

**REGISTRATION REPORT  
Part A**

**Risk Management**

**Product name: Bayer Garten Rosen-Pilzfrei  
Baymat Plus AF**

**Product code: 102000012749**

**Active Substance: Tebuconazole 0.125 g/L**

**Trifloxystrobin 0.125 g/L**

**COUNTRY: Germany**

**All Zones**

**Zonal Rapporteur Member State: UK**

**NATIONAL ASSESSMENT**

**Applicant: Bayer CropScience**

**Date: 29 November 2017**

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## **PART A – Risk Management**

This document describes the acceptable use conditions required for the greenhouse label extension of Bayer Garten Rosen-Pilzfrei containing tebuconazole and trifloxystrobin in Germany.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Bayer Garten Rosen-Pilzfrei where that data has not been considered in the EU review. Otherwise assessments for the safe use of Bayer Garten Rosen-Pilzfrei have been made using endpoints agreed in the EU review of tebuconazole and trifloxystrobin.

This document describes the specific conditions of use and labelling required for Germany for the re-registration/registration of Bayer Garten Rosen-Pilzfrei.

Appendix 1 of this document provides a copy of the final product authorisation Germany (will be inserted under Appendix 4).

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 of this document provides a copy of the final product authorisation Germany

### **1 Details of the application**

#### **1.1 Application background**

This application was submitted Bayer CropScience Deutschland on 13 January 2014.

The application was for approval of Bayer Garten Rosen-Pilzfrei Baymat Plus AF, a Ready to use formulation containing 0.125 g/L of tebuconazole and 0.125 g/L of trifloxystrobin for use as a fungicide for fruiting vegetables in home and garden greenhouse.

#### **1.2 Annex I inclusion**

##### **Trifloxystrobin**

The active substance trifloxystrobin was included into Annex I of Directive 91/414 on 1 October 2003 (Directive 2003/68/EC dated 11 July 2003).

For the implementation of the uniform principles of Annex VI, the draft assessment report on the active substance trifloxystrobin, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.

The Annex I Inclusion Directive for trifloxystrobin provides specific provisions under Part B which need to be considered by the MS prior to granting an authorisation. In this overall assessment Member States must pay particular attention to:

- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and /or climate conditions.

Risk mitigation measures should be applied and/or monitoring programs may be initiated where appropriate.

The Review Report for trifloxystrobin (SANCO/4339/2000, final – 7 April 2003) is considered to provide the relevant scientific information or a reference to where such information can be found for the review of the product.

### **Tebuconazole**

Tebuconazole was included into the Annex I of Directive 91/414 on 1 September 2009 (Directive 2008/125/EC dated 19 December 2008). The Annex I Inclusion Directive for tebuconazole 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 of Annex VI, the conclusions of the review reports on the active substance tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to:

- operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the dietary exposure of consumers to the tebuconazole (triazole) metabolites;
- the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measure;
- the protection of aquatic organism and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

These concerns were all addressed in the submission, except the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops and products of animal origin. All the data and information on the common triazole metabolite derivatives will be submitted once for all the azole active substances for an assessment by UK CRD as the RMS.

The EFSA Scientific Report (2008) 176, 1-109 for tebuconazole is considered to provide the relevant scientific information or a reference to where such information can be found for the review of the product.

These concerns were all addressed in the submission

Furthermore the Commission asked the RMS for the active substance to request the submission of further information to confirm the risk assessment for birds and mammals. They shall ensure that the notifier at whose request tebuconazole has been included in this Annex provide such information to the Commission

by 31 August 2011 at the latest and that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.

### 1.3 Regulatory approach

To obtain a label extension the product TBZ+TFS AL 0.25 (0.125+0.125) must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow a label extension of an already approved product in accordance with the above.

### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Bayer Garten Rosen-Pilzfrei Baymat Plus AF, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 7 and Part C.

### 1.5 Letters of Access

The applicant submitted a Letter of Access as regards a. i. and product data.

## 2 Details of the authorisation

### 2.1 Product identity

Product Name	Bayer Garten Rosen-Pilzfrei Baymat Plus AF
Authorization Number (for re-registration)	006867-00/01
Function	fungicide
Applicant	Bayer CropScience Deutschland GmbH
Composition	0.125 g/L tebuconazole 0.125 g/L trifloxystrobin
Formulation type	Ready to use [Code: AL]
Packaging	<i>for non-professional users:</i> PET bottle for 100 mL to 1 L PET bottle for 3 to 5 L PET bag in can 200 or 400 mL

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

## 2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

<i>Hazard classes and categories:</i>	
None	
<i>Hazard pictograms:</i>	
None	
<i>Signal word:</i>	
None	
<i>Hazard statements:</i>	
None	
H412	Harmful to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
None	
P501	Dispose of contents/container to ...
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
EUH 208 - Contains 5-chloro-2-methyl, mixture with 2-methyl-3(2H)-isothiazolone at the ratio of 3:1. May produce an allergic reaction.	

