

REGISTRATION REPORT
Part A

Risk Management

Product code: Bayer Garten Rosen-
Pilzfrei Baymat

Active Substance: Tebuconazole 25 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: UK

NATIONAL ASSESSMENT

Applicant: Bayer CropScience

Date: December 2014

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This document is to be used by the notifier of a plant protection product for registration at Member State level. It has been designed as an example of how Part A (Risk Management) of the draft Registration Report document could be prepared. It does not contain detailed examples of possible risk management approaches but does provide guidance and options on how sections could be completed. Part A of the draft Registration Report is considered to be country specific, so the guidance provided here is applicable to national assessments.

Notes:

- Text in blue provides general information/support.
- Text in red has been taken from the new registration report templates. The text summarises the minimum information that should be provided in each section.
- Text in black is example text that could be inserted by the notifier/authorities. The text/tables are not fixed and should be adapted by the notifier / authorities to suit the product being evaluated.

PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration/registration of *<product code>* containing *<active substance(s)>* in *<MS country>*. This evaluation is required subsequent to the inclusion of *<active substance>* on Annex 1.

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 *<country>*. 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 *<product code>* where that data has not been considered in the EU review. Otherwise assessments for the safe use of *<product code>* have been made using endpoints agreed in the EU review of *<active substance>*.

This document describes the specific conditions of use and labelling required for *<MS country>* for the re-registration/registration of *<product code>*.

Appendix 1 of this document provides a copy of the final product authorisation *<MS country>*.

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 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

1 Details of the application

This section should include the following info:

- Reference to applicant details and summary of what has been submitted for evaluation
- Reference to Inclusion Directive
 - include any specific provisions to be addressed as listed in Annex I of Inclusion Directive

- Overall statement on context in which the dossier is submitted
- Summary of data protection claims

1.1 Application background

- Reference to applicant details and summary of what has been submitted for evaluation

This application was submitted by <applicant name> (and where relevant include ‘on behalf of <approval holder>’) on <date of submission>.

The application was for approval of <product name>, a <formulation type> containing <amount(s) & active substance name(s)> for use as a <field of use and brief details of uses applied for>.

1.2 Annex I inclusion

- Reference to Inclusion Directive
 - include any specific provisions to be addressed as listed in Annex I of Inclusion Directive

<Active substance> was included on Annex I of Directive 91/414/EEC on < entry into force date> under Inclusion Directive <xxxx/xxx/EC>.

The Annex I Inclusion Directive for <active substance> (xxxx/xxx/EC) 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 report on the <active substance>, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on <xx/xx/xxxx>, shall be taken into account. In this overall assessment:

Member States should/must/may pay particular attention to the:

- xxxxx
- xxxxx
- xxxxx

These concerns were all addressed in the submission.

1.3 Regulatory approach

- Statement on context in which the dossier is submitted

To obtain re-approval/approval the product < product code > 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.

Either: This application was submitted in order to allow the re-registration of an already approved product <specify MS country> in accordance with the above.

Or: This application was submitted in order to allow the first approval of this product/use in <specify MS country> in accordance with the above.

Or: This application was submitted under Article 10 of Directive 91/414/EEC and assessment was on the basis of an authorisation granted in <reference MS >, for the product <product code> registration number <reference>.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Bayer Garten Rosen-Pilzfrei Baymat, 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

Data access has been proven.

Bayer CropScience is the owner of all data. This point is not relevant.

2 Details of the authorisation

2.1 Product identity

Product Name	Bayer Garten Rosen-Pilzfrei Baymat
Authorization Number (for re-registration)	007626 – 00
Function	fungicide
Applicant	Bayer CropScience Deutschland GmbH
Composition	25 g/L tebuconazole
Formulation type	Suspension concentrate [Code: SC]
Packaging	100; 125; 200 mL HDPE bottle with closing cap and dosing device (for non-professional users) 250 – 500 mL for professional users

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

<i>Symbol(s)/Indication(s) of danger:</i>	
None	
N	Dangerous for the environment
<i>Risk phrases:</i>	
None	
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
<i>Safety phrases:</i>	
S35	This material and its container must be disposed of in a safe way.
S57	Use appropriate container to avoid environmental contamination.

SP001	To avoid risks to man and the environment, comply with the instructions for use.
<i>Specific labelling requirement:</i>	
To avoid risks to man and the environment, comply with the instructions for use.	
Contains 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.	
Contains 5-chloro-2-methyl-2H-isothiazole-3-on and 2-methyl-2H-isothiazole-3-one. May produce allergic reactions.	

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	
GHS09	environment
<i>Signal word:</i>	
None	
<i>Hazard statements:</i>	
None	
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
None	
Not proposed for all sections by zRMS Germany, to be decided by applicant	
P501	Dispose of contents/container to ..
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
<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 208-0098 - Contains 1,2-benzisothiazole-3(2H)-one. May produce an allergic reaction.	
EUH 208-0101 - Contains 5-chloro-2-methyl-2H-isothiazole-3-on and 2-methyl-2H-isothiazole-3-one. 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.
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	
NN3001	The product is classified as harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant predatory mites and spiders.
WMF G1	FRAC-Code G1 (Inhibitor of C14-demethylase in sterol biosynthesis in fungal membranes).
Ecosystem protection	
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing 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.

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

Integrated pest management (IPM)/sustainable use	
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)

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)

Integrated pest management (IPM)/sustainable use	
WH915 (for uses 001-018 and 020- 022)	The instructions for use must include a list of species and/or varieties of crops which are compatible with the application rate provided for (positive list).

WW750 (for uses 001-018 and 020- 022)	The maximum number of applications is limited due to active substance-specific reasons. Sufficient control is therefore not expected in all cases. If necessary, use products containing other active substances afterwards or alternately.
WW7091 (for uses 001-018 and 020- 022)	Repeated applications of the product, or products of the same active substance group, or those with cross-resistance, may result or have resulted in a reduction of efficacy. To prevent resistance, the product should if possible be applied alternately with products from other active substance groups with no cross-resistance. If in doubt, consult extension services.
Ecosystem protection	
NW642-1 Uses 007, 010, 019, 020	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.
NW608-1 Uses 00-001 +002 +011 +012 +013 +014	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR. Buffer zone. 5 m

2.4 Product uses

Reg.-No.	007626-00/00	GAP rev.
PPP (product name/code) active substance 1	Bayer Garten Rosen-Pilzfrei Baymat Tebuconazol	Formulation Type: Conc. of a.s. 1:
Applicant: Zone(s):	Bayer CropScience central/EU	SC 25.00 g/L
Verified by MS:	yes	professional use non professional use
		No Yes

1	2	3	4	5	6	7	8	9	10
Use -No.	Membe r state(s)	Crop and/ or situation (crop destination /	F G or	Pests or Group of pests controlled (additionally:	Application			Application ra	
					Method / Kind	Timing / Growth stage	Max. number	kg, L product / ha	g, kg a.s./ha

		purpose of crop)	I	developmental stages of the pest or pest group)		of crop & season	(min. interval between applications) a) per use b) per crop/season	a) max. rate per appl. b) max. total rate per crop/season	a) max. rate per appl. b) max. total rate per crop/season
001	DE	roses ROSSS	F	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
002	DE	roses ROSSS	F	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
003	DE	roses ROSSS	I*	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
004	DE	roses ROSSS	I*	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
005	DE	roses ROSSS	G	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
006	DE	roses ROSSS	G	powdery mildew of rose (<i>Sphaerotheca pannosa</i>) SPHRPA	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
007	DE	ornamentals NNNZZ (except: roses ROSSS)	F	powdery mildew	spraying	At beginning of infestation and/or when	a) 4 (7 to 14 days)	a) plant height up to 50 cm: 4 mL	a) 0.10 kg/ha

						first symptoms become visible	b) 4	per 10 m ² b) 16.00 mL per 10 m ²	b) 0.40 kg/ha
008	DE	ornamentals NNNZZ (except: roses ROSSS)	I*	powdery mildew	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
009	DE	ornamentals NNNZZ (except: roses ROSSS)	G	powdery mildew	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
010	DE	common box BUXSE	F	Cylindrocladium CYLIND	spraying	In danger of infection	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
011	DE	roses ROSSS	F	black spot (<i>Diplocarpon rosae</i>) DIPCRO	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
012	DE	roses ROSSS	F	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
013	DE	roses ROSSS	F	black spot (<i>Diplocarpon rosae</i>) DIPCRO	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
014	DE	roses ROSSS	F	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL	a) 0.15 kg/ha b) 0.60 kg/ha

								per 10 m ²	
015	DE	roses ROSSS	I*	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
016	DE	roses ROSSS	I*	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
017	DE	roses ROSSS	G	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
018	DE	roses ROSSS	G	rust (<i>Phragmidium mucronatum</i>) PHRAMU	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height more than 50 cm: 6 mL per 10 m ² b) 24.00 mL per 10 m ²	a) 0.15 kg/ha b) 0.60 kg/ha
019	DE	ornamentals NNZZ (except: roses ROSSS)	F	fungal leaf spot diseases	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
020	DE	ornamentals NNZZ (except: roses ROSSS)	F	rust fungi (<i>Uredinales</i>)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
021	DE	ornamentals NNZZ (except: roses ROSSS)	I*	rust fungi (<i>Uredinales</i>)	spraying	At beginning of infestation and/or when first symptoms become visible	a) 4 (7 to 14 days) b) 4	a) plant height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	a) 0.10 kg/ha b) 0.40 kg/ha
022	DE	ornamentals	G	rust fungi	spraying	At beginning	a) 4	a) plant	a) 0.10

		NNZZ (except: roses ROSS)		(<i>Uredinales</i>)		of infestation and/or when first symptoms become visible	(7 to 14 days) b) 4	height up to 50 cm: 4 mL per 10 m ² b) 16.00 mL per 10 m ²	kg/ha b) 0.40 kg/ha
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- (1) Numeration of uses in accordance with the application/as verified by MS
- (2) Member State(s) or zone for which use is applied for
- (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) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (5) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
- (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 of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 38263-3152-4), including where relevant, information on season at time of application

- (8) The maximum number of applications for each single application and per year must be provided
- (8) Min. interval between applications
- (9) The application rate of the product crop/season must be given in metric units (*e.g.* kg/ha)
- (10) The application rate of the active substance total rate per crop/season must be given in metric units (*e.g.* kg/ha)
- (11) The range (min/max) of water volume given (L/ha)
- (12) PHI - minimum pre-harvest interval
- (13) Remarks may include: importance/restrictions/minor use etc.

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:

The product Tebuconazole SE 25 g/L is a suspension concentrate consisting of a yellow-beige homogeneous liquid, with a moderate oily odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 440 °C. Undiluted, it has a pH value around 6. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for a SC formulation. The physical/chemical properties from this study indicate that the product would give satisfactory handling and dilution properties in the field when it is used as recommended. High density polyethylene (HDPE) containers have been found suitable for storage of this product.

Accelerated storage stability data, 54 °C for 14 days, and low temperature storage stability data, 0 °C for 7 days were submitted in HDPE packaging. All appropriate tests were carried out and there are no outstanding areas of concern with data submitted demonstrating the stability of the formulation on storage.

Implications for labelling: None

Compliance with FAO guidelines:

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

Compatibility of mixtures:

No tank mixtures are recommended for the product.

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 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 of analysis for the determination of tebuconazole in the formulation is method 2001-0053301-02. The GC-method was sufficiently validated in accordance with SANCO/3030/99 rev. 4.

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

Analytical methods for the determination of tebuconazole in soil, water and air were provided in the EU review and were considered adequate. For the intended uses in roses and ornamentals no methods for food of plant and animal origin are required. Methods for body fluids and tissues are also not required since tebuconazole is not classified as toxic or highly toxic. Tebuconazole residues can be determined by LC-MS/MS, GC-MS and GC-NPD.

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 AT. In addition to the evaluation of UK Germany propose two sentences for classification and labelling (EUH 208-0098 and -0101)

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 and 2.3

3.1.4 Residues and Consumer Exposure

The intended uses in ornamentals will not result in residues above the MRLs set in Regulation (EC) No 396/2005. Residue studies were not considered relevant for evaluation.

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)

A full exposure assessment for the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in its intended uses in roses and ornamental plants is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat dated from August 2014 performed by United Kingdom.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of Bayer Garten Rosen-Pilzfrei Baymat in Germany according to its intended use in roses and ornamental plants (Use No. 00-001-00-022).

For reasons of better readability the intended uses in of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in Germany are summarised as follows:

Table: Classification of intended uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001, 002, 011, 012, 013, 014,	Roses and ornamental plants at first symptoms on moderate foliage (BBCH 30)* outdoor use	spraying	4 x 6 Lppp, 7 d, 15.05. interception 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 150 = 600	Tebuconazole 1. 75 2. 75 3. 75 4. 75 = 225

B/ 00-007, 010, 019, - 020	Ornamental plants at first symptoms on moderate foliage (BBCH 30)* outdoor use	spraying	4 x 4 Lppp, 7 d, interception 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 100 = 400	Tebuconazole 1. 50 2. 50 3. 50 4. 50 = 200
C/ ** 0000- 008, 009, 021, 022	indoor	spraying	4 x 4 Lppp, 7 d,	Tebuconazole 4 x 100 = 400	-
D/ ** 00-003 – 006, , 015, 016, 017, 018	indoor	spraying	4 x 6 Lppp, 7 d,	Tebuconazole 4 x 150 = 600	-

* the considered BBCH stage corresponds to the BBCH stage presented in the GAP table of the core assessment by zRMS UK (GAP for Germany), however no BBCH stage was defined by BVL

** Indoor application for potted plants in living rooms or offices and in green houses respectively

Tebuconazole


A representative worst-case DT50 in soil of 107.8 days (maximum field; not normalised for PECsoil, n=11) and 32 days (normalised to 20°C and pF2; for PEC groundwater, n=10) respectively as well as a KOC of 769 mL/g were included in the evaluation of the active ingredient tebuconazole (relating to the LoE; EFSA Scientific Report (2008) 176, 1-109 taking into account the additionally degradation studies). Due to the long degradation times in soil also possible chronic effects on soil organisms have to be assessed.

Tebuconazole has a vapour pressure of 1.3×10^{-6} Pa at 20°C, a water solubility of 36000 mg/L, a DT50 in water of 365 days and a photolysis/hydrolysis DT50 in water of 1000 d (LoEP; EFSA Scientific Report (2008) 176, 1-109). Tebuconazol can be found in the sediment in relevant amounts.

