143.5 g/ha
Minor uses conform article 51 EG 1107/2009												

Use No.	Member State(s)	Crop and/ or situation (a)	F G or I (b)	Pests or Group of pests controlled (c)	Application					Application rate per treatment		
					Method kind (f-h)	Timing /growth stage & season (j)	Number per 12 months (k)		Min. interval between applications (days)	L product / ha min max	water L/ha min / max	CFU/ha - a.s. g/ha min / max
							Min.	Max.				
3	NL	Strawberry	G	Powdery mildew *Sphaerotheca macularis* (SPHRMA)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1200	$1x10^{13}$ CFU/ha 143.5 g/ha
4	NL	Currant (Red and white currant Black currant)	G	Powdery mildew *Sphaerotheca mors-uvae* (SPHRMU) *Microsphaera grossulariae* (MCRSGR) *Erysiphe suffulta* (PHYLGU)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1200	$1x10^{13}$ CFU/ha 143.5 g/ha
5	NL	Blackberry and raspberry	G	Powdery mildew *Sphaerotheca macularis* (SPHRMA)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1200	$1x10^{13}$ CFU/ha 143.5 g/ha

Use No.	Member State(s)	Crop and/ or situation (a)	F G or I (b)	Pests or Group of pests controlled (c)	Application					Application rate per treatment		
					Method kind (f-h)	Timing /growth stage & season (j)	Number per 12 months (k)		Min. interval between applications (days)	L product / ha min max	water L/ha min / max	CFU/ha - a.s. g/ha min / max
							Min.	Max.				
6	NL	Endive	G	Powdery mildew *Sphaeroteca fuliginea* (SPHRFU) *(syn. Podosphaera xanthii,* PODOXA*)* *Erysiphe cichoracearum* (ERYSCI)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1000	$1x10^{13}$ CFU/ha 143.5 g/ha
7	NL	Lambs lettuce	G	Powdery mildew *Oidium neolycopersici* (OIDINL) *Sphaeroteca fuliginea* (SPHRFU) *(syn. Podosphaera xanthii,* PODOXA*)* *Erysiphe cichoracearum* (ERYSCI)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1000	$1x10^{13}$ CFU/ha 143.5 g/ha
8	NL	Fruiting vegetables of Cucurbits non-edible peel	G	*Sphaerotheca fuliginea* (SPHRFU) (syn. *Podosphaera xanthii* (PODOXA)) *Erysiphe cichoracearum* (ERYSCI)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200 - 1500	$1x10^{13}$ CFU/ha 143.5 g/ha

Use No.	Member State(s)	Crop and/ or situation (a)	F G or I (b)	Pests or Group of pests controlled (c)	Application					Application rate per treatment		
					Method kind (f-h)	Timing /growth stage & season (j)	Number per 12 months (k)		Min. interval between applications (days)	L product / ha min max	water L/ha min / max	CFU/ha - a.s. g/ha min / max
							Min.	Max.				
9	NL	Cucumber, Zucchini	G	*Sphaerotheca fuliginea* (SPHRFU) *(*syn. *Podosphaera xanthii (*PODOXA*))* *Erysiphe cichoracearum* (ERYSCI)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200 - 1500	$1x10^{13}$ CFU/ha 143.5 g/ha
10	NL	Parsley	G	Powdery mildew *Erysiphe spp* (ERYSSP)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1000	$1x10^{13}$ CFU/ha 143.5 g/ha
11	NL	Flower seed crops	G	*Leveillula taurica* (LEVETA)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1500	$1x10^{13}$ CFU/ha 143.5 g/ha
12	NL	Plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops	G	*Leveillula taurica* (LEVETA)	Spray	BBCH 11 – 89 Jan-Dec	1	6	5	10	200-1500	$1x10^{13}$ CFU/ha 143.5 g/ha

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 and the results are deemed to be acceptable. The appearance of the product is that of a light brown, opaque liquid with an intensely sourly odour. It is not explosive and not highly flammable as the flash-point is >100°C. It is not considered self-heating as the auto-ignition temperature is 652°C and it has no oxidising properties. In a 1% aqueous solution it has a pH value of 5.28. The kinematic viscosity at 40°C is 51.0 mm^2/s with no H304 classified components present in the formulation, therefore the product is not classified as an aspiration hazard. The surface tension of a 1g/L solution at 20°C is 47.4 mN/m, therefore the formulation is considered surface active. The relative density is D_4^{20} 1.0421.