### 2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

### 2.3 Other phrases notified under Regulation (EC) No 547/2011

#### 2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS201	Wear working clothes (at least long-sleeved shirt and long trousers) and gloves when applying/handling the product.
SS703	Wear sturdy shoes (e.g. rubber boots) when applying/handling the product.
Integrated pest management (IPM)/sustainable use	
WMFC3	Mode of action (FRAC-group): C3 (for trifloxystrobin)
WMFG1	Mode of action (FRAC-group): G1 (for tebuconazole)
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
NN2002	The product is classified as slightly harmful for populations of relevant predatory mites and spiders.
NN3001	The product is classified as harmful for populations of relevant beneficial insects
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 467	The product and its remains, empty containers and packaging and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

#### 2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):



See 2.4 (Product uses)

<b>Integrated pest management (IPM)/sustainable use</b>	
-	none
<b>Ecosystem protection</b>	
-	none

## 2.4 Product uses

PPP (product name/code):	Bayer Garten Rosen-Pilzfrei Baymat Plus AF / 006867-00/01	Formulation type:	AL (a, b)
Active substance 1:	Tebuconazol	Conc. of as 1:	0.125 g/L (c)
Active substance 2:	Trifloxystrobin	Conc. of as 2:	0.125 g/L (c)
Active substance....:	-	Conc. of as ....:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Bayer CropScience	Professional use:	<input type="checkbox"/>
Zone(s):	central/interzonal (d)	Non professional use:	<input checked="" type="checkbox"/>
Verified by MS:	Yes		

GAP rev.1, date: 2015-11-12

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
001	DE	cucumber (CUMSA)  plant height up to 50 cm	G	powdery mildew ( <i>Erysiphe cichoracearum</i> ) (ERYSCI), powdery mildew ( <i>Sphaerotheca fuliginea</i> ) of cucumber (SPHRFU)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3  b) 3	10 to 14 days	a) 50 mL/m <sup>2</sup>  b) 300 mL/m <sup>2</sup>	a) a.s. 1: 0.0625 kg/ha a.s. 2: 0.0625 kg/ha  b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	- Ready to use	3	

001	DE	cucumber (CUMSA) plant height 50 up to 125 cm:	G	powdery mildew ( <i>Erysiphe cichoracearum</i> ) (ERYSCI), powdery mildew ( <i>Sphaerotheca fuliginea</i> ) of cucumber (SPHRFU)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3 b) 3	10 to 14 days	a) 75 mL/m <sup>2</sup>  b) 300 mL/m <sup>2</sup>	a) a.s. 1: 0.09375 kg/ha a.s. 2: 0.09375 kg/ha  b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	- Ready to use	3	
001	DE	cucumber (CUMSA) plant height more than 125 cm:	G	powdery mildew ( <i>Erysiphe cichoracearum</i> ) (ERYSCI), powdery mildew ( <i>Sphaerotheca fuliginea</i> ) of cucumber (SPHRFU)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3 b) 3	10 to 14 days	a) 100 mL/m <sup>2</sup>  b) 300 mL/m <sup>2</sup>	a) a.s. 1: 0.125 kg/ha a.s. 2: 0.125 kg/ha  b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	- Ready to use	3	
002	DE	tomato (LYPES) plant height up to 50 cm	G	powdery mildew (ERYSSP)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3 b) 3	10 to 14 days	a) 50 mL/m <sup>2</sup>  b) 300 mL/m <sup>2</sup>	a) a.s. 1: 0.0625 kg/ha a.s. 2: 0.0625 kg/ha  b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	- Ready to use	3	Negative efficacy evaluation in accordance with zRMS
002	DE	tomato (LYPES) plant height 50 up to 125 cm	G	powdery mildew (ERYSSP)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3 b) 3	10 to 14 days	a) 75 mL/m <sup>2</sup>  b) 300 mL/m <sup>2</sup>	a) a.s. 1: 0.09375 kg/ha a.s. 2: 0.09375 kg/ha  b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	- Ready to use	3	Negative efficacy evaluation in accordance with zRMS
002	DE	tomato (LYPES)	G	powdery mildew (ERYSSP)	spraying	At beginning of infestation	a) 3	10 to 14 days	a) 100 mL/m <sup>2</sup>	a) a.s. 1: 0.125 kg/ha	- Ready	3	Negative efficacy evaluation in

		plant height more than 125 cm				and/or when first symptoms become visible	b) 3		b) 300 mL/m <sup>2</sup>	a.s. 2: 0.125 kg/ha b) a.s.1: 0,375 kg/ha a.s.2: 0,375 kg/ha kg/ha	to use		accordance with zRMS
003	DE	zucchini (CUUPG)	G	powdery mildew ( <i>Erysiphe cichoracearum</i> ) (ERYSCI), powdery mildew ( <i>Sphaerotheca fuliginea</i> ) of cucumber (SPHRFU)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 3 b) 3	10 to 14 days	a) 50 mL/m <sup>2</sup>  b) 150 mL/m <sup>2</sup>	a) a.s. 1: 0.0625 kg/ha a.s. 2: 0.0625 kg/ha  b): a.s. 1: 0,1875 kg/ha a.s. 2: 0,1875 kg/ha	- Ready to use		

**Remarks table heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/l

- (d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

- 1 Numeration necessary to allow references  
 2 Use official codes/nomenclatures of EU Member States  
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
 8 The maximum number of application possible under practical conditions of use must be provided.  
 9 Minimum interval (in days) between applications of the same product  
 10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
 13 PHI - minimum pre-harvest interval  
 14 Remarks may include: Extent of use/economic importance/restrictions

### **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 (Part B, Section 1, Points 2 and 4)**

###### **Overall Summary:**

Since the first registration in Germany, no new data concerning the physical, chemical or technical properties have been submitted.

No changes compared to the main application.

**Implications for labelling:** none

###### **Compliance with FAO guidelines:**

The product Bayer Garten Rosen-Pilzfrei Baymat Plus AF complies with the general requirements according to the FAO/WHO manual (2010).

###### **Compatibility of mixtures:**

The product is ready-for-use, no mixtures are recommended.