Metabolites

Environmental occurring metabolites of Tebuconazole requiring further assessment according to the results of the assessment of Tebuconazole for EU approval are summarized in the following table:

Metabolites of Tebuconazole potentially relevant for exposure assessment

> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study			
Metabolite	Structural formula/Molecular formula	Occurrence in compartments (Max. at day)	Status of Relevance according to the core assessment by zRMS United Kingdom
1,2,4-triazole M26 CGA 71019 CGA 98032	 <chem>C2H3N3</chem>	Soil/Water/Sediment: <5 %	Not relevant as < 5 % occurrence for all compartments Aquatic organism: Water: - Sediment:- Terrestrial organism: - Groundwater: not relevant (Step 2/Step 3-4) ¹⁾ (*-remark: The in the EU-List of Endpoints documented formation rate of 0.9-9 % on day 318-378 d (n= 1) is corresponding to not valid study of Fritz and Brauner, 1989)

¹⁾ According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

The risk assessment for the metabolites of Tebuconazole has already been performed for EU approval (see SANCO/171/08-rev.1-09/09/2008).

Deviating from the EU risk assessment (for details see DAR and Addenda) the soil metabolite 1, 2, 4-triazole will not be further considered as relevant because the study of Fritz and Brauner (1989) in which this metabolite was identified is not valid because of the study conditions.

In the three newly submitted field degradation studies of Tebuconazole (summarized in Annex 2) no new potentially relevant soil metabolites were identified. Hence no additionally metabolites need to be considered in the risk assessment.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamental plants according to use No 00-001/ 00-002/ 00-007 / 00-011 - 00-014 (Group A) PEC_{soil} was calculated for the active substance Tebuconazole considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance Tebuconazole in soil the accumulation potential of Tebuconazole was not considered.

Table: Overview PEC soil values relevant for risk assessment

plant protection product:		Bayer Garten Rosen-Pilzfrei Baymat				
use:		Group A/ worst case				
Number of applications/intervall		4				
application rate:		150 g/ha 5994 g/ha for the product with a density of 0.9991				
crop interception:		50/50/50/50%				
active substance/ formulation	soil relevant application rate (g/ha)	soil depth_{act} (cm)	PEC_{act} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Bayer Garten Rosen-Pilzfrei Baymat	2997/ 2997/2997/ 2997	2.5	29.9043	-	-	-
	2997/ 2997/2997/ 2997	1	74.7607	-	-	-
Tebuconazole	75/75/75/75	1	1.8709	-	-	-

The results for PEC soil for the active substance and the metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance Tebuconazole in concentrations $\geq 0.1 \mu\text{g/L}$ is not expected for all the intended use in roses and ornamental plants. No metabolites were considered.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations $\geq 0.1 \mu\text{g/L}$ by the active substance Tebuconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded. No metabolites were considered.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{sw}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamental plants according to use No 00-001/ 00-002/ 00-007 / 00-011 - 00-014 (Group A) PEC_{sw} was calculated for the active substance Tebuconazole considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.

The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier.

The vapour pressure at 20 °C of the active substance Tebuconazole is $< 10^{-5}$ Pa. Hence the active substance Tebuconazole is regarded as non-volatile. Therefore, exposure of surface water by the active substance Tebuconazole due to deposition following volatilization was not considered.

The concentrations of the active substance Tebuconazole in adjacent ditch due to surface run-off and drainage were calculated using the model EXPOSIT.

Table: Summary of PEC_{sw} values for the intended use in roses (Group A) used for German risk assessment

active substance/ formulation	PEC_{sw} Spray- Drift (incl. volatilisation) [µg/L] – with 3 m default buffer – scenario agriculture	PEC_{sw} run-off [µg/L] – without buffer home gardenin g F=0.32	PEC_{sw} drainage [µg/L] – scenario autumn/wi nter/early spring	PEC_{sw} drainage [µg/L] – scenario spring/su mmer
Tebuconazole	0.804	0.62	n.r.	0.40
Preparation	36	-	-	-

Table: Summary of PEC_{sw} values for the intended use in ornamentals (Group B) used for German risk assessment

active substance/ formulation	PEC_{sw} Spray- Drift (incl. volatilisation) [µg/L] – with 3 m default buffer – scenario agriculture	PEC_{sw} run-off [µg/L] – without buffer home gardenin g F=0.32	PEC_{sw} drainage [µg/L] – scenario autumn/wi nter/early spring	PEC_{sw} drainage [µg/L] – scenario spring/su mmer home gardenin g F=0.32
Tebuconazole	0.536	0.42	n.r	0.18
Preparation	21.44	-	-	-

n.r. not relevant for home gardening

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The fate and behaviour in air of tebuconazole was evaluated during the respective EU review for Annex I inclusion. No additional studies have been performed.

The low vapour pressure of 1.7×10^{-6} Pa at 20 °C rules out a direct evaporation of tebuconazole or a volatilisation driven by the evaporation of water.

Implications for labelling resulting from environmental fate assessment: (Phrase **R53** should be added to the label)

For the authorization of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat following labeling and conditions of use are mandatory:

Classification and labelling

Based on the data on the active substance Tebuconazole (list of endpoints 2014 and CLH report 2012) the plant protection product Bayer Garten Rosen-Pilzfrei Baymat is considered to be not readily degradable in the sense of the CLP regulation. Thus the formulation Bayer Garten Rosen-Pilzfrei Baymat is regarded as a candidate for R 53.

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

Not required

Further data requirements:

None

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

A full risk assessment according to Uniform Principles for the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in its intended uses in ornamental plants is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat dated from August 2014 performed by United Kingdom. The intended use of Bayer Garten Rosen-Pilzfrei Baymat in Germany is generally covered by the uses evaluated in the course of the core assessment by United Kingdom.

Within Part A of the United Kingdom nothing is stated if the authorization in United Kingdom is linked with any risk mitigation measures regarding effects on non-target organisms.

The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of Bayer Garten Rosen-Pilzfrei Baymat in Germany according to its intended use in ornamental plants (uses group A and B, explanation see below).

For reasons of better readability the intended uses in of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in Germany are summarised under 3.1.5.:

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

Table: Endpoints used for risk assessment for birds and mammals

Test system	Species	Results
Tebuconazole		
Acute toxicity	<i>Colinus virginianus</i> (Bobwhite quail)	LD ₅₀ 1988 mg/kg bw
Reproductive toxicity	<i>Colinus virginianus</i> (Bobwhite quail)	≥ 5.8 mg as/kg bw/d
Acute toxicity	rat	1700 mg as/kg bw/d
Reproductive toxicity	rat	10 mg as/kg bw/d

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Based on the presumptions of the screening step and Tier 1, the calculated TER values for the acute risk resulting from an exposure of birds and mammals to the active substance tebuconazole according to the intended use of the formulation Bayer Garten Rosen-Pilzfrei Baymat in ornamentals (group A and B) achieve the acceptability criteria $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The Tier 1 long-term risk assessment for

birds and mammals results in an unacceptable TER value for at least some of the relevant scenarios thus a refined long-term assessment was necessary.

Long-term risk for birds

The RMS UK has identified a long-term risk for small insectivorous (e.g. blue tit) in tier 1 and is addressing this risk with reference to a report by Ebeling (2012), in which it is highlighted that the home garden is unlikely to be a monoculture of a single crop as is the case in the agricultural environment and that the garden is a more heterogeneous environment for which it is unlikely that all gardens will be treated at the same time. It is considered that the garden is unlikely to be a monoculture but nevertheless there could be largish areas e.g. of ornamentals and so an adequate risk assessment is still required. They further refer to Barfknecht R. (2006); a study in which the DT50 on arthropods is examined. Based on the concluded DT50 of 1.2 d the refined risk is acceptable. Co-RMS Germany is not convinced that the study by Barfknecht R. (2006) is really representative for home garden areas as the DT50 for arthropods was examined for a treated cereal field. It is not clear if the arthropods which were examined are really representative for home garden areas. However the applicant also provided a study by Chapple et al. (2007) examining German and French model gardens and their plant composition and especially the percentages of different plant groups. Especially for Germany one has to consider two types of “home gardens”, as there are the “real” home gardens connected to a house and additionally the allotments. According to Chapple et al. considering both variants a maximum of approximately 32 % roses and ornamental plants are cultivated in home gardens. Beside that it has to be considered that the total area of garden connected to a house or of an allotment only has a mean size of 500 m². Thus the application rate always is lower as for the conventional use. Even if it cannot be excluded that the product is also applied in the neighbouring garden it can be assumed that birds will not consume only exposed food.

Based on the presented reasoning, we agree with the overall conclusion of an acceptable long-term risk for birds.

Long-term risk for mammals

Based on tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to tebuconazole (oral exposure) according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat do not achieve the acceptability criterion $TER \geq 5$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles for the relevant scenario small herbivorous mammal “vole”. The results of the assessment indicate an unacceptable long-term risk for mammals due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamentals (group A and B) according to the label.

In cases where the relevant model species for assessment of the risk from the intended use of Bayer Garten Rosen-Pilzfrei containing the active substance tebuconazole is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a $TER \geq 5$ in the acute exposure scenario and a $TER \geq 2$ in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures).

However for the intended uses group A and B the scenarios BBCH 40 – 49 and BBCH \geq 50 based on the generic focal species “vole” also the modified acceptability criterion of TER \geq 2 for the long-term exposure is not met. Thus further refinement is required for these scenarios.

The applicant provided a higher tier risk assessment for birds and mammals (Ebeling and Hahne, 2011). Two main points are highlighted: i) that the assumptions made in the EFSA GD (2009) are based on a large scale use of a plant protection product in agricultural landscapes and hence clearly overestimate the use in the scale of home gardens ii) voles are not the relevant species in private gardens.

We agree that the exposure of mammals in intensively managed agricultural areas is not directly comparable to the exposure in home/private gardens and presents a relatively pronounced worst case. The provided reports by Meunier (2012) and Chapple et al. (2007) can be taken into account to refine the exposure for private gardens. According to Chapple et al. (2007) in Germany in total (meaning for private house gardens and allotments) 17 % are comprised by ornamentals and 15 % by roses and other flowers. This means that up to 32 % of a private garden can be covered by a plant group which is included in the intended uses of Bayer Garten Rosen-Pilzfrei Baymat. This portion is also supported by Meunier (2012) if one takes the uncorrected percentages of the covered area into account. Based on the corrected (i.e. referring to 100% total area covered) values Meunier (2012) concludes that only 19.1 % of the total area of a private garden are covered with plants of the groups relevant for the application of Bayer Garten Rosen-Pilzfrei Baymat. As the data used by Meunier are based on the assessment of French gardens for which it is not clear if they are completely comparable to German gardens the cRMS does not agree to use directly the 19.1 % derived from the report by Meunier. However we agree that the data for the German model garden does not differ so much and thus can be accepted as generally representative. Hence the cRMS considered a correction factor of 0.32 for the exposure to address the fact that not the whole garden is treated with the plant protection product.

But we do not agree with the argumentation that voles are not a relevant focal species for private gardens. It is acceptable that a more or less “typical” private garden does not present the typical habitat of voles as the common vole *Microtus arvalis* prefers open agricultural used landscapes and short grass meadows. Within the provided higher tier risk assessment document (Ebeling and Hahne, 2012) the applicant himself stated that voles have a home range of 100-200 m². For private gardens in vicinity to agricultural used areas it can hence not be excluded that a vole also enters private gardens. Thus it cannot be concluded that the vole is not relevant at all. Beside that it has to be considered that the vole *M. arvalis* is a representative for small herbivorous mammals in general. Even if the directly exposed ornamental plants do not present a food source for *M. arvalis* it can also not completely excluded that a vole finds some suitable food which maybe was exposed to the product by drift. Overall we agree that the chance that *M. arvalis* takes up contaminated food to a larger amount is rather unlikely however it cannot completely be excluded and no data is available to address this in a certain way.

The lowest TER of 0.6 was calculated for the intended use group A for the scenario BBCH 40 -49 for the small herbivorous mammal “vole”. If the above stated correction factor of 0.32 is considered for the daily dietary dose the TER calculation results in a value of 1.9. This does still not exactly meet the modified long-term acceptability criterion of 2 for the model species vole however based on the explanations stated before it can be assumed that the risk for the small herbivorous mammal vole overall is acceptable. For the other scenarios for which the acceptability criterion was not met based on the tier 1 assessment (group A: BBCH \geq 50 small herbivorous; group B: BBCH 40 – 49 and BBCH \geq 50 small herbivorous) an acceptable TER can be calculated considering the correction factor of 0.32.

Based on the refined long-term risk assessment overall the risk for mammals following the intended uses of Bayer Garten Rosen-Pilzfrei Baymat is considered to be acceptable.

The results of the assessment overall indicate an acceptable risk for birds and mammals.

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

The cRMS does not follow the approach considered by the zRMS and instead uses the NOEC of 6.25 µg a.s./L and an assessment factor of 10 for the long-term risk assessment of fish. This leads to a regulatory acceptable concentration of 0.625 µg/L in surface waters.

Results of aquatic risk assessment for the intended for uses of Bayer Garten Rosen-Pilzfrei Baymat in ornamentals based on FOCUS Surface Water PEC values were not presented in the core assessment (Part B, Section 6). The zRMS stated that there is no agreed approach to assess the risk for aquatic organisms by the use of a plant protection product in home gardens. Thus the zRMS did not perform a risk assessment within the core assessment and explains that this has to be addressed at Member State level. The applicant provided PEC surface water values and a risk assessment based on these values, however these values were calculated using a model developed by the applicant which was not evaluated by the zRMS. As the cRMS Germany has an own approach to address the risk of aquatic organisms following the use of a plant protection product in home gardens an assessment was included in the national addendum.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift

Based on the relevant toxicity of Tebuconazole, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to Bayer Garten Rosen-Pilzfrei Baymat according to the uses group A and B achieve the acceptability criteria of $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. For the uses included in group A risk mitigation measures (5 m buffer stripe) have to be applied.

2. Exposure by surface run-off and drainage

The concentrations of Tebuconazole in adjacent ditch due to surface runoff and drainage, was calculated using the model EXPOSIT. Where necessary, refined concentrations were used, to address the fact that the product is used in smaller scales in private gardens as it is the case for the conventional use of a plant protection product.

The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by Tebuconazole due to run-off and drainage according to the uses group A and B achieve the acceptability criteria of $TER \geq 10$, according to commission implementing regulation (EU) No 546/2011,

Annex, Part I C , 2. Specific principles, point 2.5.2 for the exposure via run-off.

For the intended uses of group A it has to be considered that the risk for aquatic organisms via run-off is only acceptable, i.e. no risk mitigation measures are required, if an interception of 50% is assumed. Thus it has to be made sure that the application does not take place before adequate foliar development is reached to give the assumed interception.

Consequences for authorization:

For the authorization of the intended uses of group A, B, C and D of Bayer Garten Rosen-Pilzfrei Baymat the following labelling and conditions of use are mandatory:

Required Labelling

NW 264	Tebuconazole: <i>P. promelas</i> NOEC = 0.00625 mg/L
	Tebuconazole: <i>D. magna</i> NOEC = 0.01 mg/L
NW 265	Tebuconazole: <i>L. gibba</i> NOEC = 0.0623 mg/L

Safety precautions / Conditions of use

All uses	NW 468
group A	NW608-1
group B	NW642-1

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

Bees

Honey-bees may be exposed to the formulated product Bayer Rosen-Pilzfrei Baymat by direct spraying of the plant protection product while honey bees are foraging on flowers and weeds present in or adjacent to the crop treated. They may also be exposed through contact with fresh or dry residues or by oral uptake of contaminated pollen, nectar and honey dew.