The data indicate that Sonata is stable when stored at high temperature (40 °C for 8 weeks) and does not separate or crystallise at 0° C after 7-day test period when tested in HDPE. The product should be protected from the light. However spontaneity of dispersion was found to be slightly below recommended guideline limits (58%). As the application should be performed under continuous agitation, the result of spontaneity of dispersion was deemed acceptable. The shelf life study proves a stability of 2 years when Sonata is stored at ambient temperature in its original HDPE container. However the microbial contaminants before and after storage were determined on a different product BALLAD for which the data cannot be extrapolated to Sonata. The zRMS proposed that data on the determination of microbial contaminants in the formulation Sonata after 2-year storage at ambient temperature using validated methods or international standard methods can be provided in post-registration. This statement cannot be accepted by NL. The applicant thereby provided the composition of the formulated product (BALLAD, batches BP-10-02 and T002S) in comparison to the new formulated product compositions of Sonata in the bridging statement (M-566610-01-1). The composition change was considered non-significant by the French authority for the registration of Ballad in support of a recipe change from spec. 102000028244-01 to spec. 102000028244-02. According to SANCO/12638/2011 rev. 2 d.d.d 20, NL proposes that the formulation change cannot be considered non-significant as the content changes of the co-formulants are more than 30%. However it is not expected that the formulation change would significantly affect the physical-chemicalproperties. This indicates that all endpoints, including the determination of microbial contaminants, from the physical-chemical studies with batches BP-10-02 and T002S are also valid for the new formulation Sonata. The 2-year shelf life can be granted for Sonata in the HDPE packaging.
The physical, chemical and technical characteristics of Sonata are acceptable for a suspension concentrate [SC] formulation.

Implications for labelling: As the application should be performed under continuous agitation, the following restriction sentence should be included on the label:
De spuitvloeistof roeren tijdens gebruik.

Compliance with FAO specifications: The product complies with the FAO specification of suspension concentrate. Currently a FAO specification does not exist for microbial plant protection products.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging (HDPE), have been submitted, evaluated and is considered to be acceptable for Sonata.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of Sonata has been provided and is considered to be acceptable.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Method for the determination of *Bacillus pumilus* in formulation Sonata using CFU count of *Bacillus pumilus* was developed and validated. The method is considered appropriate and sufficiently validated.

3.1.2.2 Analytical methods for residues

Bacillus pumilus QST2808 is a candidate to be on Annex IV of Regulation 396/2005. Therefore, analytical methods for residues are not required.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

The toxicity, irritancy and sensitisation potential of Sonata (identical to *Bacillus pumilus* QST2808 SC QRD 228, Sonata and Sonata ASO) containing *Bacillus pumilus* QST 2808 as active substance, have been studied in rats, rabbits and guinea pigs.
The microbial plant protection product Sonata has a low potential of toxicity following oral, dermal or inhalation exposure and was not irritating to the skin or eyes of the rabbit.
Sonata was as a strong sensitiser in the Guinea pig maximisation test and was not sensitizing in the modified Buehler method in Guinea pigs, likely due to different routes of exposure. As the existing test methods are not generally considered to be appropriate to test the skin sensitisation properties of microorganisms no labelling for skin sensitisation is proposed. However, in accordance with the PRAPeR Expert Meeting on micro-organisms in June 2009 the following labelling is proposed:

"Sonata may have the potential to provoke sensitising reactions."

The following should be included on the WG:
Bevat *Bacillus pumilus* QST 2808: Micro-organismen kunnen mogelijk sensibiliserende reacties veroorzaken.

3.1.3.2 Operator Exposure

Sonata is formulated as a suspension concentrate (SC) and contains as active substance (a.s.) spores of *Bacillus pumilus* QST 2808 (13.8 g/kg). It is used as a fungicide amongst others in vegetables, berries and grapes in greenhouses.

Bacillus pumilus QST 2808 did not show toxicity, pathogenicity and infectiveness in many studies. As no reference values have to be established an exposure assessment for operators, workers and bystanders/residents is not necessary.