###### **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, have been submitted, evaluated and is considered to be acceptable.

###### **Nature and characteristics of the protective clothing and equipment:**

Information regarding the required protective clothing and equipment for the safe handling of Bayer Garten Rosen-Pilzfrei Baymat Plus AF has been provided and is considered to be acceptable.

##### **3.1.2 Methods of analysis (Part B, Section 2, Point 5)**

###### **3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)**

The method submitted for the main application is considered valid.

###### **3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)**

Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be also applied for the product. The analytical methods were provided in the EU review of tebuconazole and trifloxystrobin. They were considered adequate for food of plants, soil, water and air. For the determination of trifloxystrobin residues in animal matrices, adequate methods are also available. Methods for body fluids and tissues are not required, because tebuconazole and trifloxystrobin are not considered to be toxic or very toxic (T / T+) nor are they classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

However, the following minor data gaps have been identified according to the requirements of SANCO/825/00 rev. 8.1:

- A primary method, an independent laboratory validation (ILV) and a confirmatory method for the determination of residues of tebuconazole (sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole) in foodstuffs of animal origin is missing.
- A confirmatory method for the determination of residues of trifloxystrobin (sum of trifloxystrobin and its metabolite CGA 321113) in foodstuffs of animal origin is missing.

These data gaps can be addressed in the context of the next renewal of the approval of tebuconazole and trifloxystrobin, respectively, according to Reg. (EC) No 1107/2009 or in the context of the assessment of existing MRLs of according to Reg. (EC) No 396/2005.

### **3.1.3 Mammalian Toxicology**

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS UK.

#### **3.1.3.1 Acute Toxicity**

Please refer to the registration report of the zonal RMS UK.

#### **3.1.3.2 Operator Exposure**

Please refer to the registration report of the zonal RMS UK.

#### **3.1.3.3 Bystander Exposure**

Please refer to the registration report of the zonal RMS UK.

#### **3.1.3.4 Worker Exposure**

Please refer to the registration report of the zonal RMS UK.

### **Implications for labelling resulting from operator, worker, bystander assessments:**

See 2.2

#### **3.1.3.5 Groundwater Metabolites**

As described in the registration report of the zonal RMS UK the trifloxystrobin metabolite NOA413161 is calculated above the drinking water limit of 0.1 µg/L in the groundwater (FOCUS PEARL, Hamburg Scenario 0.221 µg/L). This metabolite is regarded as toxicological not relevant in the groundwater.

### 3.1.4 Residues and Consumer Exposure

The intended uses in cucumber, zucchini and tomatoes will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.

For further details please refer to the registration report of the zonal RMS UK.

#### 3.1.4.1 Residues

Please refer to the registration report of the zonal RMS UK.

#### 3.1.4.2 Consumer exposure

Please refer to the registration report of the zonal RMS UK.

### 3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

The exposure assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus in its intended uses in tomato, zucchini and cucumber in greenhouses of home gardens (amateur uses only) is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus dated from January 2016 (date of circulation of final report) performed by UK.

As stated within Part A of zRMS UK the requirements for authorisation of amateur (Home garden) products are not yet harmonised across the EU. However in this case the intended uses only include applications in greenhouses with a ready to use product. Hence the exposure of the environment is really limited. In this case the risk assessment performed by zRMS UK can be considered as acceptable for specific German environmental or agricultural circumstances.

The plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus has already been authorized in Germany for different field uses in home gardens (use No. 00-028 to 00-031). These already evaluated uses fully cover the new intended use of Bayer Garten Rosen-Pilzfrei Baymat Plus in zucchini, tomato and cucumber according to use No. 01-001 to 01-003. Therefore the exposure assessment refers also to the German 'Bewertungsbericht' for ZA 006867-00/00 dated from September 2011.

#### 3.1.5.1 Predicted Environmental Concentration in Soil (PEC<sub>soil</sub>) (Part B, Section 5, Points 9.4 and 9.5)

Results of PEC<sub>soil</sub> calculation for Bayer Garten Rosen-Pilzfrei Baymat Plus and its intended for uses in cucumber, tomato and zucchini (home gardening, greenhouses) according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 5, chapter IIIA 9.4. In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>1</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a  $K_{f,oc} < 500$ , whereas a soil layer depth of 1 cm is applied for active substances with a  $K_{f,oc} > 500$ . A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment. Thus Germany normally performs an own PEC soil calculation in the national addendum. However as explained at the beginning of this national addendum the exposure in this case, application only in greenhouses with a ready to use product, is really limited. Thus based on the core assessment by zRMS UK and also based on the already existing German assessment for the product Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to 'Bewertungsbericht' for ZA 006867-00/00) there is no need for further PEC soil calculation on national level in this case.

<sup>1</sup> Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999

### **3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC<sub>GW</sub>) (Part B, Section 5, Point 9.6)**

Results of the PEC<sub>gw</sub> calculation of Trifloxystrobin and Tebuconazole for the intended uses of Bayer Garten Rosen-Pilzfrei Baymat Plus in cucumber, tomato and zucchini (home gardening, greenhouses) according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment, part B, section 5, chapter IIIA 9.6.

Risk assessment for groundwater for authorisation of plant protection products in Germany considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface runoff and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater. The latter pathway was not addressed neither by core assessment nor for EU assessment of the active substances.

The risk assessment for groundwater of the pathway direct leaching after soil passage follows the recommendation of the Ground Water Work Group of FOCUS as provided by the Commission Services (Sanco/13144/2010, version 3, 10 October 2014) as also done by the zRMS in the core assessment.