Acceptable acute oral and contact risks to bees from the active substance and the formulation have been demonstrated.

Acute oral and contact toxicity data were provided as LD₅₀ after 48 h of bee exposure to the formulated product Bayer Rosen-Pilzfrei Baymat. LD₅₀-values for oral and contact exposure were 17.8 µg a.s./bee and 36.5 µg a.s./bee, respectively.

The risks of the formulated product Bayer Rosen-Pilzfrei Baymat and of the active substance tebuconazole to honey-bees were also assessed from hazard quotients between toxicity endpoints,

estimated from acute oral and contact studies with active substance and the formulated product. The hazard quotients $Q_{H(oral)}$ and $Q_{H(contact)}$ are calculated from the ratio between the application rate and the lowest laboratory LD_{50} -values. $Q_{H(oral)}$ was <2.2 for the active substance tebuconazole and 10.3 for the formulated product. $Q_{H(contact)}$ was <0.9 for tebuconazole and 5.0 for the formulated product. All the hazard quotients are considerably less than 50, indicating that the active substance and formulated product pose a low risk to bees.

Other non-target arthropods

The relevant toxicity endpoint is an $ER_{50} > 680$ g a.s./ha (*T. pyri* and all other 3 tested species) derived from an extended laboratory study with the formulation.

Based on the calculated rates of tebuconazole in off-field areas, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to tebuconazole contained in Bayer Garten Rosen-Pilzfrei Baymat according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat achieve the acceptability criteria of $TER \geq 10$ (Tier 1) resp. 5 (Higher tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants according to the label.

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

The risk assessment is based on a chronic earthworm study with the formulation resulting in a NOEC of 241 mg/kg soil.

Based on the predicted concentrations of tebuconazole and Bayer Garten Rosen-Pilzfrei Baymat in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to tebuconazole and Bayer Garten Rosen-Pilzfrei Baymat according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat achieves the acceptability criteria $TER \geq 10$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. For the active substance tebuconazole and the formulation the long-term acceptability criterion $TER \geq 5$ is not met considering the calculated worst case PEC_{soil}, however it is achieved considering a refined PEC soil. The results of the assessment overall indicate an acceptable risk for soil organisms due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants group A (worst case covering all other intended uses) according to the label.

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

Since no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of Bayer Garten Rosen-Pilzfrei Baymat in ornamentals (group A and B), data on the effects on organic matter breakdown (litterbag) is not required.

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

Based on the worst case application rate of tebuconazole, the risk to soil microbial processes following exposure to tebuconazole according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

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

Terrestrial plants

The relevant toxicity endpoint is an ER₅₀ > 388 g a.s./ha (vegetative vigour, *all 6 test species*) conducted with the formulation.

Based on the predicted rates of tebuconazole in off-field areas, the TER values describing the risk for non-target plants following exposure to tebuconazole according to the GAP of the Bayer Garten Rosen-Pilzfrei Baymat achieves the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants according to the label.

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat the following labelling and conditions of use are mandatory:

Classification and labeling for the product

Relevant toxicity	Active substance: tebuconazole (content 2.5 %) → according to CLH report Aug. 2012: LC50 = 0.46 mg a.s./L (<i>M. bahia</i>); M-factor = 1 NOEC = 0.01 mg a.s./L (<i>D. magna</i>); M-factor = 10 Formulation: EC50 = 158.6 mg product/L (<i>D. magna</i>)
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerous for the environment
Risk phrases	R 50/53
Classification and labelling according to Regulation 1272/2008	

Hazard symbol	GHS09
Signal word	warning
Hazard statement	H410 (based of chronic M-factor 10 * 2.5% a.s. content)

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

All uses:

NW 468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing 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.

Use group B

NW642-1 The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

Uses group A:

NW 608 -1 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR.

Buffer: 5 m

Other labels

NW 264 The product is toxic for fish and aquatic invertebrates.

NW 265

The product is toxic for higher aquatic plants.

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

Bayer Garten Rosen-Pilzfrei Baymat is a spray fungicide for control of powdery mildew, black spot and rust in ornamentals. An authorisation can be granted for all intended uses regarding the aspect of efficacy, except for use no. 019. In terms of the intended use 010 an adjustment in the time of application needs to be done. For application time it was applied for “at beginning of infestation and/or when first symptoms become visible” that must be changed into “danger of infection” because in the efficacy trials the application time was prior to the inoculation.

Hence, a positive assessment of the efficacy is only granted, if treatment is started under the latter condition. For use no. 019 no separate studies on the efficacy of the product in terms of fungal leaf spot diseases in ornamentals (except for roses) were provided by the applicant. Therefore, a general approval of the product against fungal leaf spot diseases cannot be provided.

Use No 001-006 and 011-018 (powdery mildew, black spot, and rust in roses): All efficacy trials in roses were carried out with the same dose of the plant protection product, independent of plant height. A sufficient efficacy is given, but a lower dose might have been sufficient for smaller plants. Because all minimum effective dose tests were carried out with higher plants, it is not possible to prove this assumption. However, the leaf surface area does not necessarily vary between plants of lower or larger height. Hence, the same dose of the product might be required for a sufficient efficacy of plants smaller and higher than 50 cm. Therefore, an authorisation is granted for equal dose for different plant heights of roses.

The toxicity of Tebuconazole SE 25 g/L on beneficial organisms has been investigated by carrying out tests under extended laboratory conditions on *Aphidius rhopalosiphi*, *Coccinella septempunctata*, *Aleochara bilineata* and *Typhlodromus pyri*. On the basis of the presented results no effects $\geq 25\%$ are expected for populations of *Coccinella septempunctata* and *Aleochara bilineata*, when Bayer Rosen-Pilzfrei Baymat is applied according to the recommended use pattern, i.e. 4 applications of 4.0 L/ha or 6.0 L/ha to ornamentals. However, with *Aphidius rhopalosiphi*, application rates ≥ 2.7 L/ha resulted in lethal effects $\geq 73.3\%$ in a normal extended laboratory test. Therefore, the product is classified as harmful for populations of relevant beneficial insects.

The results for *Typhlodromus pyri* indicate that effects $> 50\%$ cannot be excluded for all relevant predatory mite species and spiders in ornamentals, when Bayer Rosen-Pilzfrei Baymat is applied according to the recommended use pattern. The products is therefore classified as harmful for populations of relevant predatory mite and spiders.

The instructions for use must include a list of species and/or varieties of crops which are compatible with the application rate provided for (positive list).

The maximum number of applications is limited due to active substance-specific reasons. Sufficient control is therefore not expected in all cases. If necessary, use products containing other active substances afterwards or alternately.

Repeated applications of the product, or products of the same active substance group, or those with cross-resistance, may result or have resulted in a reduction of efficacy. To prevent resistance, the product should if possible be applied alternately with products from other active substance groups with no cross-resistance.

There is no indication of unacceptable adverse effects on soil macro- or soil microorganisms relevant for the maintenance of soil quality.

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 and residues) an authorisation can be granted.

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

With respect to efficacy all uses, except for use no. 19, can be granted in Germany.

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

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.

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.

Or: The following information is required in order to obtain (a prolongation of) the authorisation:

AnnexIII point	Data
	A new study on the effects on algae growth allowing calculation of the EbC50 value...
	...

Appendix 1 – Copy of the product authorisation

- Will be inserted in the final version.

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

- Will be inserted in the final version.



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007626-00/00.66062
(bitte bei Antwort angeben)

DATUM 30. November 2015

ZV3 007626-00/00

Bayer Garten Rosen-Pilzfrei Baymat
Zulassungsverfahren für Pflanzenschutzmittel
Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff: 25 g/l Tebuconazol

Zulassungsnummer: 007626-00

Versuchsbezeichnungen: BAY-21020-F-0-SC

Antrag vom: 3. April 2012

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. August 2020.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007626-00/00-010	Cylindrocladium	Buchsbaum (Gemeiner -)	
007626-00/00-007, 007626-00/00-008, 007626-00/00-009	Echte Mehltaupilze	Zierpflanzen (ausgenommen: Rosen)	
007626-00/00-001, 007626-00/00-002, 007626-00/00-003, 007626-00/00-004, 007626-00/00-005, 007626-00/00-006	Echter Mehltau (Sphaerotheca pan- nosa)	Rosen	
007626-00/00-012, 007626-00/00-014, 007626-00/00-015, 007626-00/00-016, 007626-00/00-017, 007626-00/00-018	Rost (Phragmidium mucronatum)	Rosen	
007626-00/00-020, 007626-00/00-021, 007626-00/00-022	Rostpilze	Zierpflanzen (ausgenommen: Rosen)	
007626-00/00-011, 007626-00/00-013	Sternrußtau (Diplo- carpon rosae)	Rosen	

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 375 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), festgesetzt:

(NW468)

Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.

Begründung:

Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Tebuconazol weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von

Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

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

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Dosierflasche	HDPE	1		500,00		ml
Dosierflasche	HDPE	1		250,00		ml

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Gemäß § 36 Abs. 1 S. 2 Nr. 1 und 2 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für die Anwendung durch nichtberufliche Anwender zugelassen:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Dosierflasche	HDPE	1	4	100,00	200,00	ml

Die Verpackungen für den nichtberuflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung durch nichtberufliche Anwender zulässig.

Auflagen

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

(NN3001)

Das Mittel wird als schädigend für Populationen relevanter Nutzinsekten eingestuft.

(NN3002)

Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW264)

Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)

Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)

Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SF245-01)

Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS201)

Arbeitskleidung (mindestens langärmeliges Hemd und lange Hose) und Handschuhe tragen bei der Ausbringung/Handhabung des Mittels.

(SS703)

Festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des Mittels.

(WMFG1)

Wirkungsmechanismus (FRAC-Gruppe): G1

Siehe anwendungsbezogene Kennzeichnungsaufgaben in Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0098)

Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

(EUH 208-0101)

Enthält 5-Chlor-2-methyl-2H-isothiazol-3-on und 2-Methyl-2H-isothiazol-3-on. Kann allergische Reaktionen hervorrufen.

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H400)

Sehr giftig für Wasserorganismen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):

(P101)

Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)

Darf nicht in die Hände von Kindern gelangen.

(P264)

Nach Gebrauch ... gründlich waschen.

(P270)

Bei Gebrauch nicht essen, trinken oder rauchen.

(P501)

Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007626-00/00-019	Pilzliche Blattfle- ckenerreger	Zierpflanzen (ausge- nommen: Rosen)	

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

Weitere Hinweise und Bemerkungen

Zu KIIIA1 6.2.8:

Hinweis und Begründung für die Kennzeichnungsaufgabe zum Wirkungsmechanismus (WMFG1: Tebuconazol):

Die FRAC-Klassifizierung ist als neutrale Information direkt dem Wirkstoff zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Fungiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

Zum Etikett:

Auf dem Etikett ist zusätzlich zum Wirkstoffgehalt anzugeben:

Enthält ca. 200 g/L Sonnenblumenöl als Lösemittel

Eine Erläuterung zu dem Anwendungszeitpunkt (BBCH31) für den Anwender im Haus- und Kleingartenbereich in der Gebrauchsanleitung ist notwendig.

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

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: 007626-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Stadium der Kultur: ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4
- für die Kultur bzw. je Jahr: 4
- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 6 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Freiland: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Der im Pflanzenschutzmittel Bayer Garten Rosen-Pilzfrei Baymat enthaltene Wirkstoff Tebuconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für *P. promelas* von 6,25 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 608-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Tebuconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.5.4.2).

Anlage 1 zugelassene Anwendung: 007626-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Stadium der Kultur:	ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 14 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße über 50 cm	6 ml/10 m ² in 1,5 l Wasser/10 m ²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Siehe unter AWG 001.

Anlage 1 zugelassene Anwendung: 007626-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Zimmer, Büroräume, Terrassen und Balkone
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 14 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	6 ml/10 m ² in 1 l Wasser/10 m ²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein. Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden. Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Zimmer, Büroräume, Terrassen und Balkone: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Zimmer, Büroräume, Terrassen und Balkone

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße über 50 cm 6 ml/10 m² in 1,5 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Zimmer, Büroräume, Terrassen und Balkone: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 6 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Sphaerotheca pannosa*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße über 50 cm 6 ml/10 m² in 1,5 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echte Mehltaupilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echte Mehltaupilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Zimmer, Büroräume, Terrassen und Balkone

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Zimmer, Büroräume, Terrassen und Balkone: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echte Mehltaupilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Cylindrocladium

Pflanzen/-erzeugnisse/Objekte: Buchsbaum (Gemeiner -)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Anwendungszeitpunkt:	Bei Infektionsgefahr
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 14 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	4 ml/10 m ² in 1 l Wasser/10 m ²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein. Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden. Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Freiland: Buchsbaum (Gemeiner -)
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-011

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Sternrußtau (*Diplocarpon rosae*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Stadium der Kultur: ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 6 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Siehe unter AWG 001.

Anlage 1 zugelassene Anwendung: 007626-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Stadium der Kultur:	ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 14 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße bis 50 cm	6 ml/10 m ² in 1 l Wasser/10 m ²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Freiland: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Der im Pflanzenschutzmittel Bayer Garten Rosen-Pilzfrei Baymat enthaltene Wirkstoff Tebuconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die NOEC für *P. promelas* von 6,25 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 608-1 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Tebuconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.5.4.2).

Anlage 1 zugelassene Anwendung: 007626-00/00-013

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Sternrußtau (*Diplocarpon rosae*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Stadium der Kultur: ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße über 50 cm 6 ml/10 m² in 1,5 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Siehe unter AWG 001.

Anlage 1 zugelassene Anwendung: 007626-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Zierpflanzenbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Ja
Stadium der Kultur:	ab 10 % des arttypischen max. Längen- bzw. Rosettenwachstums erreicht; 1-Knoten-Stadium
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	4
- Abstand:	7 bis 14 Tage
Anwendungstechnik:	spritzen
Aufwand:	
- Pflanzengröße über 50 cm	6 ml/10 m ² in 1,5 l Wasser/10 m ²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW608-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Siehe unter AWG 001.