Nevertheless, as microorganisms are generally considered as potential sensitizers the use of adequate personal protective equipment for operators and workers have to be considered where appropriate. Operator exposure may occur during mixing, loading and application. However, *Bacillus pumilus* will not penetrate intact skin, as this is an effective barrier for microorganisms. Thus, external skin exposure will not lead to systemic exposure and skin protection equipment is not necessary from a risk assessment point of view. Sonata is a suspension concentrate and as such cannot be inhaled during mixing and loading. No inhalation will be expected during spraying due to the diluted suspension concentrate. Therefore, also no respiratory protection equipement is necessary.

3.1.3.3 Bystander Exposure

Please refer to 3.1.3.2.

3.1.3.4 Worker Exposure

Please refer to 3.1.3.2.

3.1.4 Residues and Consumer Exposure

Bacillus pumilus QST2808 is a candidate to be on Annex IV of Regulation 396/2005. Therefore, no MRL and no consumer risk assessment are required.
According to EU guidelines (European Commission, 1997g) a 1 day PHI is proposed for the intended uses on all edible crops under evaluation. This is in line with the zRMS conclusion.

3.1.5 Environmental fate and behaviour

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil)

Based on available information derived from published literature on *B. pumilus*, the environmental fate and population dynamics of *B. pumilus* QST 2808 can be summarized as follows:
B. pumilus QST 2808 will transiently establish vegetative populations on crop surfaces required for control of fungal pathogens. Spray drift and wash-off during raining events might lead to spread from plant surfaces for example to soils. Spores introduced into soils are likely to germinate, grow and exhibit plant protective activity under favourable conditions in the rhizosphere where root exudates provide sufficient nutrients for bacterial growth. In the surrounding soils the population will quickly decline reaching equilibrium densities after a few days. Survival of the endospores is very likely for a period of a few months during which time a natural breakdown begins and gradually reduces the number of spores remaining mainly due to grazing activity of other soil macro- or microorganisms or due to UV-mediated degradation if deposited at the soil surface. Vegetative cells are likely to be far more rapidly degraded. This reduction in cell numbers will be greatly augmented by competition with indigenous soil microbes, predation or phage infection and also to photo-degradation effects when exposed to sunlight.

In conclusion, it is very unlikely that *B. pumilus* endospores will germinate and grow into vegetative cells in the environment, unless appropriate conditions exist.

Interzone
According to the PEC calculation the expected accumulated concentration in soil is 93.1 µL product/kg dry weight (d.w.) soil, corresponding to 97.1 mg prod./kg d.w. soil. In terms of spores, this is equivalent to 0.971×10^8 CFU/kg dry weight soil (1.34 mg a.s./kg dry weight soil). Based on seven applications in ornamental crops.

For greenhouse applications PECs calculations are not deemed necessary since greenhouse soils are not considered as natural soils.

3.1.5.2 Predicted Environmental Concentration in Surface water (PECsw)

Under natural conditions, residues of *B. pumilus* QST 2808 in water are not considered to be able to persist for very long periods. Insufficient nutrient availability, exposition to solar radiation and microbial attack (competition, phage infection, grazing) are considered factors limiting survival and multiplication of *B. pumilus* populations in surface waters. Once nutrient availability is insufficient as in water courses, *B. pumilus* populations, if even, will be present as dormant spores, which settle down and persist in sediments but will be finally degraded by sediment-dwelling organisms.

Interzone
According to the PEC calculation the expected accumulated concentration in surface water following spray drift is 34.67 µg product/L, corresponding to 0.48 µg a.s./L. In terms of spores, this is equivalent to 3.47×10^4 CFU/L. Based on seven applications in ornamental crops with a ditch volume of 210 L/m^2.
According to the OECD guidance (2012) and EFSA guidance (EFSA Journal 2014;12(3):3615), only the discharge to surface water should be considered for permanent structures. No further calculation was provided by the notifier.