Risk assessment for groundwater for the pathway surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01 stipulating also risk mitigation measures, if applicable. However as explained at the beginning of this national addendum the exposure in this case, application only in greenhouses with a ready to use product, is really limited. Thus based on the core assessment by zRMS UK and also based on the already existing german assessment for the product Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to 'Bewertungsbericht' for ZA 006867-00/00) there is no need for further calculations on national level in this case.

#### **Consequences for authorization:**

None

### **3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC<sub>sw</sub>) (Part B, Section 5, Points 9.7 and 9.8)**

The intended uses only include applications in greenhouses, thus a relevant exposure is not expected and no further consideration is required on national level. However the zRMS UK performed a risk assessment for aquatic organisms which fully covers the intended uses for Germany. Please refer to the core assessment, part B, section 5, chapter IIIA 9.7 for PEC calculations used for risk assessment by zRMS UK.

### **3.1.5.4 Predicted Environmental Concentration in Air (PEC<sub>Air</sub>) (Part B, Section 5, Point 9.9)**

Please refer to the core assessment, part B, section 5, chapter IIIA 9.9.

**Implications for labelling resulting from environmental fate assessment:** none



### 3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

The exposure assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus in its intended uses in tomato, zucchini and cucumber in greenhouses of home gardens (amateur uses only) is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus dated from January 2016 (date of circulation of final report) performed by UK.

As stated within Part A of zRMS UK the requirements for authorisation of amateur (Home garden) products are not yet harmonised across the EU. However in this case the intended uses only include applications in greenhouses with a ready to use product. Hence the exposure of the environment is really limited. In this case the risk assessment performed by zRMS UK can be considered as acceptable for specific German environmental or agricultural circumstances.

The plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus has already been authorized in Germany for different field uses in home gardens (use No. 00-028 to 00-031). These already evaluated uses fully cover the new intended use of Bayer Garten Rosen-Pilzfrei Baymat Plus in zucchini, tomato and cucumber according to use No. 01-001 to 01-003. Therefore the exposure assessment refers also to the German `Bewertungsbericht` for ZA 006867-00/00 dated from September 2011.

#### 3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Please refer to the core assessment by zRMS UK.

#### Consequences for authorisation

None

#### 3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

The intended uses only include applications in greenhouses, thus a relevant exposure of aquatic organisms is not expected and no further consideration is required on national level (refer also to `Bewertungsbericht ZA 006867-00/00). However the zRMS UK performed a risk assessment for aquatic organisms which fully covers the intended uses for Germany. Please refer to the core assessment, part B, section 6, chapter IIIA 10.2.

#### Consequences for authorisation

For the authorisation of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus, labelling and conditions of use are mandatory as follows:

**Table 0-1 Labelling requirements according to § 36 (3) PflSchG**

NW 262	trifloxystrobin: <i>S. subspicatus</i> NOEC = 0.00192 mg a.s./L
NW 264	tebuconazole: <i>O. mykiss</i> LC <sub>50</sub> = 4.4 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.46 mg a.s./L trifloxystrobin: <i>O. mykiss</i> LC <sub>50</sub> = 0.015 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.0086 mg a.s./L
NW 265	tebuconazole: <i>L. gibba</i> NOEC ≤ 0.0307 mg a.s./L trifloxystrobin: <i>L. gibba</i> NOEC = 0.236 mg a.s./L

NW467	
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### **3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)**

#### **Bees**

Effects on bees for Bayer Garten Rosen-Pilzfrei Baymat Plus were not evaluated as part of the EU review of tebuconazole and trifloxystrobin. Further data on the product were submitted by the applicant. This data has been reviewed by the zRMS and are considered valid. The zRMS comes to the conclusion that no unacceptable risk to bees is expected using the product according to the proposed use pattern.

For Germany, the labelling NB6641 (The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)) is assigned.

#### **Other non-target arthropods**

Please refer to the core assessment by zRMS UK.

#### **Consequences for authorisation**

None

### **3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)**

Please refer to the core assessment by zRMS UK. Although the risk assessment normally is based on PEC soil calculations special for Germany, in this case no assessment was performed on national level. As the intended uses only include applications in greenhouses and the product is a ready to use spray which is applied directly to single plants, the exposure of soil organisms is limited. This is also in line with the assessment of the already approved intended home gardening field uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to `Bewertungsbericht` ZA 006867-00/00).

#### **Consequences for authorisation**

None

### **3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)**

Please refer to core assessment.

### **3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)**

Please refer to the core assessment by zRMS UK. Please refer to the core assessment by zRMS UK. Although the risk assessment normally is based on PEC soil calculations special for Germany, in this case no assessment was performed on national level. As the intended uses only include applications in greenhouses and the product is a ready to use spray which is applied directly to single plants, the exposure of soil organisms is limited. This is also in line with the assessment of the already approved intended home gardening field uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to

‘Bewertungsbericht’ ZA 006867-00/00).