Anlage 1 zugelassene Anwendung: 007626-00/00-015

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Zimmer, Büroräume, Terrassen und Balkone

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 6 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Zimmer, Büroräume, Terrassen und Balkone: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-016

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Zimmer, Büroräume, Terrassen und Balkone

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße über 50 cm 6 ml/10 m² in 1,5 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N) Zimmer, Büroräume, Terrassen und Balkone: Rosen
Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-017

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 6 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-018

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rost (*Phragmidium mucronatum*)

Pflanzen/-erzeugnisse/Objekte: Rosen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße über 50 cm 6 ml/10 m² in 1,5 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Rosen

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-020

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rostpilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt. Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Freiland: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-021

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rostpilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Zimmer, Büroräume, Terrassen und Balkone

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Zimmer, Büroräume, Terrassen und Balkone: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007626-00/00-022

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rostpilze

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Gewächshaus

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

2.2 Sonstige Kennzeichnungsauflagen

(WH915)

In die Gebrauchsanleitung ist eine Arten- und/oder Sortenliste der Kulturpflanzen aufzunehmen, für die der vorgesehene Mittelaufwand verträglich ist (Positivliste).

(WW7091)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe oder solcher mit Kreuzresistenz können Wirkungsminderungen eintreten oder eingetreten sein.

Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln anderer Wirkstoffgruppen ohne Kreuzresistenz verwenden.

Im Zweifel einen Beratungsdienst hinzuziehen.

(WW750)

Die maximale Anzahl der Anwendungen ist aus wirkstoffspezifischen Gründen eingeschränkt.

Ausreichende Bekämpfung ist damit nicht in allen Fällen zu erwarten. Gegebenenfalls deshalb anschließend oder im Wechsel Mittel mit anderen Wirkstoffen verwenden.

2.3 Wartezeiten

(N)

Gewächshaus: Zierpflanzen (ausg. Rosen)

Die Festsetzung einer Wartezeit ist ohne Bedeutung.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 2 nicht zugelassene Anwendung: 007626-00/00-019

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Pilzliche Blattfleckenerreger

Pflanzen/-erzeugnisse/Objekte: Zierpflanzen (ausgenommen: Rosen)

Verwendungszweck:

2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Zierpflanzenbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Ja

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten
Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 14 Tage

Anwendungstechnik: spritzen

Aufwand:

- Pflanzengröße bis 50 cm 4 ml/10 m² in 1 l Wasser/10 m²

3 Begründung

Wirksamkeit

Nach Artikel 4 Absatz 3 a) der Verordnung (EG) Nr. 1107/2009 muss ein Pflanzenschutzmittel hinreichend wirksam sein.

Nach Abschnitt 6 - Wirksamkeitsdaten - der Verordnung (EU) Nr. 284/2013 zur Festlegung der Datenanforderungen zu Pflanzenschutzmittel müssen die vorgelegten Daten für eine Bewertung des Pflanzenschutzmittels ausreichen. Die vorgelegten Daten müssen hinreichend bestätigen, dass die Anwendungsmuster für das Pflanzenschutzmittel repräsentativ für die Regionen und alle dort vorraussichtlichen Bedingungen sind, für die der Einsatz des Mittels bestimmt ist.

Da keine Versuche zu pilzlichen Blattfleckenerregern an Zierpflanzen (ausgenommen Rosen) eingereicht wurden, sind die Voraussetzungen für eine Zulassung nicht erfüllt. Es wurden nur Ergebnisse mit *Cylindrocladium buxicola* in Buchs vorgelegt, eine Zulassung gegen pilzliche Blattfleckenerreger allgemein in Zierpflanzen wird daher abgelehnt.

**REGISTRATION REPORT
Part B**

**Section 5 Environmental Fate
Detailed summary of the risk assessment**

Product code: Bayer Garten Rosen-
Pilzfrei Baymat

Active Substance: Tebuconazole 25 g/L

**Central Zone
Zonal Rapporteur Member State: United Kingdom**

NATIONAL ADDENDUM – Germany

**Applicant: Bayer CropScience Ltd
Date: August 2014 (CA UK)**

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in its intended uses in roses and ornamentals is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat dated from August/2014 performed by United Kingdom.

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in Germany according to uses listed in in Table 5.2-1.

Regarding PEC_{gw} relevant risk mitigation measures, if necessary, are documented in this document. PEC_{soil}, PEC_{sw} are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Bayer Garten Rosen-Pilzfrei Baymat

Code			
Plant protection product	Bayer Garten Rosen-Pilzfrei Baymat (Former name/UK): tebuconazole SE		
Applicant	Bayer CropScience Ltd		
Date of application	03.04.2012		
Formulation type (WP, EC, SC, ...; density)	SE Density:0.9991		
Active substances (as)	Tebuconazole		
Concentration of as (g/L)	25		
Data pool/task force	-		
Letter of access/cross reference	-		

5.2 Proposed use pattern

The intended uses in Germany classified according to the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1.

Full details of the proposed uses that will be assessed is included in Appendix 2 according to the registration report of UK (core assessment B1 / GAP table in Appendix 2 / Central zone: Germany). These intended uses in Germany corresponding to the intended uses determined by BVL use No. of application for authorisation.

Table 5.2-1: Classification of intended uses in Germany for Bayer Garten Rosen-Pilzfrei Baymat

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001, 002, 011, 012, 013, 014,	Roses and ornamental plants at first symptoms on moderate foliage (BBCH 30) outdoor use	spraying	4 x 6 Lppp, 7 d, 15.05. interception ** 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 150 = 600	Tebuconazole 1. 75 2. 75 3. 75 4. 75 = 225
B/ 00-007, 010, 019, - 020	Ornamental plants at first symptoms on moderate foliage (BBCH 30) outdoor use	spraying	4 x 4 Lppp, 7 d, interception ** 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 100 = 400	Tebuconazole 1. 50 2. 50 3. 50 4. 50 = 200
C/ *** 0000- 008, 009, 021, 022	indoor	spraying	4 x 4 Lppp, 7 d,	Tebuconazole 4 x 100 = 400	-
D/ *** 00-003 – 006, , 015, 016, 017, 018	indoor	spraying	4 x 6 Lppp, 7 d,	Tebuconazole 4 x 150 = 600	-

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL).

** Interception of roses and orchard are not defined in APPDATE or FOCUS. Hence the interception of potatoes at BBCH 30 is used instead of as in the core assessment. In MS UK the PEC_{soil} and $PEC_{surface\ water}$ calculations has been made assuming crop the same interception of 50%.

*** The uses in the groups C and D are not outdoor applications (indoor in pots) and a relevant environmental exposition is not supposed.

5.3 Information on the active substances

5.3.1 Tebuconazole

Please refer to the core assessment (August 2014), part B, section 5.

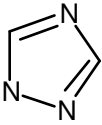
Metabolites of Tebuconazole

Environmental occurring metabolites of Tebuconazole requiring further assessment according to the results of the assessment of Tebuconazole for EU approval are summarized in Table 5.3-1:
Metabolites of Tebuconazole potentially relevant for exposure assessment

Deviating from the EU risk assessment performed on the EU level (for details see DAR and Addenda) the soil metabolite 1, 2, 4-triazole will not be further considered as relevant because the study of Fritz and Brauner (1989) in which this metabolite was identified is not valid because of the study conditions.

In the three newly submitted field degradation studies of tebuconazole (summarized in Annex 2) no new potentially relevant soil metabolites were identified. Hence no additionally metabolites need to be considered in the risk assessment.

Table 5.3-1: Metabolites of Tebuconazole potentially relevant for exposure assessment

> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study			
Metabolite	Structural formula/Molecular formula	Occurrence in compartments (Max. at day)	Status of Relevance according to the core assessment by zRMS United Kingdom
1,2,4-triazole M26 CGA 71019 CGA 98032	 <chem>C2H3N3</chem>	Soil/Water/Sediment: <5 %	Not relevant as < 5 % occurrence for all compartments Aquatic organism: Water: - Sediment: - Terrestrial organism: - Groundwater: not relevant (Step 2/Step 3-4) ¹⁾ (*-remark: The in the EU-List of Endpoints documented formation rate of 0.9-9 % on day 318-378 d (n= 1) is corresponding to not valid study of Fritz and Brauner, 1989)

¹⁾ According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

No further metabolites were considered.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Tebuconazole

Please refer to the core assessment of Fezan (5/2013), part B, section 5, point 5.4.1. and registration number 006400-00-00, 19January2012 Fezan.

The DT₅₀ values of Tebuconazole listed in the following table were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-1: Summary of aerobic degradation rates for tebuconazole - laboratory studies

Soil type	pH	DT ₅₀ (d)	Kinetic, Fit	Reference
Sandy loam, Label 1	4.5	>365 d @23°C and 75% of 1/3bar	-	Lee, 1987 (SANCO/171/08-rev.1- 09/09/2008)
Aggregated DT ₅₀ (n=1)	Coefficient of variation (%)	-	Using of laboratory data for PEC modeling is not possible.	
	Geometric mean (d)	-		

Laboratory data presented in Table 5.4-1 seem to suggest a slow degradation in soil with a half-life longer than 1 year in contrast to the behaviour observed under field conditions.

5.4.1.2 Field studies

Tebuconazole

Please refer to the core assessment of Fezan (5/2013), part B, section 5, point 5.4.1. and registration number 006400-00-00, 19January2012 Fezan.

The field dissipation rates of tebuconazole were evaluated during EU assessment.

Three new studies (Ginzburg, 2008, Brachet, 2009 a and b) on the soil dissipation of tebuconazole under field conditions together with a kinetic modeling analysis of this data (Hardy and Patterson, 2009) have been submitted. A detailed evaluation of these studies is presented in Appendix 2. The recalculated DT₅₀ values of the new studies together with the DT₅₀ values from the EU assessment are summarized in Table 5.4-2.

The DT₅₀ values of Tebuconazole listed in the following table were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011). See Table 5.4-3.

Table 5.4-2: Field degradation studies of tebuconazole fulfilling etgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT50 (d)	DT90 (d)	Kinetic, Fit (SFO/ r ²)	DT50 (d) 20 °C, pF2	fit, kinetic (X ² / SFO)	Reference
Italy Pradelle, (SE) loamy sand	7.7	0-10	34.5	115	0.92	48.4	12.5 SFO	Sommer, 1997 Chapple, 2009
South-France St.Etienne, (SE) loamy silt	7.7	0-10	19.9	66	0.97	25.8	9.9 SFO	Sommer, 1997 Chapple, 2009
UK Thurston/ Bury St. Edmunds, (NE) sandy clay loam	7.6	0-10	77	256	0.88	57.7	9.5 SFO	Schramel, 2001 Chapple, 2009
North-France Vatteville, (NE) Silt loam	7.0	0-10	57	189	0.96	28.9	8.6 SFO	Schramel, 2001 Chapple, 2009
Germany Burscheid (Höfchen) (NE) Silt loam	6.4	0-10	35	116	0.93	29.5	9.7 SFO	Schramel, 2001 Chapple, 2009
Germany Monheim (Laacherhof) (NE) Sandy loam	6.5	0-10	58	193	0.82	65.3	10.5 SFO	Schramel, 2001 Chapple, 2009
Germany Sandelsbronn (NE) Silt loam	7.5	0-10	107	355	0.971	33.1	10.5 SFO	Ginzburg, 2009 Hardy & Patterson, 2009
Germany Haßfelden (NE) Clay loam	7.3	0-10	63.4	210.8	4.8	51.6	5.4 SFO	Brachet, 2009a Hardy & Patterson, 2009
France, Saint Soulan (SE) loam	6.2	0-10	28.4	94.3	17.3	26.2	14.6 SFO	Brachet, 2009b Hardy & Patterson, 2009
France, Lombez (SE) loam	6.5	0-10	90	299	7.1	61.3	6.6 SFO	Brachet, 2009b Hardy & Patterson, 2009

*) Chapple, 2009: DT50 calculated from FOMC with: DT90/3.32 NE: North Europe SE: South Europe		
aggregated DT50 (n = 10) pF2 and 20°C:		
Coefficient of variation	37	Calculated with Excel program INPUTDECISION3.2
Geometric mean	40.2	
Median	40.8	
10./90. percentile	26.2/61.7	
The DT ₅₀ values of tebuconazole do not show any pH dependency. The geometric mean of 40.2 d is used for PEC groundwater calculations and the maximum (not normalised) of 107d is used for PEC soil calculations.		

Table 5.4-3: Statistical values according to INPUT DECISION 3.3 for Tebuconazole for PEC_{GW} modelling

Does the active substance dissociate?	no	
Correlation DT ₅₀ and pH	Kendall-τ: -0.023 p-value: 1.000	not significant
Coefficient of variation	37	sufficiently low
DT ₅₀ for PEC _{GW} (d)	40.2	geometric mean

5.4.2 Adsorption/desorption

Tebuconazole

No new studies have been submitted regarding adsorption/desorption in soil of tebuconazole. The exposure modeling is based on the EU assessment (List of Endpoints, June 2008, LoEP and EFSA-Conclusion, Sept. 2008) as summarized in Table 5.4-4.

The K_{Foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

Table 5.4-4: K_F, K_{Foc} and 1/n (Freundlich exponent) values for Tebuconazole

Soil Type	OC (%)	pH (-)	K _f (mL g ⁻¹)	K _{foc} (mL g ⁻¹)	1/n (-)	Reference
Silt loam Euro soil 2	3.7	7.4	9.86	266	1.179	Geffke, 2001

Loamy sand Lufa 2.2	2.19	5.6	12.59	575	0.747	Geffke, 2001
Sandy loam Lufa 2.3	1.18	6.6	1.52	128	1.204	Geffke, 2001
Sandy loam, Kansas	1.4	5.2	12.69	906	0.739	Fritz,1988
Silt, Burscheid, DE	1.8	5.2	16.39	910	0.721	Fritz,1988
Low-humus sand, Jockgrim, DE	0.75	5.6	7.67	1023	0.711	Fritz,1988
Sandy loam, Monheim, DE	1.27	5.2	15.86	1249	0.737	Fritz,1988
Sandy loam, Borstel, Hannover, DE	1.2	5.7	12.69	1057	0.8054	Fritz,1993
Sandy loam, Laacher Hof, DE	1.35	6.4	10.84	803	0.7631	Fritz,1993
Arithmetic mean (n=9, coefficient of variation=49%)				769	0.84	Agreed with LoEP SANCO/17 1/08-rev.1-09/09/2008
<p>Tebuconazole is not a dissociated substance. Hence no check of correlation to pH is required. No other significant correlations between K_f and soil parameter (clay, CEC) were identified and hence not to consider.</p>						

Table 5.4-5: Statistical values according to INPUT DECISION 3.2 for Tebuconazole for PEC_{GW} modelling

Does the active substance dissociate?	no	
correlation K _f and oc	Kendall-τ:0.197 p-value:0.265	not significant, not positiv (p-Wert > significance level)
coefficient of variation K _{foc}	49	sufficiently low (≤ 60)
Correlation K _f and pH	Not to check	-
Correlation K _f and other soil parameter (clay, CEC)	no	-
K _{foc} /K _f for PEC _{GW}	769	arithmetic mean all soils/ n= 9 accordingly EU
1/n PEC _{GW}	0.845	arithmetic mean all soils n= 9 accordingly EU

5.4.3 Rate of degradation in water/sediment

Tebuconazole

Please refer to the core assessment (5/2013), part B, section 5, point 5.4.3. and registration number 006400-00-00, 19 January 2012 Fezan).