3.1.5.3 Predicted Environmental Concentration in Air (PECair)

A rapid degradation of *B. pumilus* QST 2808 spores in air is assumed since inactivation by solar radiation is a very important factor causing loss of activity and degradation of bacteria spores in the field environment. 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.
Spray drift, however, can occur following the application of *B. pumilus* QST 2808 which may lead to temporary concentrations in the atmosphere which are capable of drifting with wind currents before the spores in finer spray droplets settle out. Depending on the spraying equipment (high/low-pressure sprayer) Bacillus spore loads in air were shown to strongly decline with increasing distance to the source. Environmental stressors encountered in air are solar radiation, adverse temperatures and evaporation. Even though dormant spores might resist unfavourable temperature and water regimes, solar radiation likely restricts survival of air-dwelling *B. pumilus* populations to few hours or if the spores reach sunlight protected zones to 1-2 days as it was shown for other Bacillus species.
In conclusion, there are minimal risks to contamination via the air.

3.1.6 Ecotoxicology

Interzone
According to the presented risk assessment, the use of Sonata at the proposed label rates according to good agricultural practice poses no risk to any of the non-target species.

3.1.6.1 Effects on Terrestrial Vertebrates

Interzone
Effect on Birds and Terrestrial Vertebrates Other Than Birds
Since greenhouses can be regarded as enclosed spaces and birds and mammals will not enter greenhouses regularly, a direct exposure of birds and mammals to *B. pumilus* residues in greenhouses is not to be anticipated. Therefore a risk assessment is not relevant.
No risk mitigation measures are required.

3.1.6.2 Effects on Aquatic Species

Based on the worst case agricultural use in ornamental crops of seven (interzonal core) applications at an application rate of 10L/ha Sonatade (1 x 10^{12} CFU/ha), the PEC calculation of the expected accumulated concentration in surface water following spray drift the final maximal PECsw was 3.47 × 10^4 CFU/L according to the fate assessment.

Margins of Safety values for active substance *B. pumilus*

Use	PIEC (CFU/L)	MoS			
		Daphnid EC50 6.2× 10^8 CFU/L	Daphnid NOEC 2.3x1^8 CFU/L	Fish NOEC 8.5x10^9 CFU/L	Algae E_rC50 >6.57x10^8 CFU/L
Ornamental crops (G)	3.47 × 10^4	1787	663	24496	>1873

Based on the high MoS and considering that no infectivity and pathogenity was recorded in the studies, the risk to aquatic organisms is low.

3.1.6.3 Effects on Bees and Other Arthropod Species

Effect on bees and other non-target arthropods
The endpoint expressed in CFU/L is compared to the potential exposure for honeybee which is the spores density in spray liquid. This concentration is 5.2 x 10^{10} CFU/L (as indicated in IIIM 10.1), based on a density of 1.04 x 10^{12} CFU/L and 10 L of Sonata in 200 L water per hectare. The toxicity endpoint is 9 fold higher than the CFU concentration in spray liquid indicating an acceptable risk to honeybees exposed to SONATA at the recommended GAP.

For non-target arthropods, the LR50 of >3.5 × 10^{14} CFU/ha is considerable higher than the application rate of 1x10^{13} CFU/ha. Therefore, based on the high MoS and considering that no infectivity and pathogenity was recorded in the studies, the risk to non-target organisms is considered low.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

Interzone

The risk assessment for earthworms indicates that no adverse effects are to be expected upon application at recommended use levels. No adverse effects on earthworms are to be expected even upon prolonged exposure to Sonata or *B. pumilus* QST 2808. Taking into consideration host specificity, mode of action and ecology of *Bacillus pumilus* any long-term effects on earthworms are considered unlikely.

3.1.6.5 Effects on Soil Non-target Micro-organisms

Interzone
Due to its natural occurrence in soils, absence of active growth and restricted field persistence and resilience or resistance of highly diverse microbial assemblages against disturbances no significant alterations in soil microbial communities or negative effects on their activity are to be expected after application of *B. pumilus* QST 2808.

3.1.7 Efficacy

NL is CMS, FR is zRMS. FR concluded that all applied for uses are supported in FR and leaves to cMS to confirm.

For interzonal uses, the evaluator efficacy of NL checks if trials were conducted under conditions similar to those encountered in the maritime climate zone to which NL belongs, even if the uses applied for are for protected uses. Although protected cultivation is considered as 1 zone, EPPO standard PP 1/278 states: “Testing of the product should occur in extremes of the conditions encountered to ensure performance across the range of conditions”.