### Consequences for authorisation

None

### 3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Please refer to the core assessment by zRMS UK.

### Consequences for authorisation

None

### Implications for labelling resulting from ecotoxicological assessment:

#### Classification and labelling of Bayer Garten Rosen-Pilzfrei Baymat Plus

product	<i>D. magna</i> EC <sub>50</sub> = 86 mg/L
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	none
Signal word	none
Hazard statement	H412

### National labelling

#### Labelling requirements according to § 36 (3) PflSchG

NW 262	trifloxystrobin: <i>S. subspicatus</i> NOEC = 0.00192 mg a.s./L
NW 264	tebuconazole: <i>O. mykiss</i> LC <sub>50</sub> = 4.4 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.46 mg a.s./L trifloxystrobin: <i>O. mykiss</i> LC <sub>50</sub> = 0.015 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.0086 mg a.s./L
NW 265	tebuconazole: <i>L. gibba</i> NOEC ≤ 0.0307 mg a.s./L trifloxystrobin: <i>L. gibba</i> NOEC = 0.236 mg a.s./L
NW467	

### 3.1.7 Efficacy (Part B, Section 7, Point 8)

The application is an amendment for new uses to an already existing authorisation. It is supported with new data but also reference is made to the existing authorisation.

The zRMS proposed that the data provided should be sufficient for authorisation in the cMS, but recommends to consider the data evaluated under this application and the zRMS conclusions in relation to their specific circumstances.

According to the zRMS, data from the preliminary range finding tests justified the co-formulation and that the proposed dose can be considered acceptable, given that the product is already authorised for other similar uses.

There is sufficient efficacy data to support the proposed control claims against powdery mildew for the use in cucumbers (use 001) and zucchini (use 003). No phytotoxic effects were observed in trials conducted on these crops.

The zRMS concluded however that insufficient evidence of effectiveness has been presented to support the proposed use in tomatoes, and phytotoxic effects were observed in trials conducted on tomatoes. An authorisation of use 002 is therefore not possible.

According to the zRMS, Resistance to relevant powdery mildew pathogens has been reported in commercial high selection pressure situations, but risk development in amateur situations is considered low and co-formulation can additionally lower the risk.

The product is classified as slightly harmful for populations of relevant predatory mites and spiders and as harmful for populations of relevant beneficial insects.

### 3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.

With respect to analytical methods (formulation) an authorisation can be granted.

With respect to analytical methods for residues, an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

With respect to efficacy assessment, **an authorisation can be granted to use 001 in cucumbers and 003 in zucchini. No authorisation is possible for use 002** in tomatoes in accordance with the decision of the zRMS UK due to insufficient efficacy data.

### 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

No further information is required.

**Appendix 1 – Copy of the product authorisation see Appendix 4**

## **Appendix 2 – Copy of the product label**

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

### **Appendix 3 – Letter of Access**

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

**Appendix 4 – Copy of the product authorisation see Appendix 4**





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IHR ZEICHEN  
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.006867-00/01.97150  
(bitte bei Antwort angeben)

DATUM 29. November 2017

**ZV3 006867-00/01**

**Bayer Garten Rosen-Pilzfrei Baymat Plus AF**

**Zulassungsverfahren für Pflanzenschutzmittel**

Ergänzungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit den Wirkstoffen:           0,12 g/l           Trifloxystrobin  
                                          0,12 g/l           Tebuconazol

Zulassungsnummer:           006867-00

Versuchsbezeichnungen:    SDE-18210-F-0-AL

Antrag vom:                    13. Januar 2014

ändere ich wie folgt:

### **Zusätzliche Anwendungsgebiete bzw. Anwendungen**

Die Zulassung wird um folgende Anwendungsgebiete bzw. Anwendungen erweitert (siehe Anlage 1):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006867-00/01-001	Echter Mehltau (Erysiphe cichoracearum), Echter Mehltau (Sphaerotheca fuliginea)	Gurke	
006867-00/01-003	Echter Mehltau (Erysiphe cichoracearum), Echter Mehltau (Sphaerotheca fuliginea)	Zucchini	

### Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

### Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

### Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

### Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006867-00/01-002	Echte Mehltäupilze	Tomate	

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

## **Rechtsbehelfsbelehrung**

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen  
im Auftrag

gez. Dr. Martin Streloke  
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

## **Anlage**

## Anlage 1 zugelassene Anwendung: 006867-00/01-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Erysiphe cichoracearum*), Echter Mehltau (*Sphaerotheca fuliginea*)

Pflanzen/-erzeugnisse/Objekte: Gurke

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3
- für die Kultur bzw. je Jahr: 3
- Abstand: 10 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 50 ml/m<sup>2</sup>
- Pflanzengröße 50 bis 125 cm 75 ml/m<sup>2</sup>
- Pflanzengröße über 125 cm 100 ml/m<sup>2</sup>

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

3 Tage Gewächshaus: Gurke

### 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

## Anlage 1 zugelassene Anwendung: 006867-00/01-003

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Erysiphe cichoracearum*), Echter Mehltau (*Sphaerotheca fuliginea*)

Pflanzen/-erzeugnisse/Objekte: Zucchini

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3

- für die Kultur bzw. je Jahr: 3

- Abstand: 10 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- 50 ml/m<sup>2</sup>

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

3 Tage Gewächshaus: Zucchini

### 3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

## Anlage 2 nicht zugelassene Anwendung: 006867-00/01-002

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echte Mehltaupilze

Pflanzen/-erzeugnisse/Objekte: Tomate

Verwendungszweck:

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und  
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten  
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 3
- für die Kultur bzw. je Jahr: 3
- Abstand: 10 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 50 ml/m<sup>2</sup>
- Pflanzengröße 50 bis 125 cm 75 ml/m<sup>2</sup>
- Pflanzengröße über 125 cm 100 ml/m<sup>2</sup>

### 3 Begründung

Wirksamkeit

Aufgrund der Ablehnung der Anwendung gegen Echten Mehltau an Tomaten durch den zRMS UK wegen fehlendem Nachweis der Wirksamkeit ist auch in Deutschland keine Zulassung dieser Anwendung möglich. Für die Bewertung der Wirksamkeit des Prüfmittels gegen Echten Mehltau an Tomaten wurden vier Versuche vorgelegt. Der zRMS UK hat von diesen vier nur einen Versuch als valide akzeptiert und die vorgelegten Daten damit als nicht ausreichend erachtet.