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of tebuconazole (Fritz, 1987a and b, Fritz, 1988) reviewed in the DAR/AR/Addendum.

The DT₅₀ values of the water/sediment study are summarized in Table 5.4-6.

Table 5.4-6: Degradation in water/sediment of tebuconazole

Water/sediment system	DegT ₅₀ / DegT ₉₀ whole system	Kinetic, Fit	DissT ₅₀ / DegT ₅₀ water	Kinetic, Fit	DissT ₅₀ / DegT ₅₀ sed.	Kinetic, Fit	Reference
Lienden pH 8.8	>364	SFO	366	0.83	627	R ² =0.99	Fritz, 1987 and 1988
Ijzendoorn pH 8.5	>>364	SFO	169	0.55	1135	R ² =0.99	Fritz, 1987 and 1988
Geometric mean	-		-		-		

The degradation values agreed at EU level (LoEP, September/2008) for PEC_{sw} and PEC_{sediment} calculations (DT₅₀ of 365 days for the water phase (dissipation) and 1000 days for sediment) are used for the PEC calculation in national assessment

Accumulation of active substance and relevant metabolites in the sediment

active substance	Tebuconazole
accumulation potential in sediment	yes (DT _{90,whole system} > 1 year)
accumulation factor (SFO) $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	1 based on DT _{50, whole system} = 365 d (maximum) t = 365 d

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PEC_{soil} calculation for Bayer Garten Rosen-Pilzfrei Baymat according to EU assessment considering 5 cm soil depth are given in the core assessment august 2014, part B, section 5, chapter IIIA 9.4 (ZV3 007626-00/00)

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittel-wirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{Foc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{Foc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

Due to the fast degradation of the active substance Tebuconazole in soil ($DT_{90} < 365 \text{ d}$, Kinetic, laboratory/field data) the accumulation potential of Tebuconazole does not need to be considered.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in Table 5.5-1.

Table 5.5-1: Input parameters for Bayer Garten Rosen-Pilzfrei Baymat for PEC_{soil} calculation

Active substance	DT ₅₀
Tebuconazole	107 d (SFO Kinetik, Maximum, Field studies, see see chapter 5.4.1.2)

Additional PEC_{soil,act} was calculated for the formulation Bayer Garten Rosen-Pilzfrei Baymat for a soil depth of 2.5 cm. No short-term and long-term PEC_{soil} were calculated since PEC_{soil,act} is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for Tebuconazole as well as for the formulation Bayer Garten Rosen-Pilzfrei Baymat are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in roses and ornamental plants used for German risk assessment

plant protection product:		Bayer Garten Rosen-Pilzfrei Baymat				
use:		Group A/ worst case				
Number of applications/intervall		4				
application rate:		150 g/ha 5994 g/ha for the product with a density of 0.9991				
crop interception:		50/50/50/50%				
active substance/ formulation	soil relevant application rate (g/ha)	soil depth _{act} (cm)	PEC _{act} (mg/kg)	tillage depth (cm)	PEC _{bkgd} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{bkgd} (mg/kg)
Bayer Garten Rosen- Pilzfrei Baymat	2997/ 2997/2997/ 2997	2.5	29.9043	-	-	-
	2997/ 2997/2997/ 2997	1	74.7607	-	-	-
Tebuconazole	75/75/75/75	1	1.8709	-	-	-

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5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PEC_{sw} calculation of Tebuconazole for the intended uses of Bayer Garten Rosen-Pilzfrei Baymat in all applied indications /crops using FOCUS Surface Water are given in the core assessment August 2104, part B, section 5, chapter III A 9.8.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{sw} after exposure by spraydrift and volatilization with subsequent deposition

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Tebuconazole is < 10⁻⁵ Pa. Hence the active substance Tebuconazole is regarded as non-volatile. Therefore exposure of surface water by the active substance Tebuconazole due to volatilization with subsequent deposition does not need to be considered.

The calculation of PEC_{sw} after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. In this case only exposure via spraydrift have to be considered.

For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling of surface water exposure via spray drift with EVA 3 are summarized below.

Table 5.6-1: Endpoints of Tebuconazole used for the PEC_{sw} calculations with EVA 3

Parameter	Tebuconazole	Reference (EFSA Scientific Report (2008) 176)
vapour pressure at 20 °C (Pa)	1.3E-06	EU agreed endpoint
Solubility in water at 20 °C (mg/L)	36	EU agreed endpoint
DissT ₅₀ water (d)	365* (only for multiple application)	SFO (worst case total system) EU agreed endpoint
DegT ₅₀ water/sediment study, total system (d)	1000** (only for multiple application)	SFO (worst case) EU agreed endpoint

The calculated PEC_{sw} values after exposure via spray drift for Tebuconazole for the intended use of Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamental plants according to use No. 00-001/ 00-002/ 00-007,00-011-00-014 are presented in the National addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-2: Input parameters for Bayer Garten Rosen-Pilzfrei Baymat used for PEC_{sw} calculations with EVA 3

Use No.:	Group A/ worst case
Number of applications/ interval:	4 / 7days
Application rate (g a.s./ha)	Tebuconazole:150 g/ha
Drift scenario:	Arable crops

5.6.2 PEC_{sw} after exposure by surface run-off and drainage

The concentration of the active substance Tebuconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The substance specific input parameters used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in chapter 5.7.2 of this document.

The calculated PEC_{sw} in an adjacent ditch due to surface run-off and drainage for the active substance Tebuconazole for the intended use of Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamental plants according to use No. 00-001/ 00-002/ 00-007,00-011-00-014 are presented in the National addendum Germany, part B, section 6, chapter 6.5 considering the following input parameters related to the application.

Table 5.6-3: Input parameters related to the application for PEC_{sw} calculations with Exposit 3.01

Use No.:	Group A/ worst case
Number of applications/ interval:	4 / 7 days
Application rate (g a.s./ha)	Tebuconazole: 150
Crop interception:	50/50/50/50 %

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of the PEC_{gw} calculation of Tebuconazole for the intended uses of Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamentals according to EU assessment using FOCUS PEARL are given in the core assessment august 2014, part B, section 5, chapter 5.7.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster” of FOCUS PELMO.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenario used for PEC_{gw} modelling is summarized in Table 5.7-1. It covers the intended uses of Bayer Garten Rosen-Pilzfrei Baymat in roses and ornamental plants according to Table 5.2-1.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

Use evaluated	Group A/ worst case
Application rate (kg as/ha)	Tebuconazole: 4 x 0.150 kg/ha Soil application rates: 75/75/75/75
Crop (crop rotation)	Roses → crop szenario potatoes
Date(s) of application(s)	1.5. / 8.5. /15.5./ 22.5
Interception (%)	50/50/50/50%
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7
Plant uptake	0
Simulation period (years)	26

Tebuconazole

The endpoints used for groundwater modelling for Tebuconazole according to INPUT DECISION 3.1 are in Table 5.7-2.

Table 5.7-2: Input parameters related to Tebuconazole for PEC_{GW} modelling

Parent	Tebuconazole	Remarks/Reference to core assessment, part B, section 5
Molecular weight (g/mol)	307.8	-
DT ₅₀ in soil (d)	40.2	Field studies / Geomean, n=10 (normalised, SFO, 20°C and pF2)
K _{Foc}	769	arithm mean of all soils n=9
1/n	0.84	arithm mean of all soils n=9
Metabolite	Not relevant	-

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3: PEC_{GW} at 1 m soil depth of Tebuconazole considered relevant for German exposure assessment

Use No.	Scenario	80 th Percentile PEC _{GW} at 1 m soil depth (µg L ⁻¹) modeled by FOCUS PELMO 5.5.3		
		Tebuconazole	-	-
Group A	Hamburg	0.000	-	-

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance Tebuconazole in concentrations ≥ 0.1 µg/L is not expected for all the intended use in roses and ornamental plants.

5.7.1.2 Experimental data to the leaching behaviour

Tebuconazole

Not necessary.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with Focus PELMO 5.5.3 show that the active substance Tebuconazole is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended of Bayer Garten Rosen-Pilzfrei Baymat uses in all intened crops according to use No. 00-001- 00-022.

Consequences for authorization:

none

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

Tebuconazole

The input parameters for Tebuconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized in Table 5.7-4.

Table 5.7-4: Input parameters for Tebuconazole used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Tebuconazole	Reference
K _{Foc, Runoff}	769	arithm. mean (see LoEP SANCO/171/08-rev.1-09/09/2008)
K _{Foc, mobility class}	769	arithm. mean (see LoEP SANCO/171/08-rev.1-09/09/2008)
DT ₅₀ soil (d)	107	(SFO Kinetik, Maximum, Field studies, see see chapter 5.4.1.2)
Solubility in water (mg/L)	36	EU agreed endpoint
Mobility class	2	
Reduction by bank filtration	75%	

The calculated PEC_{gw} for Tebuconazole after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-5.

Table 5.7-5: PEC_{gw} for Tebuconazole after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		Tebuconazole			
Use No.	application rate interception	PEC _{gw} due to			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
Group A	4 x150 50/50/50/50%	0	0.039	spring/summer	0.017
		5	0.034		
		10	0.029	autumn/winter/ early spring	0.053
		20	0.020		
required labelling		none			

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Tebuconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

None

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Table of Intended Uses in Germany (according to BVL dd.mm.yyyy)

PPP (product name/code) Bayer Garten Rosen-Pilzfrei Baymat **Formulation type:** SE
 active substance 1 Tebuconazole **Conc. of as 1:** 25 g/L
 active substance 2 - **Conc. of as 2:** ...
 active substance 3 -

CENTRAL ZONE : GERMANY

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate treatment per			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
roses	DE	TBZ SE 25	F, I, G	Mildew Black spot Rust	SE	25 g/L	Spraying	at first symptoms on moderate foliage (BBCH 30)	Max 4	7-14	10-15	1000-1500	150	-	small plants: 6 ml/L and 1000 L/ha bigger plants: 4 ml/L and 1500 L/ha
ornamentals	DE	TBZ SE 25	F, I, G	Mildew Rust Leaf spot	SE	25 g/L	Spraying	at first symptoms on moderate foliage (BBCH 30)	2-4	7-14	10	1000	100	-	4 mL/L and 1000 L/ha

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate treatment per			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
Woody ornamentals (Box trees)	DE	TBZ SE 25	F	Cylindrocladium buxicola	SE	25 g/L	Spraying	at first symptoms on moderate foliage (BBCH 30)	Max 5	7-14	10	1000	100	-	4 mL/L and 1000 L/ha

- Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

DRAFT REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product code: Bayer Garten Rosen-Pilzfrei Baymat
Active Substance: 25 g/L

Central Zone
Zonal Rapporteur Member State: UK

NATIONAL ADDENDUM

Applicant: Bayer CropScience
Date: August 2014 (CA UK)

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

A full risk assessment according to Uniform Principles for the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in its intended uses in ornamentals is documented in detail in the core assessment of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat dated from August 2014 performed by zRMS UK.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product Bayer Garten Rosen-Pilzfrei Baymat in Germany according to the uses listed in Appendix 2.

General information on the formulation Bayer Garten Rosen-Pilzfrei Baymat can be found in Table 5.1-1 of Section 5 of the National addendum Germany (October 2015).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

The intended uses in Germany are generally covered by the core assessment performed by zRMS UK. It has to be considered that all intended uses are non professional uses, in Germany so called HuK uses.

Full details of the proposed uses that will be assessed are included in Appendix 2 of the core assessment prepared by zRMS UK (Section B1 / GAP table in Appendix 2 / Central zone: Germany). These intended uses in Germany correspond to the intended uses defined by BVL.

Table 6.1-1: Critical use pattern of Bayer Garten Rosen-Pilzfrei Baymat

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001, 002, 011, 012, 013, 014,	Roses and ornamental plants at first symptoms on moderate foliage (BBCH 30)* outdoor use	spraying	4 x 6 Lppp, 7 d, 15.05. interception 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 150 = 600	Tebuconazole 1. 75 2. 75 3. 75 4. 75 = 225
B/ 00-007, 010, 019, - 020	Ornamental plants at first symptoms on moderate foliage (BBCH 30)* outdoor use	spraying	4 x 4 Lppp, 7 d, interception 1. 50 % 2. 50 % 3. 50 % 4. 50 %	Tebuconazole 4 x 100 = 400	Tebuconazole 1. 50 2. 50 3. 50 4. 50 = 200
C/ ** 0000- 008, 009, 021, 022	indoor	spraying	4 x 4 Lppp, 7 d,	Tebuconazole 4 x 100 = 400	-

D/ ** 00-003 – 006, , 015, 016, 017, 018	indoor	spraying	4 x 6 Lppp, 7 d,	Tebuconazole 4 x 150 = 600	-
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* the considered BBCH stage corresponds to the BBCH stage presented in the GAP table of the core assessment by zRMS UK (GAP for Germany), however no BBCH stage was defined by BVL

** Indoor application for potted plants in living rooms or offices and in green houses respectively

Group C and D include only indoor applications or applications in greenhouses thus no exposure of non target organisms has to be expected. As no exposure is expected and beside that the application rates are covered by group A and B no risk assessment ist performed for group C and D.

For groups A and B no BBCH stage for the first application was defined by the BVL. However within the GAP table presented in the core assessment of zRMS UK for Germany an application the first application is defines to take place at BBCH 30. The risk assessment for Germany presented in the following chapters is based on the assumption that Bayer Garten Rosen-Pilzfrei Baymat is not applied before BBCH 30 and the corresponding interception is taken into account. Thus applications before BBCH 30 are not covered by the presented risk assessment.

6.1.2 Consideration of metabolites

Please refer to the core assessment.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

Please refer to the core assessment for acute risk assessment.

The RMS UK has identified a long-term risk for small insectivorous (e.g. blue tit) in tier 1 and is addressing this risk with reference to a report by Ebeling (2012), in which it is highlighted that the home garden is unlikely to be a monoculture of a single crop as is the case in the agricultural environment and that the garden is a more heterogeneous environment for which it is unlikely that all gardens will be treated at the same time. It is considered that the garden is unlikely to be a monoculture but nevertheless there could be largish areas e.g. of ornamentals and so an adequate risk assessment is still required. They further refer to Barfknecht R. (2006); a study in which the DT50 on arthropods is examined. Based on the concluded DT50 of 1.2 d the refined risk is acceptable. Co-RMS Germany is not convinced that the study by Barfknecht R. (2006) is really representative for home garden areas as the DT50 for arthropods was examined for a treated cereal field. It is not clear if the arthropods which were examined are really representative for home garden areas. However the applicant also provided a study by Chapple et al. (2007) examining German and French model gardens and their plant composition and especially the percentages of different plant groups. Especially for Germany one has to consider two types of “home gardens”, as there are the “real” home gardens connected to a house and additionally the allotments. According to Chapple et al. considering both variants a maximum of approximately 32 % roses and ornamental plants are cultivated in home gardens. Beside that it has to be considered that the total area of garden connected to a house or of an allotment only has a mean size of 500 m². Thus the application rate always is lower as for the conventional use. Even if it cannot be excluded that the product is also applied in the neighbouring garden it can be assumed that birds will not consume only exposed food.