And in EPPO standard PP1/135 on phytotoxcicity is stated that phytotoxicity trials for protected crops should be conducted in the most sensitive period within the intended use (young crop, low light conditions).
For this application it is considered that:
Almost all efficacy trials were performed in the Southern zone (IT-FR-ES). For fruiting vegetables, crop safety was assessed in the efficacy trials. For ornamentals (rose and multi-plant trials with 15 different potting plant species) special crop safety trials were performed in NL under protected conditions. The product was demonstrated to be selective even at double dose rate.

The formulated product Sonata contains the active substance *B. pumilis*.
EPPO standard PP1/276 on Principles of efficacy evaluation of microbial plant protection products describes data requirements for evaluating the effectiveness and crop safety for products containing microbials.

The active substance, *B.pumilis* has not been approved as low risk substance but is on the list of active substances that are expected to be low risk (2018/C 265/02, COMMISSION NOTICE, concerning a list of potentially low-risk active substances approved for use in plant protection). Formulated plant protection products based on low risk active substances may or may not be classified as low risk. Low risk products are assessed for efficacy in accordance with the EPPO standard on low risk products PP1/296.

According to the EPPO standards mentioned above and the commission notice, NL confirms the zRMS conclusions that:
- the efficacy level of Sonata is considered as partial and variable for all the claimed uses. However it is considered as acceptable considering the kind of product based on micro-organisms.
- the selectivity level of Sonata is considered as satisfactory for all the claimed uses.

- the risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
-the risk of resistance development or appearance to Bacillus pumilus QST 2808 is considered as very low.

3.2 Conclusions

The assessment conducted for Sonata was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted.

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 proposed product label

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegelaten als schimmelbestrijdingsmiddel 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	Veiligheidstermijn in dagen
Vruchtgroenten van Solanaceae (bedekte teelt)	Echte meeldauw [1,2]	10 L/ha	6	5	1
Bloemisterijgewassen (bedekte teelt)	Echte meeldauw [3, 4, 5, 6]	10 L/ha	7	5	-

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.
[1] Echte meeldauw (*Leiveillula taurica)*
[2] Echte meeldauw *(Oidium neolycopersici)*
[3] Echte meeldauw (*Erysiphe* spp.)
[4] Echte meeldauw (*Sphaerotheca* spp.)
[5] Echte meeldauw (*Oidium* spp.)
[6] Echte meeldauw (*Microsphaera* spp.).

Het gebruik in onderstaande toepassingsgebieden 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. Het risico voor het gewas bij gebruik van dit middel in dit/deze toepassingsgebied/en valt onder verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Werkzaamheid	Dosering*	Maximaal aantal	Minimum interval	Veiligheidstermijn

	aannemelijk tegen	middel per toepassing	toepassingen per 12 maanden	tussen toepassingen in dagen	in dagen
Aardbei (bedekte teelt)	Echte meeldauw[7]	10 L/ha	6	5	1
Aalbes (bedekte teelt)	Echte meeldauw[8,9,12]	10 L/ha	6	5	1
Braam (bedekte teelt)	Echte meeldauw[7]	10 L/ha	6	5	1
Framboos (bedekte teelt)	Echte meeldauw[7]	10 L/ha	6	5	1
Andijvie (bedekte teelt)	Echte meeldauw[10,11]	10 L/ha	6	5	1
Veldsla (bedekte teelt)	Echte meeldauw [2,10,11]	10 L/ha	6	5	1
Courgette (bedekte teelt)	Echte meeldauw[10,11]	10 L/ha	6	5	1
Komkommer (bedekte teelt)	Echte meeldauw[10,11]	10 L/ha	6	5	1
Vruchtgroenten van Cucurbitaceae niet-eetbare schil (bedekte teelt)	Echte meeldauw[10,11]	10 L/ha	6	5	1
Peterselie (bedekte teelt)	Echte meeldauw[3]	10 L/ha	6	5	1
Bloemenzaadteelt (bedekte teelt)	Echte meeldauw[1]	10 L/ha	6	5	-
Veredelingsteelt en basiszaadproductie van akkerbouw-, groente- en fruitgewassen, kruiden en sierteeltgewassen (bedekte teelt)	Echte meeldauw[1]	10 L/ha	6	5	-