Neben der nicht nachgewiesenen Wirksamkeit wird vom zRMS weiterhin darauf hingewiesen, dass bei den Tomatenversuchen phytotoxische Schäden aufgetreten sind. Daher fehlen für diese Anwendung zusätzlich auch Versuche zur Phytotoxizität.

# REGISTRATION REPORT

## Part B

### Section 8

#### Environmental Fate

Detailed summary of the risk assessment

Product code: ZV3 006867-00/01

Product name(s): Bayer Garten Rosen-Pilzfrei Baymat Plus

Chemical active substances:

Trifloxystrobin 0.125 g/L

Tebuconazole 0.125 g/L

Central Zone

Zonal Rapporteur Member State: UK

NATIONAL ADDENDUM – GERMANY  
(extension of use)

Applicant: Bayer CropScience

Submission date: January 2016 (RR by zRMS UK)

MS Finalisation date: September 2017

## Version history

<b>When</b>	<b>What</b>
September 2017	final assessment by UBA



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## **8 Fate and behaviour in the environment (KCP 9)**

The exposure assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus in its intended uses in tomato, zucchini and cucumber in greenhouses of home gardens (amateur uses only) is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus dated from January 2016 (date of circulation of final report) performed by UK.

As stated within Part A of zRMS UK the requirements for authorisation of amateur (Home garden) products are not yet harmonised across the EU. However in this case the intended uses only include applications in greenhouses with a ready to use product. Hence the exposure of the environment is really limited. In this case the risk assessment performed by zRMS UK can be considered as acceptable for specific German environmental or agricultural circumstances.

The plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus has already been authorized in Germany for different field uses in home gardens (use No. 00-028 to 00-031). These already evaluated uses fully cover the new intended use of Bayer Garten Rosen-Pilzfrei Baymat Plus in zucchini, tomato and cucumber according to use No. 01-001 to 01-003. Therefore the exposure assessment refers also to the German `Bewertungsbericht` for ZA 006867-00/00 dated from September 2011.

## 8.1 Critical GAP and overall conclusions

### 8.1.1 Table of critical GAPs

**Table 8.1-1:** Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/or situa- tion (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I*	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
<b>Intended for uses in Germany</b>														
01- 001	DE	cucumber	Gn	<i>Erysiphe cichoracearum</i> , <i>Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) plants up to 50 cm: 50 mL/m <sup>2</sup> plants 50-125 cm: 75 mL/m <sup>2</sup> plants > 125 cm: 100 mL/m <sup>2</sup> b) plants up to 50 cm: 150 mL/m <sup>2</sup> plants 50-125 cm: 225 mL/m <sup>2</sup> plants > 125 cm: 300 mL/m <sup>2</sup>	a) plants up to 50 cm: 62.5 g as/ha plants 50-125 cm: 93.75 g as/ha plants > 125 cm: 125 g as/ha b) plants up to 50 cm: 187.5 g as/ha plants 50-125 cm: 281.25 g as/ha plants > 125 cm: 375 g as/ha	-	-	-	A

01-002	DE	tomato	Gn	<i>Erysiphe cichoracearum</i> , <i>Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) plants up to 50 cm: 50 mL/m <sup>2</sup> plants 50-125 cm: 75 mL/m <sup>2</sup> plants > 125 cm: 100 mL/m <sup>2</sup> b) plants up to 50 cm: 150 mL/m <sup>2</sup> plants 50-125 cm: 225 mL/m <sup>2</sup> plants > 125 cm: 300 mL/m <sup>2</sup>	a) plants up to 50 cm: 62.5 g as/ha plants 50-125 cm: 93.75 g as/ha plants > 125 cm: 125 g as/ha b) plants up to 50 cm: 187.5 g as/ha plants 50-125 cm: 281.25 g as/ha plants > 125 cm: 375 g as/ha	-	-	-	A
01-003	DE	zucchini	Gn	<i>Erysiphe cichoracearum</i> , <i>Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) 50 mL/m <sup>2</sup> b) 150 mL/m <sup>2</sup>	a) 62.5 g as/ha b) 187.5 gas/ha	-	-	-	A

\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

## **8.2 Metabolites considered in the assessment**

Please refer to the core assessment.

## **8.3 Rate of degradation in soil (KCP 9.1.1)**

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

### **8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)**

Please refer to the core assessment.

### **8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)**

Not relevant for assessment.

## **8.4 Field studies (KCP 9.1.1.2)**

### **8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)**

Please refer to the core assessment.

### **8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)**

Please refer to the core assessment.

## **8.5 Mobility in soil (KCP 9.1.2)**

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

### **8.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.2 Column leaching (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.3 Lysimeter studies (KCP 9.1.2.2)**

Please refer to the core assessment.

#### **8.5.4 Field leaching studies (KCP 9.1.2.3)**

Please refer to the core assessment.