Based on the presented reasoning, we agree with the overall conclusion of an acceptable long-term risk.

6.2.1.1 Effects of secondary poisoning (MIIIA 10.1.9)

Risk assessment for earthworm-eating birds via secondary poisoning

Dry soil approach

Table 6.2-1: Assessment of the risk for earthworm eating birds from an exposure to tebuconazole through secondary poisoning for the intended use group A (worst case)

Parameter	tebuconazole	comments
PEC _{soil} (twa = 21 d) [mg/kg soil]	0.305	4 × 150 g/ha, interception 50%, soil layer depth 5 cm, DT50 = 107 d, twa interval = 21 d
K _{ow}	5012	log Pow 3.7
K _{oc}	769	
F _{oc}	0.02	Default
BCF _{worm}	3.965	BCF _{worm} = (PEC _{worm} /PEC _{soil}) = (0.84 + 0.012 × K _{ow})/ f _{oc} × K _{oc}

PEC _{worm}	1.387	PEC _{worm} = PEC _{soil} x BCF
Daily dietary dose (mg/kg bw/d)	1.457	DDD = PEC _{worm} x 1.05
NOEL (mg/kg bw/d)	5.8	<i>C. virginianus</i>
TER _{lt}	4.0	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

Table 6.2-2: Assessment of the risk for fish eating birds from an exposure to tebuconazole through secondary poisoning for the intended use group A (worst case)

Parameter	tebuconazole	comments
RAC [mg/L]	0.0006	NOEC = 0.006 mg/L with SF 10 for <i>P. promelas</i>
BCF _{fish}	78	According to LOEP
PEC _{fish}	0.047	PEC _{fish} = PEC _{water} x BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} x 0.159
NOEL (mg/kg bw/d)	5.8	<i>C. virginianus</i>
TER _{lt}	779.4	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Table 6.2-3: Assessment of the risk for earthworm eating birds from an exposure to tebuconazole through secondary poisoning for the intended use group B

Parameter	tebuconazole	comments
PEC _{soil} (twa = 21 d) [mg/kg soil]	0.233	4 x 100 g/ha, interception 50%, soil layer depth 5 cm, DT50 = 107 d, twa interval = 21 d
K _{ow}	5012	log Pow 3.7
K _{oc}	769	
F _{oc}	0.02	Default
BCF _{worm}	3.965	BCF _{worm} = (PEC _{worm} /PEC _{soil}) = (0.84 + 0.012 x K _{ow}) / f _{oc} x K _{oc}
PEC _{worm}	0.925	PEC _{worm} = PEC _{soil} x BCF
Daily dietary dose (mg/kg bw/d)	0.971	DDD = PEC _{worm} x 1.05
NOEL (mg/kg bw/d)	5.8	<i>C. virginianus</i>
TER _{lt}	6.0	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

Table 6.2-4: Assessment of the risk for fish eating birds from an exposure to tebuconazole through secondary poisoning for the intended use group B

Parameter	tebuconazole	comments
RAC [mg/L]	0.0006	NOEC = 0.006 mg/L with SF 10 for <i>P. promelas</i>
BCF _{fish}	78	According to LOEP
PEC _{fish}	0.047	PEC _{fish} = PEC _{water} x BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} x 0.159
NOEL (mg/kg bw/d)	5.8	<i>C. virginianus</i>
TER _{it}	779.4	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Refined risk assessment for secondary poisoning

The applicant provided the following bioaccumulation study for earthworms.

Species	Substance	Exposure System	Results	Reference	Internal code
Earthworm					
<i>Eisenia fetida</i>	Tebuconazole	42 d, on the basis of OECD 207 and 305, test concentration 0.33 mg/kg soil (nominal)	BAF = 1.35 kg soil dw/ kg worm dw	Heimbach, F. 25.10.1994 HBF/Rg 189	65553

The study was accepted and considered for a refined risk assessment for secondary poisoning by the zRMS. Germany agrees that the study is acceptable and hence the refined risk assessment presented by the zRMS in the core assessment is also acceptable. Based on the refined assessment the risk for earthworm eating birds via secondary poisoning is acceptable.

Consequences for authorization:

none

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

Please refer to the core assessment for the acute risk assessment.

Within the core assessment the zRMS identified an unacceptable long-term risk for the vole BBCH 40-49 and BBCH > 50. The zRMS stated that this unacceptable risk has to be considered/addressed at member state level. In the following chapter the long-term risk for mammals is assessed by the cRMS Germany.

6.3.1.1 Tier-1 risk assessment

The results of the reproductive Tier 1 risk assessment is summarised in the following table.

Table 6.3-1: Reproductive tier 1 risk assessment for terrestrial vertebrates other than birds for tebuconazole

Intended use	Generic focal species	Generic diet composition	Endpoint [mg/kg bw/d]	SV	MAF _{mean} x t _{wa}	DDD _{LT} [mg/kg bw/d]	TER
Intended use group A (4 x 150 g a.s./ha, interval 7 d)							
appl. to plant exposure to underlying ground	small insectivorous "shrew"	100% ground arthropods	10	1.9	1.54	0.439	22.8
BBCH 40 - 49	small herbivorous "vole"	100% grass	10	72.3	1.54	16.721	0.6
BBCH ≥ 50	small herbivorous "vole"	100% grass	10	36.1	1.54	8.349	1.2
appl. crop directed BBCH 10 - 49	small omnivorous "mouse"	25% weeds 50% weed seeds 25% ground arthropods (with interception)	10	7.8	1.54	1.804	5.5
appl. crop directed BBCH ≥ 50	small omnivorous "mouse"	25% weeds 50% weed seeds 25% ground arthropods (with interception)	10	3.9	1.54	0.902	11.1
Intended use group B (4 x 100 g a.s./ha, interval 7 d)							
appl. to plant exposure to underlying ground	small insectivorous "shrew"	100% ground arthropods	10	1.9	1.54	0.293	34.1
BBCH 40 - 49	small herbivorous "vole"	100% grass	10	72.3	1.54	11.147	0.9
BBCH ≥ 50	small herbivorous "vole"	100% grass	10	36.1	1.54	5.566	1.8
appl. crop directed BBCH 10 - 49	small omnivorous "mouse"	25% weeds 50% weed seeds 25% ground arthropods (with interception)	10	7.8	1.54	1.203	8.3
appl. crop directed BBCH ≥ 50	small omnivorous "mouse"	25% weeds 50% weed seeds 25% ground arthropods (with interception)	10	3.9	1.54	0.601	16.6

SV: shortcut value; MAF_{mean}: multiple application factor (mean); DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Based on tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to tebuconazole (oral exposure) according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat do not achieve the acceptability criterion $TER \geq 5$, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles for the relevant scenario small herbivorous mammal “vole”. The results of the assessment indicate an unacceptable long-term risk for mammals due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamentals (group A and B) according to the label.

In cases where the relevant model species for assessment of the risk from the intended use of Bayer Garten Rosen-Pilzfrei containing the active substance tebuconazole is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a $TER \geq 5$ in the acute exposure scenario and a $TER \geq 2$ in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures).

However for the intended uses group A and B the scenarios BBCH 40 – 49 and $BBCH \geq 50$ based on the generic focal species “vole” also the modified acceptability criterion of $TER \geq 2$ for the long-term exposure is not met. Thus further refinement is required for these scenarios.

Refined long-term risk assessment small herbivorous mammal “vole”

The applicant provided a higher tier risk assessment for birds and mammals (Ebeling and Hahne, 2011). Two main points are highlighted: i) that the assumptions made in the EFSA GD (2009) are based on a large scale use of a plant protection product in agricultural landscapes and hence clearly overestimate the use in the scale of home gardens ii) voles are not the relevant species in private gardens.

We agree that the exposure of mammals in intensively managed agricultural areas is not directly comparable to the exposure in home/private gardens and presents a relatively pronounced worst case. The provided reports by Meunier (2012) and Chapple et al. (2007) can be taken into account to refine the exposure for private gardens. According to Chapple et al. (2007) in Germany in total (meaning for private house gardens and allotments) 17 % are comprised by ornamentals and 15 % by roses and other flowers. This means that up to 32 % of a private garden can be covered by a plant group which is included in the intended uses of Bayer Garten Rosen-Pilzfrei Baymat. This portion is also supported by Meunier (2012) if one takes the uncorrected percentages of the covered area into account. Based on the corrected (i.e. referring to 100% total area covered) values Meunier (2012) concludes that only 19.1 % of the total area of a private garden are covered with plants of the groups relevant for the application of Bayer Garten Rosen-Pilzfrei Baymat. As the data used by Meunier are based on the assessment of fresh gardens for which it is not clear if they are completely comparable to German gardens the cRMS does not agree to use directly the 19.1 % derived from the report by Meunier. However we agree that the data for the German model garden does not differ so much and thus can be accepted as generally representative. Hence the cRMS considered a correction

factor of 0.32 for the exposure to address the fact that not the whole garden is treated with the plant protection product.

But we do not agree with the argumentation that voles are not a relevant focal species for private gardens. It is acceptable that a more or less “typical” private garden does not present the typical habitat of voles as the common vole *Microtus arvalis* prefers open agricultural used landscapes and short grass meadows. Within the provided higher tier risk assessment document (Ebeling and Hahne, 2012) the applicant himself stated that voles have a home range of 100-200 m². For private gardens in vicinity to agricultural used areas it can hence not be excluded that a vole also enters private gardens. Thus it cannot be concluded that the vole is not relevant at all. Besides that it has to be considered that the vole *M. arvalis* is a representative for small herbivorous mammals in general. Even if the directly exposed ornamental plants do not present a food source for *M. arvalis* it can also not be completely excluded that a vole finds some suitable food which maybe was exposed to the product by drift. Overall we agree that the chance that *M. arvalis* takes up contaminated food to a larger amount is rather unlikely however it cannot be completely excluded and no data is available to address this in a certain way.

The lowest TER of 0.6 was calculated for the intended use group A for the scenario BBCH 40 -49 for the small herbivorous mammal “vole”. If the above stated correction factor of 0.32 is considered for the daily dietary dose the TER calculation results in a value of 1.9. This does still not exactly meet the modified long-term acceptability criterion of 2 for the model species vole however based on the explanations stated before it can be assumed that the risk for the small herbivorous mammal vole overall is acceptable. For the other scenarios for which the acceptability criterion was not met based on the tier 1 assessment (group A: BBCH ≥ 50 small herbivorous; group B: BBCH 40 – 49 and BBCH ≥ 50 small herbivorous) an acceptable TER can be calculated considering the correction factor of 0.32.

Based on the refined long-term risk assessment overall the risk for mammals following the intended uses of Bayer Garten Rosen-Pilzfrei Baymat is considered to be acceptable.

6.3.1.2 *Effects of secondary poisoning (MIIIA 10.3.2.3)*

Risk assessment for earthworm-eating mammals via secondary poisoning

Dry soil approach

Table 6.3-1: Assessment of the risk for earthworm eating mammals from an exposure to tebuconazole through secondary poisoning for the intended use group A (worst case)

Parameter	tebuconazole	comments
PEC _{soil} (twa = 21 d) [mg/kg soil]	0.350	4 × 150 g/ha, interception 50%, soil layer depth 5 cm, DT50 = 107 d, twa interval = 21 d
K _{ow}	5012	log Pow 3.7
K _{oc}	769	
F _{oc}	0.02	Default
BCF _{worm}	3.965	BCF _{worm} = (PEC _{worm} /PEC _{soil}) = (0.84 + 0.012 × K _{ow}) / f _{oc} × K _{oc}

PEC _{worm}	1.387	PEC _{worm} = PEC _{soil} × BCF
Daily dietary dose (mg/kg bw/d)	1.776	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	10	
TER _{lt}	5.6	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

Table 6.3-2: Assessment of the risk for fish eating mammals from an exposure to tebuconazole through secondary poisoning for the intended use group A (worst case)

Parameter	tebuconazole	comments
RAC [mg/L]	0.0006	NOEC = 0.006 mg/L with SF 10 for <i>P. promelas</i>
BCF _{fish}	78	According to LOEP
PEC _{fish}	0.047	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	10	
TER _{lt}	1504.8	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Table 6.3-3: Assessment of the risk for earthworm eating mammals from an exposure to tebuconazole through secondary poisoning for the intended use group B

Parameter	tebuconazole	comments
PEC _{soil} (twa = 21 d) [mg/kg soil]	0.233	4 × 100 g/ha, interception 50%, soil layer depth 5 cm, DT50 = 107 d, twa interval = 21 d
K _{ow}	5012	log Pow 3.7
K _{oc}	769	
F _{oc}	0.02	Default
BCF _{worm}	3.965	BCF _{worm} = (PEC _{worm} /PEC _{soil}) = (0.84 + 0.012 × K _{ow}) / f _{oc} × K _{oc}
PEC _{worm}	0.925	PEC _{worm} = PEC _{soil} × BCF
Daily dietary dose (mg/kg bw/d)	1.184	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	10	
TER _{lt}	8.4	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

Table 6.3-4: Assessment of the risk for fish eating mammals from an exposure to tebuconazole through secondary poisoning for the intended use group B

Parameter	tebuconazole	comments
RAC [mg/L]	0.0006	NOEC = 0.006 mg/L with SF 10 for <i>P. promelas</i>
BCF _{fish}	78	According to LOEP
PEC _{fish}	0.047	PEC _{fish} = PEC _{water} x BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.007	DDD = PEC _{fish} x 0.159
NOEL (mg/kg bw/d)	10	
TER _{lt}	1504.8	TER ≥ 5

TER values shown in bold fall below the relevant trigger.

Consequences for authorization:

none

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

No data provided.

Consequences for authorization:

none

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

No aquatic risk assessment was performed in the CA. The zRMS UK stated that a risk assessment based on FOCUS surface water PEC values is not possible as the FOCUS approach does not present an agreed approach for uses in home gardens. The zRMS concluded that the risk for aquatic organisms has to be evaluated on the national level considering national approaches for home gardening.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

The risk assessment for aquatic organism for authorization of Bayer Garten Rosen-Pilzfrei Baymat is outlined in the following chapters.