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken.
[1] Echte meeldauw (*Leiveillula taurica)*
[2] Echte meeldauw *(Oidium neolycopersici)*
[3] Echte meeldauw (*Erysiphe* spp.)
[7] Echte meeldauw (*Sphaerotheca macularis)*
[8] Echte meeldauw (*Microsphaera grossulariae)*
[9] Echte meeldauw (*Sphaerotheca mors-uvae)*
[10] Echte meeldauw (*Sphaerotheca fuliginea)*
[11] Echte meeldauw (*Erysiphe cichoracearum)*
[12] Echte meeldauw (*Erysiphe suffulta*)

Overige toepassingsvoorwaarden
In de veredelingsteelt en basiszaadproductie van akkerbouw-, groente- en fruitgewassen, kruiden en sierteeltgewassen en de teelt van bloemenzaad en vruchtgroenten van Solanaceae en Cucurbitaceae het middel toepassen in 200-1500 liter water per ha.

Bevat *Bacillus pumilus* QST 2808: Micro-organismen kunnen mogelijk sensibiliserende reacties veroorzaken.

De spuitvloeistof roeren tijdens gebruik.

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

Active substance data as indicated in Bacillus pumilus QST 2808_DAR_02_volume 2 April 2012.

Physico-chemical properties

Annex point / reference number	**Year**	**Title Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protection claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 2.1 /01	2010	Physico-chemical properties of the formulation QRD 288 before and after accelerated storage at 40 degree C for 8 weeks Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02588, Report includes Trial Nos.: S10-02588-LI_PCAS Edition Number: M-487988-01-1 Date: 2010-11-29 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.2.1 /02	2010	Storage stability of the formulation QRD 288 at 0 degree C for 7 days Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02589, Report includes Trial Nos.: S10-02589-LI_PCAS Edition Number: M-487993-01-1 Date: 2010-11-29 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.2.1 /03	2012	Physico-chemical properties of the	Yes	Yes	Yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protection claimed**	**Data protection granted**	**Studies relied on**	**Owner**
2.5.2 /01 2.7.3.1 /01 2.7.3.2 /01 2.7.4.2 /01 2.7.7.2 /01		formulation QRD 288 over 2 years at 20 degree C Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02590, Report includes Trial Nos.: S10-02590-Ll_PCTY Edition Number: M-474538-01-1 Date: 2012-11-06 GLP/GEP: yes, unpublished				
KIIIM 2.2.1 /04	2015	Post-registration requests for Ballad (2140160) - Bacillus pumilus QST 2808 SC Bayer CropScience Bayer CropScience, Report No.: M-521480-01-1, Edition Number: M-521480-01-1 Date: 2015-05-12 GLP/GEP: n.a., unpublished confidential	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.3.2 /01	2010	QRD 288 - Oxidising properties of liquids A.21. Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100284.04, Edition Number: M-474583-01-1 Date: 2010-10-07 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.4.1 /01	2010	QRD 288 - Flash point A.9. Siemens AG, Frankfurt	Yes	Yes	Yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protection claimed**	**Data protection granted**	**Studies relied on**	**Owner**
		am Main, Germany Bayer CropScience, Report No.: 20100284.01, Edition Number: M-474573-01-1 Date: 2010-10-07 GLP/GEP: yes, unpublished				
KIIIM 2.4.3 /01	2010	QRD 288 - Auto-ignition temperature (liquids and gases) A.15. Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20100284.03, Edition Number: M-474568-01-1 Date: 2010-10-07 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.6.2 /01	2010	Viscosity of the formulation QRD 288 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02584, Edition Number: M-474588-01-1 Date: 2010-10-15 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.6.3 /01	2010	Surface tension of QRD 288 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02583, Report includes Trial Nos.: S10-02583-LI_PCAS	Yes	Yes	Yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protection claimed**	**Data protection granted**	**Studies relied on**	**Owner**
		Edition Number: M-487996-01-1 Date: 2010-10-15 GLP/GEP: yes, unpublished				
KIIIM 2.7 /01	2010	Relative density of QRD 288 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02582, Edition Number: M-474585-01-1 Date: 2010-10-15 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 2.7.2 /01	2010	Persistent foaming of the formulation QRD 288 Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S10-02585, Edition Number: M-474584-01-1 Date: 2010-10-15 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 4.6 /01 4.11.3 /01 PART C /02	2016	B.Pumilus QST2808 SC 1G9A Bayer CropScience Bayer CropScience, Report No.: M-566965-01-1, Edition Number: M-566965-01-1 Date: 2016-07-27 GLP/GEP: n.a., unpublished	No	No	Yes	Bayer CropScience
	2016	Explaining the changes in the recipe of the product Bacillus pumilus QST 2808 SC	Yes	Yes	Yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protection claimed**	**Data protection granted**	**Studies relied on**	**Owner**
		(min. 1.0 x 10^9 CFU/g)				