#### **8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)**

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

#### **8.6.1 Water/sediment study (KCP 9.2.2)**

Please refer to the core assessment

#### **8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)**

Results of PEC<sub>soil</sub> calculation for Bayer Garten Rosen-Pilzfrei Baymat Plus and its intended for uses in cucumber, tomato and zucchini (home gardening, greenhouses) according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 5, chapter IIIA 9.4. In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>1</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a  $K_{f,oc} < 500$ , whereas a soil layer depth of 1 cm is applied for active substances with a  $K_{f,oc} > 500$ . A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment. Thus Germany normally performs an own PEC soil calculation in the national addendum. However as explained at the beginning of this national addendum the exposure in this case, application only in greenhouses with a ready to use product, is really limited. Thus based on the core assessment by zRMS UK and also based on the already existing german assessment for the product Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to `Bewertungsbericht` for ZA 006867-00/00) there is no need for further PEC soil calculation on national level in this case.

#### **8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)**

Results of the PEC<sub>gw</sub> calculation of Trifloxystrobin and Tebuconazole for the intended uses of Bayer Garten Rosen-Pilzfrei Baymat Plus in cucumber, tomato and zucchini (home gardening, greenhouses) according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment, part B, section 5, chapter IIIA 9.6.

Risk assessment for groundwater for authorisation of plant protection products in Germany considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface runoff and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater. The latter pathway was not addressed neither by core assessment nor for EU assessment of the active substances.

The risk assessment for groundwater of the pathway direct leaching after soil passage follows the recommendation of the Ground Water Work Group of FOCUS as provided by the Commission Services (Sanco/13144/2010, version 3, 10 October 2014) as also done by the zRMS in the core assessment.

Risk assessment for groundwater for the pathway surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01 stipulating

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<sup>1</sup> Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999

also risk mitigation measures, if applicable. However as explained at the beginning of this national addendum the exposure in this case, application only in greenhouses with a ready to use product, is really limited. Thus based on the core assessment by zRMS UK and also based on the already existing german assessment for the product Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to 'Bewertungsbericht' for ZA 006867-00/00) there is no need for further calculations on national level in this case.

**Consequences for authorization:**

None

**8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)**

The intended uses only include applications in greenhouses, thus a relevant exposure is not expected and no further consideration is required on national level. However the zRMS UK performed a risk assessment for aquatic organisms which fully covers the intended uses for Germany. Please refer to the core assessment, part B, section 5, chapter IIIA 9.7 for PEC calculations used for risk assessment by zRMS UK.

**8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)**

Please refer to the core assessment, part B, section 5, chapter IIIA 9.9.

**8.11 Classification and labelling**

**8.11.1 GHS Classification and labelling**

Please refer to part A of zRMS UK.

**8.11.2 National labelling**

No specific labelling required.

**8.11.3 Standard phrases under Regulation (EU) No 547/2011**

Not required





# REGISTRATION REPORT

## Part B

### Section 9

#### Ecotoxicology

Detailed summary of the risk assessment

Product code: ZV3 006867-00/01

Product name(s): Bayer Garten Rosen-Pilzfrei Baymat Plus

Chemical active substance(s):

Trifloxystrobin, 0.125 g/L

Tebuconazole, 0.125 g/L

Central Zone

Zonal Rapporteur Member State: UK

National Addendum

Germany

(extension of use)

Applicant: Bayer CropScience

Submission date: January 2016 (RR by zRMS UK)

MS Finalisation date: September 2017

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Germany

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## Version history

<b>When</b>	<b>What</b>
September 2017	final assessment by UBA

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## **9 Ecotoxicology (KCP 10)**

The exposure assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus in its intended uses in tomato, zucchini and cucumber in greenhouses of home gardens (amateur uses only) is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus dated from January 2016 (date of circulation of final report) performed by UK.

As stated within Part A of zRMS UK the requirements for authorisation of amateur (Home garden) products are not yet harmonised across the EU. However in this case the intended uses only include applications in greenhouses with a ready to use product. Hence the exposure of the environment is really limited. In this case the risk assessment performed by zRMS UK can be considered as acceptable for specific German environmental or agricultural circumstances.

The plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus has already been authorized in Germany for different field uses in home gardens (use No. 00-028 to 00-031). These already evaluated uses fully cover the new intended use of Bayer Garten Rosen-Pilzfrei Baymat Plus in zucchini, tomato and cucumber according to use No. 01-001 to 01-003. Therefore the exposure assessment refers also to the German 'Bewertungsbericht' for ZA 006867-00/00 dated from September 2011.

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**9.1 Critical GAP and overall conclusions**

**Table 9.1-1: Table of critical GAPs**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No.	Member state(s)	Crop and/or situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
<b>Intended for uses in Germany</b>																				
01-001	DE	cucumber	Gn	<i>Erysiphe cichoracearum, Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) plants up to 50 cm: 50 mL/m <sup>2</sup> plants 50- 125 cm: 75 mL/m <sup>2</sup> plants > 125 cm: 100 mL/m <sup>2</sup> b) plants up to 50 cm: 150 mL/m <sup>2</sup> plants 50- 125 cm: 225 mL/m <sup>2</sup> plants > 125 cm: 300 mL/m <sup>2</sup>	a) plants up to 50 cm: 62.5 g as/ha plants 50- 125 cm: 93.75 g as/ha plants > 125 cm: 125 g as/ha b) plants up to 50 cm: 187.5 g as/ha plants 50- 125 cm: 281.25 g as/ha plants > 125 cm: 375 g as/ha	-	-	-	A	A	A	A	A	A	A
01-002	DE	tomato	Gn	<i>Erysiphe cichoracearum, Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) plants up to 50 cm: 50 mL/m <sup>2</sup>	a) plants up to 50 cm: 62.5 g as/ha	-	-	-	A	A	A	A	A	A	A