6.5.2 Toxicity

Table 6.5-1: Endpoints used for risk assessment for aquatic organisms for tebuconazole and its relevant metabolites

Species	Substance	Exposure System	Results [mg a.s./L]	Reference	Internal code
Acute toxicity to fish					
<i>Oncorhynchus mykiss</i>	Tebuconazole	4 d, stat.	LC ₅₀ = 3.07 mg/L ¹⁾	XXX 02.02.1999 FAR60961	68100
<i>Oncorhynchus mykiss</i>	Tebuconazole	4 d, stat.	LC ₅₀ = 4.4 mg/L	XXX 1987 BW-87-5-2394, 94860	29479
<i>Oncorhynchus mykiss</i>	Tebuconazole-ME 1,2,4-Triazol	4 d, stat.	LC ₅₀ = 498.3 mg/L (mm)	XXX 1983 82 14 18	41737
<i>Oncorhynchus mykiss</i>	Tebuconazole-ME HWG 1608 pentanoic acid	4 d, stat.	LC ₅₀ > 10 mg/L	XXX 2003 DOM 23021	59898
<i>Oncorhynchus mykiss</i>	Tebuconazole-ME HWG 1608-lactone	4 d, stat.	LC ₅₀ > 10 mg/L	XXX 2003 DOM 23007	59899
<i>Oncorhynchus mykiss</i>	Tebuconazole SE 25	4 d, stat.	LC ₅₀ = 289 mg Pr./L	XXX 23.12.2011 E 280 4292-7	84714
Chronic toxicity to fish					
<i>Pimephales promelas</i>	Tebuconazole	122 -125 d, durch. FSDT	NOEC = 0.00625 mg a.s./L (nom.) NOEC: 0.00578 mg a.s./L (measured) sublethal effects	XXX 2007 E2863254-3	67971
<i>Oncorhynchus mykiss</i>	Tebuconazole-ME 1,2,4-Triazol	28 d, semi.	NOEC= 3.2 mg a.s./L	XXX 2002 DOM 21060	45802
Acute toxicity to aquatic invertebrates					
<i>Mysidopsis bahia</i>	Tebuconazole	4 d, flow through.	LC ₅₀ = 0.46 mg a.s./L	Surprenant, D. C. 1988 97465; 87-5-2436	51764
<i>Daphnia magna</i>	Tebuconazole-ME 1,2,4-Triazol	2 d, stat.	EC ₅₀ > 100 mg/L	Bell, G. 1995 AGV 50(b)/952181/ AgrEvo Rep.No. ENVIR/95/52	48025
<i>Daphnia magna</i>	Tebuconazole-ME HWG 1608 pentanoic acid	2 d, stat.	EC ₅₀ > 100 mg/L	Dorgerloh, M. 2003 DOM 23015; E 320 2379-6	59900

<i>Daphnia magna</i>	Tebuconazole-ME HWG 1608-lactone	2 d, stat.	EC ₅₀ > 100 mg/L	Dorgerloh, M. 2003 E 320 2380-7	68319
<i>Daphnia magna</i>	Tebuconazole SE 43	2 d, stat.	EC ₅₀ = 158.6 mg Pr./L (UBA evaluation) EC ₅₀ = 316 mg Pr./L (evaluation of study author) ²⁾	Hendel, B. 19.05.2000 HDB/DM 225	51757
Chronic toxicity to aquatic invertebrates					
<i>Daphnia magna</i>	Tebuconazole	21 d, semistat.	NOEC= 0.01 mg a.s./L	Noack, M. 1999 DRE60961	51781
Chronic toxicity to sediment-dwelling organism					
<i>Chironomus riparius</i>	Tebuconazole	28 d	NOEC = 2.45 mg/L	Dorgerloh, M. 2003 DOM 22066	51799
<i>Chironomus riparius</i>	Tebuconazol technical	28 d, stat. (spiked water)	NOEC = 1.25 mg/L ¹⁾	Pupp., A. und Wydra, V., 27.01.2009 44501250	35108
<i>Chironomus riparius</i>	Tebuconazole-ME HWG 1608-lactone	28 d	EC ₁₀ = 47.8 mg/L	Dorgerloh, M. 2003 DOM 23037	59905
Toxicity to algae					
<i>Scenedesmus subspicatus</i>	Tebuconazole	3 d, stat.	EbC ₅₀ = 1.96 mg a.s./L ErC ₅₀ = 5.3 mg a.s./L NOEC = 1.0 mg a.s./L	Heimbach, F. 1987 HBF/AL 31	29458
<i>Selenastrum capricornutum</i>	ME 1,2,4-Triazol	3 d, stat.	ErC ₅₀ > 31 mg a.s./L EbC ₅₀ = 13 mg a.s./L	Palmer, S.J.; Kendall, T.Z.; Krueger, H.O. 2001 528A-101; auch 2013593	33654
<i>Pseudokirchneriella subcapitata</i>	Tebuconazole SE 25	3 d, stat.	ErC ₅₀ > 100 mg Pr./L EbC ₅₀ > 100 mg Pr./L	Bruns, E. 10.01.2012 E 323 4042-8	84705
Toxicity to aquatic plants					
<i>Lemna gibba</i>	Tebuconazole (Folicur techn. 96,7 % a.s.)	14 d, semi.	EC ₅₀ = 0.1444 mg a.s./L NOEC = 0.0623 mg a.s./L	Bowers, L. M. 1997 107681	51791
Bioconcentration in fish					
<i>Lepomis macrochirus</i>	Tebuconazole	OECD 305	BCF = 78	Grau, R. et al. 22.01.1988 2932	68905

- 1) Endpoint differing from LoEP, study with a lower endpoint known to cRMS
- 2) The study was performed with the formulation Tebuconazole SE 43 and not with Tebuconazole SE 25. According to the applicant the formulation presents a worst case due to the higher amount of tebuconazole. As already stated by the zRMS within the CA it is not proven that the formulation is comparable to the one applied here. Additionally the study has some shortcomings. For the concentrations 1000 and 1800 mg Pr./L there was a film of the test substance which was not analytically considered. After 48 hours there were some individuals lying at the bottom and hardly showing any movement however these animals were not included in the determination of the immobilisation rate. Thus a new calculation, including these animals was performed by the UBA which resulted in the cited above EC₅₀ of 158.6 mg Pr./L. Overall it is questionable if this study is reliable as formulation study for the here applied formulation Bayer Garten Rosen-Pilzfrei Baymat. However this study is not crucial for the risk assessment as the risk for the formulation is covered by the assessment for the active substance.

6.5.3 Justification for new endpoints

Within the core assessment the zRMS considered the FSDT test by Bomke (2007) but stated that there is uncertainty about the test concentration units. The full study report is known to cRMS Germany and hence the test concentration units are clear and there is no reason not to consider this test. The zRMS considered the EU agreed overall NOAEC of 12 µg tebuconazole/L for fish. Already during the peer review of the additional use of tebuconazole as plant growth regulator, where the study of Bomke (2007) was first assessed on the EU level, Germany did not agree to this NOAEC. The FSDT study is used for national authorisations since a longer time. So far Germany considered a NOEC of 5.78 µg a.s./L based on measured concentrations from this study. This refers to the nominal NOEC of 6.25 µg a.s./L which is also acceptable according to OECD 234 as the measured concentrations were between 85 and 92 % of nominal. Within the former EFSA Conclusion for tebuconazole (2008) a data gap regarding the possibility of endocrine effects for fish was identified. It was stated that a FSDT test is already under progress. This means the study by Bomke (2007) was performed to address the potential of endocrine effects. As the study was performed before the finalized OECD 234 was available, the vitellogenin content was not measured. According to OECD 234 the vitellogenin content and the sex ratio are the two core endpoints of this test which are measured as indicator as endocrine associated developmental aberrations. In the study by Bomke (2007) no effects on the sex ratio were determined. However there were significant degenerative effects on the liver and a significant reduced yolk accumulation in oocytes at 12.5 µg a.s./L. As the liver is the organ where vitellogenin is produced and as the vitellogenin is the precursor for yolk proteins it is not clear if these effects maybe indicate an endocrine effect of tebuconazole. It is not possible to decide whether vitellogenin content was also affected or not as this was not measured. Even if the sex ratio was not affected it can still not be excluded that tebuconazole has an endocrine disrupting potential. Only this one study by Bomke (2007) is available which includes the assessment of indicator parameters for endocrine effects and from our point of view this study does not sufficiently invalidate the suspicion that tebuconazole causes endocrine effects. It seems to be not justified to conclude that there are no endocrine effects and that the estab-

lished liver effects are not relevant and hence to derive an overall NOAEC of 12 µg a.s./L for fish populations. Thus the cRMS does not follow the approach considered by the zRMS and instead uses the NOEC of 6.25 µg a.s./L and an assessment factor of 10 for the long-term risk assessment of fish.

6.5.4 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance Document on Aquatic Ecotoxicology”, as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

Mixture Toxicity

The mixture toxicity has not to be considered in this case as the formulation contains only one active substance.

6.5.4.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Tebuconazole has a vapour pressure of $< 10^{-5}$ Pa and is therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters for tebuconazole are given in Section 5 chapter 5.6.1.

Several ecotoxicological endpoints are available to assess the risk of the active substance tebuconazole and the formulation Bayer Garten Rosen-Pilzfrei Baymat (see chapter 6.5.2). The choice of the relevant scenario is based on the ratio of endpoint to the highest PEC for each active substance and the formulation, related to the relevant trigger TER value.

Based on the available data, the NOEC for *P. promelas* in combination with a Safety factor of 10 provides for tebuconazole the lowest TER/SF ratio and is therefore the relevant scenario for risk assessment. The assessment based on the active substance covers also the risk for the formulation.

Table 6.5-1: Risk assessment for tebuconazole for aquatic organisms for the entry route via spraydrift and deposition under the implementation of different risk mitigation measures, group A

Compound:		tebuconazole	
Crop/Application rate:		gardening plants > 50 cm (no hight is given, thus worst case was assumed); 4 x 150 g a.s./h, interval 7 d	
Growth stage and season		no clear growth stage is given (application at infestation)	
Intended use group:		A	
DT₅₀ water (SFO):		365 d	
PEC-selection:		actual	
Drift-Percentile:		74.	
Buffer zone	Entry via spraydrift	Entry via deposition following	PEC_{sw}; conventional and drift reducing technique

[m]	[%]	[µg/ha]	volatilization		0% conv.	50% red.	75% red.	90% red.
			[%]	[µg/L]				
3	0.41	0.804	-	-	0.804	n.a.	n.a.	n.a.
5	0.11	0.216	-	-	0.216	n.a.	n.a.	n.a.
10	0.02	0.039	-	-	0.039	n.a.	n.a.	n.a.
Relevant toxicity endpoint: NOEC = 6.25 µg a.i./L (<i>P. promelas</i>) Relevant TER: 10								
Buffer zone [m]					TER			
3					7.8	n.a.	n.a.	n.a.
5					29.0	n.a.	n.a.	n.a.
Risk mitigation measures			NW 608 (5 m)					

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

Table 6.5-3: Risk assessment for tebuconazole for aquatic organisms for the entry route via spraydrift and deposition under the implementation of different risk mitigation measures, group B

Compound:		tebuconazole							
Crop/Application rate:		gardening plants > 50 cm (no height is given, thus worst case was assumed); 4 x 100 g a.s./ha, interval 7 d							
Growth stage and season		no clear growth stage is given (application at infestation)							
Intended use group:		B							
DT₅₀ water (SFO):		365 d							
PEC-selection:		actual							
Drift-Percentile:		74.							
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PECsw; conventional and drift reducing technique				
	[m]	[%]	[µg/ha]	[%]	[µg/L]	0% conv.	50% red.	75% red.	90% red.
						[µg/L]			
3	0.41	0.536	-	-	0.536	n.a.	n.a.	n.a.	n.a.
5	0.11	0.144	-	-	0.144	n.a.	n.a.	n.a.	n.a.
10	0.02	0.026	-	-	0.026	n.a.	n.a.	n.a.	n.a.
Relevant toxicity endpoint: NOEC = 6.25 µg a.i./L (<i>P. promelas</i>) Relevant TER: 10									
Buffer zone [m]					TER				
3					11.7	n.a.	n.a.	n.a.	n.a.
Risk mitigation measures				not required					

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

6.5.4.2 *TER values for the entry into surface water via run-off and drainage*

The concentration of the active substance tebuconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for tebuconazole for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Refinement option

The intended uses of the product for home gardening (German: HuK = Haus und Kleingarten) correspond to an application on a rather small area for ornamental plants. Against that the assessment of an exposure via runoff with the model Exposit assumes an extensive application of the product and considers a release from an area of one hectare into an adjacent water body with 100 m length. Due to these really different conditions a direct use of the common model scenario for applications in home gardens presents a really distinct worst case. Thus the predicted exposure concentrations based on an extensive use in conventional agriculture can be refined with a correction factor for the HuK (home gardening) scenario. Considering the provided report of Chapell et al. (2007) a correction factor of 0.32 is considered for the exposure via runoff. According to Chapple et al. a maximum of approximately 32 % roses and ornamental plants are cultivated

in German home gardens. As it cannot be excluded that the product is simultaneously applied to ornamentals like roses (group A) and other ornamental plants like box trees (group B) it is assumed that up to 32 % of the plants in a garden are exposed.

Table 6.5-2: Risk assessment for tebuconazole for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures, group A

Compound:	tebuconazole	
Application rate:	4 x 150 g a.s./ha, interval 7 days (interception 50 %)	
Intended use	Group A	
Relevant toxicity endpoint:	NOEC= 6.25 µg a.s./L (<i>P. promelas</i>)	
Relevant TER:	10	
Run-off		
Buffer zone	PEC / PEC * 0.32	TER
[m]	[µg/L]	
0	1.95 / 0.62	3.2 / 10.1
5	n.a.	-
10	n.a.	-
20	n.a.	-
Drainage		
Time of application	PEC / PEC * 0.32	TER
	[µg/L]	
Autumn/winter/early spring	not relevant for the intended uses in home gardens	
Spring/summer	0.86 / 0.28	7.27 / 22.3
Risk mitigation measures	not required (not applicable for applications in home gardens)	

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

Table 6.5-4: Risk assessment for tebuconazole for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures, group B

Compound:	tebuconazole	
Application rate:	4 x 100 g a.s./ha, interval 7 days (interception 50 %)	
Intended use	Group B	
Relevant toxicity endpoint:	NOEC= 6.25 µg a.s./L (<i>P. promelas</i>)	
Relevant TER:	10	
Run-off		
Buffer zone	PEC / PEC * 0.32	TER
[m]	[µg/L]	
0	1.30 / 0.42	4.8 / 14.9
5	n.a.	-
10	n.a.	-
20	n.a.	-
Drainage		
Time of application	PEC / PEC * 0.32	TER
	[µg/L]	
Autumn/winter/early spring	not relevant for the intended uses in home gardens	
Spring/summer	0.57 / 0.18	10.9 / 34.7
Risk mitigation measures	not required (not applicable for applications in home gardens)	

PEC: predicted environmental concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

6.5.4.3 Consideration of Metabolites

Please refer to the core assessment.