Analytical methods

Annex point / reference number	**Year**	**Title** **Source** *(where different from company)* **Company name, Report No., Date, GLP/GEP status** *(where relevant)*, **published or not**	**Data protect. claimed**	**Data protection granted**	**Studie relied on**	**Owner**
KIIIM 5.1.3 /01	2014	Method for determination of aerobic colony forming units per gram of fermentation product Bayer CropScience LP, West Sacramento, CA, USA Bayer CropScience, Report No.: FM4200, Edition Number: M-463169-02-1 Date: 2014-11-11 GLP/GEP: n.a., unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 5.1.3 /02	2015	Determination of the total spore number in different biological formulations based on bacterial spores Bayer CropScience, Report No.: BM000915MF1, Edition Number: M-526452-01-1 Date: 2015-06-18 GLP/GEP: no, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 5.1.3 /03	2016	BACILLUS PUMILUS QST2808 SC: Total Spore Number and Viable Spore Count Validation Envigo CRS Limited, Huntingdon, United Kingdom Bayer CropScience, Report No.: QM12HX, Edition Number: M-567263-01-1 Date: 2016-09-29 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience

Mammalian toxicology

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 7.1.1 /01	2010	Sonata ASO QRD 288 - Acute oral toxicity study (UDP) in rats Report No.: 13933-10, Edition Number: M-474767-01-1 Date: 2010-05-27 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 7.1.2 /01	2010	Sonata ASO QRD 288 - Acute dermal toxicity study in rabbits Report No.: 13934-10, Edition Number: M-474746-01-1 Date: 2010-06-30 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 7.1.3 /01	2010	Sonata ASO QRD 288 - Acute inhalation toxicity study in rats Report No.: 13935-10, Edition Number: M-474764-01-1 Date: 2010-05-26 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 7.1.4 /02	2010	Sonata ASO QRD 288 - Acute dermal irritation study in rabbits Report No.: 13937-10, Edition Number: M-474744-01-1 Date: 2010-05-24 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 7.1.5 /02	2010	Sonata ASO QRD 288 - Acute eye irritation study in rabbits Report No.: 13936-10, Edition Number: M-474763-01-1 Date: 2010-05-27 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 7.1.6 /01	2010	Sonata ASO QRD 288 - Guinea pig maximizing test for topically applied test substance Report No.: 13938-10, Edition Number: M-474769-01-1 Date: 2010-06-30 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience
KIIIM 7.1.6 /02	2010	Sonata ASO QRD 288 - Skin sensitization study in guinea pigs Report No.: 14375-10, Edition Number: M-474768-01-1 Date: 2010-11-30 GLP/GEP: yes, unpublished	Yes	Yes	Yes	Bayer CropScience

Residues
No new data have been submitted.

Environmental fate and behaviour
No new data have been submitted.

Ecotoxicology
No new data have been submitted.