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1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	
									plants 50-125 cm: 75 mL/m <sup>2</sup> plants > 125 cm: 100 mL/m <sup>2</sup> b) plants up to 50 cm: 150 mL/m <sup>2</sup> plants 50-125 cm: 225 mL/m <sup>2</sup> plants > 125 cm: 300 mL/m <sup>2</sup>	plants 50-125 cm: 93.75 g as/ha plants > 125 cm: 125 g as/ha b) plants up to 50 cm: 187.5 g as/ha plants 50-125 cm: 281.25 g as/ha plants > 125 cm: 375 g as/ha											
01-003	DE	zucchini	Gn	<i>Erysiphe cichoracearum</i> , <i>Sphaerotheca fuliginea</i>	spraying	at beginning of infection	a) 3 b) 3	10	a) 50 mL/m <sup>2</sup> b) 150 mL/m <sup>2</sup>	a) 62.5 g as/ha b) 187.5 g as/ha	-	-	-	A	A	A	A	A	A	A	

\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

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**Remarks  
table:**

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions

### 9.1.1 Consideration of metabolites

Please refer to the core assessment by zRMS UK.

### 9.2 Effects on birds (KCP 10.1.1)

Please refer to the core assessment by zRMS UK.

#### Consequences for authorisation

None

### 9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

Please refer to the core assessment by zRMS UK.

#### Consequences for authorisation

None

### 9.4 Effects on aquatic organisms (KCP 10.2)

The intended uses only include applications in greenhouses, thus a relevant exposure of aquatic organisms is not expected and no further consideration is required on national level (refer also to `Bewertungsbericht ZA 006867-00/00). However the zRMS UK performed a risk assessment for aquatic organisms which fully covers the intended uses for Germany. Please refer to the core assessment, part B, section 6, chapter IIIA 10.2.

#### Consequences for authorisation

For the authorisation of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat Plus, labelling and conditions of use are mandatory as follows:

**Table 9.4-1 Labelling requirements according to § 36 (3) PflSchG**

NW 262	trifloxystrobin: <i>S. subspicatus</i> NOEC = 0.00192 mg a.s./L
NW 264	tebuconazole: <i>O. mykiss</i> LC <sub>50</sub> = 4.4 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.46 mg a.s./L trifloxystrobin: <i>O. mykiss</i> LC <sub>50</sub> = 0.015 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.0086 mg a.s./L
NW 265	tebuconazole: <i>L. gibba</i> NOEC ≤ 0.0307 mg a.s./L trifloxystrobin: <i>L. gibba</i> NOEC = 0.236 mg a.s./L



### **9.5 Effects on bees (KCP 10.3.1)**

Please refer to the core assessment by zRMS UK. As the exposure to bees and accordingly also to other wild pollinators is limited (only uses in greenhouses), no further assessment is required at national level.

#### **Consequences for authorisation**

Please refer to core assessment.

### **9.6 Effects on arthropods other than bees (KCP 10.3.2)**

Please refer to the core assessment by zRMS UK.

#### **Consequences for authorisation**

None

### **9.7 Effects on non-target soil meso- and macrofauna (KCP 10.4)**

Please refer to the core assessment by zRMS UK. Although the risk assessment normally is based on PEC soil calculations special for Germany, in this case no assessment was performed on national level. As the intended uses only include applications in greenhouses and the product is a ready to use spray which is applied directly to single plants, the exposure of soil organisms is limited. This is also in line with the assessment of the already approved intended home gardening field uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to `Bewertungsbericht` ZA 006867-00/00).

#### **Consequences for authorisation**

None

### **9.8 Effects on soil microbial activity (KCP 10.5)**

Please refer to the core assessment by zRMS UK. Please refer to the core assessment by zRMS UK. Although the risk assessment normally is based on PEC soil calculations special for Germany, in this case no assessment was performed on national level. As the intended uses only include applications in greenhouses and the product is a ready to use spray which is applied directly to single plants, the exposure of soil organisms is limited. This is also in line with the assessment of the already approved intended home gardening field uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat Plus (please refer to `Bewertungsbericht` ZA 006867-00/00).

#### **Consequences for authorisation**

None

### **9.9 Effects on non-target terrestrial plants (KCP 10.6)**

Please refer to the core assessment by zRMS UK.

## Consequences for authorisation

None

### 9.10 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not provided and not required.

### 9.11 Monitoring data (KCP 10.8)

Not provided and not required.

## 9.12 Classification and Labelling

### 9.12.1 GHS Classification and Labelling

**Table 9.12-1 Classification and labelling of Bayer Garten Rosen-Pilzfrei Baymat Plus**

product	<i>D. magna</i> EC <sub>50</sub> = 86 mg/L
Classification and labelling according to Regulation 1272/2008	
Hazard symbol	none
Signal word	none
Hazard statement	H412

### 9.12.2 National labelling

**Table 9.12-2 Labelling requirements according to § 36 (3) PflSchG**

NW 262	trifloxystrobin: <i>S. subspicatus</i> NOEC = 0.00192 mg a.s./L
NW 264	tebuconazole: <i>O. mykiss</i> LC <sub>50</sub> = 4.4 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.46 mg a.s./L trifloxystrobin: <i>O. mykiss</i> LC <sub>50</sub> = 0.015 mg a.s./L <i>M. bahia</i> LC <sub>50</sub> = 0.0086 mg a.s./L
NW 265	tebuconazole: <i>L. gibba</i> NOEC ≤ 0.0307 mg a.s./L trifloxystrobin: <i>L. gibba</i> NOEC = 0.236 mg a.s./L