Efficacy

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6 /01	2016	Summary of the efficacy data and information on the plant protection product for bacillus pumilus QST2808 SC Bayer CropScience Report No.: M-568162-01-1, Edition Number: M-568162-01-1 Date: 2016-10-20 GLP/GEP: n.a., unpublished	No	No	yes	Bayer CropScience
KIIIM 6.1 /01	2016	Statement on trade names and codes - Microbial pest control product - European Union - Bacillus pumilus QST2808 SC - Sonata Bayer CropScience LP, West Sacramento, CA, USA Bayer CropScience, Report No.: M-558735-02-1, Edition Number: M-558735-02-1 Date: 2016-08-04 GLP/GEP: n.a., unpublished	No	No	yes	Bayer CropScience
KIIIM 6.1.2 /01	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Leveillula taurica and Oidium neolycopersici - Tomato and pepper Bayer CropScience Bayer CropScience, Report No.: M-561357-01-1, Edition Number: M-561357-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.3 /03** **...also filed: KIIIM 6.2.1 /03**	Yes	yes	yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6.1.2 /02	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca macularis - Strawberry Bayer CropScience Bayer CropScience, Report No.: M-561359-01-1, Edition Number: M-561359-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.3 /04** **...also filed: KIIIM 6.2.1 /04**	Yes	yes	yes	Bayer CropScience
KIIIM 6.1.3 /01	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca fuliginea and Erysiphe cichoracearum - Cucumber Bayer CropScience Bayer CropScience, Report No.: M-561352-01-1, Edition Number: M-561352-01-1 Date: 2016-07-21 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.2.1 /01**	Yes	yes	yes	Bayer CropScience
KIIIM 6.1.3 /02	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca fuliginea and Erysiphe cichoracearum - Zucchini Bayer CropScience Bayer CropScience, Report No.: M-561356-01-1, Edition Number: M-561356-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.2.1 /02**	Yes	yes	yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6.1.3 /03	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Leveillula taurica and Oidium neolycopersici - Tomato and pepper Bayer CropScience Bayer CropScience, Report No.: M-561357-01-1, Edition Number: M-561357-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.2 /01** **...also filed: KIIIM 6.2.1 /03**	Yes	yes	yes	Bayer CropScience
KIIIM 6.1.3 /04	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca macularis - Strawberry Bayer CropScience Bayer CropScience, Report No.: M-561359-01-1, Edition Number: M-561359-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.2 /02** **...also filed: KIIIM 6.2.1 /04**	Yes	yes	yes	Bayer CropScience
KIIIM 6.1.3 /05	2016	Compilation of trial reports for BP QST2808 SC - Efficacy and crop safety trials - Ornamentals Bayer CropScience Bayer CropScience, Report No.: M-561360-01-1, Edition Number: M-561360-01-1 Date: 2016-07-29 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.2.1 /05**	Yes	yes	yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6.2.1 /01	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca fuliginea and Erysiphe cichoracearum - Cucumber Bayer CropScience Bayer CropScience, Report No.: M-561352-01-1, Edition Number: M-561352-01-1 Date: 2016-07-21 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.3 /01**	Yes	yes	yes	Bayer CropScience
KIIIM 6.2.1 /02	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca fuliginea and Erysiphe cichoracearum - Zucchini Bayer CropScience Bayer CropScience, Report No.: M-561356-01-1, Edition Number: M-561356-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.3 /02**	Yes	yes	yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6.2.1 /03	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Leveillula taurica and Oidium neolycopersici - Tomato and pepper Bayer CropScience Bayer CropScience, Report No.: M-561357-01-1, Edition Number: M-561357-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.2 /01** **...also filed: KIIIM 6.1.3 /03**	Yes	yes	yes	Bayer CropScience
KIIIM 6.2.1 /04	2016	Compilation of trial reports for BP QST2808 SC - Efficacy trials - Sphaerotheca macularis - Strawberry Bayer CropScience Bayer CropScience, Report No.: M-561359-01-1, Edition Number: M-561359-01-1 Date: 2016-07-27 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.2 /02** **...also filed: KIIIM 6.1.3 /04**	Yes	yes	yes	Bayer CropScience
KIIIM 6.2.1 /05	2016	Compilation of trial reports for BP QST2808 SC - Efficacy and crop safety trials - Ornamentals Bayer CropScience Bayer CropScience, Report No.: M-561360-01-1, Edition Number: M-561360-01-1 Date: 2016-07-29 GLP/GEP: yes, unpublished **...also filed: KIIIM 6.1.3 /05**	Yes	yes	yes	Bayer CropScience

Annex point / reference number	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP/GEP status** ***(where relevant)*****, published or not**	**Data protect. claimed**	**Data protection granted**	**Studies relied on**	**Owner**
KIIIM 6.2.6 /01	2016	Information on the occurrence or possible occurrence of the development of resistance of the plant protection product Sonata for use in grape, banana, strawberry, melon, watermelon, cucumber, zucchini, pumpkin, squash, eggplant, pepper, tomato, ornamentals, and cut flowers (for submission in Europe) Bayer CropScience Bayer CropScience, Report No.: M-561442-01-1, Edition Number: M-561442-01-1 Date: 2016-07-29 GLP/GEP: n.a., unpublished	No	No	yes	Bayer CropScience