6.5.5 Overall conclusions

Based on the calculated concentrations of tebuconazole in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to tebuconazole according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat does achieve the acceptability criteria $TER \geq 10$ regarding the exposure via runoff and drainage for intended uses group A and B, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended uses of Bayer Garten Rosen-Pilzfrei in roses and ornamental plants according to the label. For group A risk mitigation measures (NW 608 with 5 m buffer) have to be applied.

It has to be considered that the risk for aquatic organisms via run-off is only acceptable, i.e. no risk mitigation measures are required, if an interception of 50% is assumed. Thus it has to be made sure that the application does not take place before adequate foliar development is reached to give the assumed interception.

Consequences for authorization:

Required Labelling and risk mitigation

NW 264 tebuconazole: *P. promelas* NOEC = 0.00625 mg/L
tebuconazole: *D. magna* NOEC = 0.01 mg/L

NW 265 tebuconazole: *Lemna gibba* NOEC = 0.0623 mg/L

Group A: NW608 (5 m)

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

Please refer to the core assessment.

Consequences for authorization:

none

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

The applicant has submitted data on the effect of Tebuconazole SE 025 on non-target arthropods.

6.7.1 Toxicity

Please refer to the core assessment.

Table 6.7-1: Toxicity of the product Tebuconazole SE 025 to non-target arthropods

Species	Substance	Exposure System	Results	Reference	Internal code
<i>Typhlodromus pyri</i>	Tebuconazole SE 025	Extended lab, 2D	LR ₅₀ > 680 g a.s./ha	Roehling, U. 28.02.2011 11 10 48 004 A	84712
<i>Aphidius rhopalosiphi</i>	Tebuconazole SE 025	Extended lab, 2D	LR ₅₀ > 60 g a.s./ha	Jans, D. 28.09.2011 CW11/043	84706
<i>Coccinella septempunctata</i>	Tebuconazole SE 025	Extended lab, 2 D	E/LR ₅₀ > 680 g a.s./ha	Roehling, U. 04.03.2011 11 10 48 002 A	84710
<i>Aleochara bilineata</i>	Tebuconazole SE 025	Extended lab, 2D	ER ₅₀ > 680 g a.s./ha	Roehling, U. 04.03.2011 11 10 48 003 A	84711

6.7.2 Justification for new endpoints

Please refer to the core assessment.

6.7.3 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

Exposure

Exposure of non-target arthropods living in non-target off-field areas to Bayer Garten Rosen-Pilzfrei Baymat will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000¹) as shown in the following equation:

$$\text{Off - field PER} = \frac{\text{Maximum in - field PER} \times \left(\frac{\text{drift percentile}}{100} \right)}{\text{vegetation distribution factor (vdf)}}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A vdf of 10 is recommended in the ESCORT 2 report when the off-field risk assessment is based on toxicity endpoints obtained in a test design with two-dimensional exposure but has been questioned. Germany considers a vdf of five as a more reliable value to extrapolate from a two dimensional exposure situation to the exposure situation in the field. The exposure estimation was based mainly on the ‘Retention Area Index’ (RAI) characterizing the total retention area of sprayed plant protection products in a canopy per base area. As a ‘realistic worst case scenario, meadow canopies < 20 cm height was chosen (Koch and Weisser, 2004²; German Federal Environment Agency UBA, 2006³). The derived vdf of 5 agrees well with

¹ BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abdrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

² Koch H and Weisser P, 2004. Die Gesamtoberfläche in Saumstrukturen als potentielle Retentionsfläche fuer Driftpartikel, Retention Area Index (RAI). Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 56, 65-69.

³ German Federal Environment Agency (UBA), 2006. Exposure calculation for arthropods in field border structures - selection of an appropriate ‘vegetation distribution factor’. Parma.

field data by Koch et al. (2003)⁴, who compared measured residues of plant protection products on two dimensional surfaces with the measured residues on meadows next to a treated area (factor of 4.4 to 6.5 between median spray residues on leaves when a standard nozzle was used for spray application). For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the vdf is not used.

Tebuconazole has a vapour pressure of $< 10^{-5}$ and is therefore classified as non volatile. Hence, deposition following volatilization has not to be considered. The input parameters for tebuconazole are given in Section 5.

For the results of all studies, a vegetation distribution factor has to be considered (study conducted in 2D environment).

Risk assessment

The assessment of the risk to non-target arthropods due to an exposure to Bayer Garten Rosen-Pilzfrei Baymat was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50 (L \text{ product} / \text{ha})}{\text{Off - field PER} (L \text{ product} / \text{ha})}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from Tier 1 tests on glass plates or TER off-field > 5 when the data were obtained in higher tier test (extended lab or field tests).

The results of the risk assessment are summarized in the following table.

Table 6.7-2: Risk assessment for tebuconazole (tested as Tebuconazole SE 025) for non-target arthropods for the entry route via spraydrift under the implementation of different risk mitigation measures, group A

Compound:		tebuconazole							
Intended use group:		A (4 x 150 g a.s./ha, interval 7 d; gardening plants > 50 cm (worst case assumed as no height is given))							
Drift-Percentile:		74.							
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PER_{off-field}; conventional and drift reducing technique				
	[m]	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.
3	0.41	0.331	-	-	0.331	n.a.	n.a.	n.a.	n.a.
Relevant toxicity endpoint: ER ₅₀ > 680 g a.s./ha (<i>T. pyri</i> and all other 3 tested species)									
Relevant TER: 5									
Buffer zone [m]					TER				
3					2054				
Risk mitigation measures					not required (not applicable for applications in home gardens)				

⁴ Koch H, Weisser P and Landfried M, 2003. Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 55, 181-188.

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

Table 6.7-2: Risk assessment for tebuconazole (tested as Tebuconazole SE 025) for non-target arthropods for the entry route via spraydrift under the implementation of different risk mitigation measures, group B

Compound:		tebuconazole							
Intended use group:		B (4 x 100 g a.s./ha, interval 7 d, gardening plants > 50 cm (worst case assumed as no height is given))							
Drift-Percentile:		74.							
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PER_{off-field}; conventional and drift reducing technique				
	[m]	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.
						[g/ha]			
3	0.41	0.221	-	-	0.221	n.a.	n.a.	n.a.	n.a.
Relevant toxicity endpoint: ER ₅₀ > 680 g a.s./ha (<i>T. pyri</i> and all other 3 tested species)									
Relevant TER: 5									
Buffer zone [m]					TER				
3					3081				
					n.a.				
					n.a.				
					n.a.				
Risk mitigation measures			not required (not applicable for applications in home gardens)						

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

6.7.4 Conclusion

Based on the calculated rates of tebuconazole in off-field areas, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to tebuconazole contained in Bayer Garten Rosen-Pilzfrei Baymat according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat achieve the acceptability criteria of TER ≥ 10 (Tier 1) resp. 5 (Higher tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants according to the label.

Consequences for authorization:

None

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

Table 6.8-1: EU agreed endpoints and new endpoints for earthworms and other soil macro- and mesofauna

Species	Substance	Exposure System	Results	Reference	Internal code
Earthworm					
<i>Eisenia fetida</i>	Tebuconazole	14 d, 10 % peat, mixed in	LC ₅₀ = 1381 mg a.s./kg LC _{50,corr.} = 690.5 mg a.s./kg**	Heimbach, F. 1987 HBF/Rg 82	29454
<i>Eisenia fetida</i>	ME 1,2,4-Triazol	14 d	LC ₅₀ > 1000 mg/kg	Heimbach, F. 1986 HBF/Rg 59	41735
<i>Eisenia fetida</i>	Tebuconazole	56 d, 5 % peat, mixed in	NOEC _{repro} = 3.2 mg a.s./kg [according to EU-LoEP: NOEC = 10 mg/kg Boden] ¹	Bätscher, R. 1999 729112	42925
<i>Eisenia fetida</i>	ME 1,2,4-Triazol	56 d, 10 % peat, mixed in	NOEC _{Repro} = 1 mg/kg soil dw	Moser, T. 04.03.2004 P13RR	52013
<i>Eisenia fetida</i>	Tebuconazole SE 025	56 d, 5 % peat, mixed in	NOEC = 241 mg Pr./kg soil dw* NOEC = 6.025 mg a.s./kg soil dw	Kratz, M.A. 09.12.2011 E 312 4302-5; KRA-RG-R-124/11	84718
Other soil non target macroorganism					
<i>Folsomia candida</i>	Tebuconazole	28 d	NOEC _{Repro} = 250 mg a.s./kg NOEC corr. = 125 mg a.s./kg EC _{50,Repro} > 1000 mg/kg	Wilhelmy, H., 1999 ICR64011	44232
<i>Folsomia candida</i>	1,2,4-Triazol	28 d	NOEC = 1.8 mg/kg soil dw	Moser and Scheffczyk, 2001 Report Nr: P31CR	48035
<i>Hypoaspis aculeifer</i>	Tebuconazole	14 d Labor	NOEC = 100 mg a.s./kg NOEC corr. = 50 mg a.s./kg	Hoogendoorn, G.M. 1999 B052HAE	44229

**Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (for substances with a log K_{ow} > 2 and 10% peat in the study).

* Endpoint differing from LoEP / New study submitted

1) the deviation from the NOEC of LoEP is caused by the usage different statistical tests. Whereas the RMS conducted a dunnett – test, the zRMS decided to use the Williams-test in order to recognize statistical significance. The Williams –test is regarded to be more sensitive when analyzing dose depending effects. As the Williams-test showed first significant deviations from control at a concentration of 10 mg/kg dw soil. Thus, the NOEC is 3.6 mg/kg dw soil (the next lowest concentration).

6.8.1 Justification for new endpoints

Please refer to the core assessment.

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances tebuconazole and the major soil degradation products are presented in the table below.

For Germany experimental data for representative soils (Fent et al. 1999; FKZ 360 03 018, UBA) are available which show a correlation between chemical characteristics and the penetration depth of plant protection products in the soil. For highly sorptive substances ($K_{f,oc} > 500$) it was shown that for a relevant time window of 100 days the major amount of the active substance reaches 1 cm soil depth. For less sorptive substances ($K_{f,oc} < 500$) a penetration depth of 2.5 cm was shown for soils representative for Germany. This exposition model is also supported by current research results with German soils (Poßberg et al. 2014; Toschki et al. 2013, 2014⁵). For German exposure assessment the applied soil depth is based on the stated before experimental data (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). Thus generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm⁻³ is assumed.

⁵ POßBERG C., B. SCHMIDT, M. ROß-NICKOLL, A. TOSCHKI, M. HAMMERS-WIRTZ & A. SCHÄFFER (2014): Fate of lindane and imidacloprid in Terrestrial Model Ecosystems (TMEs) during a sampling period of one year. SETAC Europe 24th Meeting Basel 2014

TOSCHKI A., U. HOMMEN, M. KLEIN, W. KÖNIG, S. PIEPER, C. POßBERG, J. RÖMBKE, M. ROß-NICKOLL, A. SCHÄFFER, B. SCHMIDT, B. SCHOLZ-STARKE & M. HAMMERS-WIRTZ (2014): Evaluation of the risk for soil organisms under real life conditions. SETAC Europe 24th Meeting Basel 2014

TOSCHKI A., U. HOMMEN, M. KLEIN, W. KÖNIG, S. PIEPER, C. POßBERG, J. RÖMBKE, M. ROß-NICKOLL, A. SCHÄFFER, A. SCHEFFCZYK, B. SCHMIDT, B. SCHOLZ-STARKE & M. HAMMERS-WIRTZ (2013): Evaluation of the risk for soil organisms based on the analysis of different soil layers. SETAC Europe 23rd Meeting Glasgow 2013.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Bayer Garten Rosen-Pilzfrei Baymat and tebuconazole was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC₅₀ value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50} \text{ (mg/kg)}}{PEC_{soil} \text{ (mg/kg)}}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to Bayer Garten Rosen-Pilzfrei Baymat and tebuconazole was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC \text{ (mg/kg)}}{PEC_{soil} \text{ (mg/kg)}}$$

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in ornamental plants group A (worst case)

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC _{SOIL} [mg/kg soil dw]	TER
<i>Eisenia fetida</i>	tebuconazole	Acute	690.5	1.8709	369.1
	tebuconazole	Chronic	3.2 * 10.0**	1.8709	1.7 5.3
	tebuconazole (derived from product study)	Chronic	6.025	1.8709	3.2
	Tebuconazole SE 025	Chronic	241	74.6707 (1.0 cm)	3.2
<i>Folsomia candida</i>	tebuconazole	Chronic	125	1.8709	66.8
<i>Hypoaspis aculeifer</i>	tebuconazole	Chronic	50	1.8709	26.7

TER values shown in bold fall below the relevant trigger.

*according to German assessment of the study by Bättscher (1999)

** according to list of endpoints

6.8.3 Higher tier risk assessment

The only point that can be considered for a higher tier assessment is the fact that an application in private gardens does not include the whole area. Considering the provided report of Chapell et al. (2007) a correction factor of 0.32 can be considered for the exposure. According to Chapple et al. a maximum of approximately 32 % roses and ornamental plants are cultivated in German home gardens. As it cannot be excluded that the product is simultaneously applied to ornamentals like roses (group A) and other ornamental plants like box trees (group B) it is assumed that up to 32 % of the plants in a garden are exposed. If the PEC soil

for the formulation (PEC = 74.67 mg/kg soil) is multiplied by a factor of 0.32 the calculated TER based on the NOEC of 241 mg/kg soil dw is 10.1 and hence above the acceptability criterion.

6.8.4 Overall conclusions

Based on the predicted concentrations of tebuconazole and Bayer Garten Rosen-Pilzfrei Baymat in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to tebuconazole and Bayer Garten Rosen-Pilzfrei Baymat according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat achieves the acceptability criteria $TER \geq 10$ according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. For the active substance tebuconazole and the formulation the long-term acceptability criterion $TER \geq 5$ is not met considering the calculated worst case PECsoil, however it is achieved considering a refined PEC soil. The results of the assessment overall indicate an acceptable risk for soil organisms due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants group A (worst case covering all other intended uses) according to the label.

Consequences for authorization:

none

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

Table 6.9-1: EU agreed endpoints and new endpoints for soil microorganisms

Substance	Test design	Results	Source	Internal code
Tebuconazole (tested as Tebuconazole 250 EW)	N-/C-transform.	No detrimental effects ($E < \pm 25\%$ of the control) on N-transformation (28 d) and C-mineralisation (28 d) up to 6.25 kg a.s./ha	Anderson, J.P.E. 17.04.2001 AJO/217601	68894

6.9.1 Justification for new endpoints

No new endpoints are considered.

6.9.2 Risk assessment

The evaluation of the risk for earthworms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The results of the risk assessment are summarized in the following table.

Table 6.9-2: Risk assessment for effects on soil micro-organisms

Test substance	Test concentration (adverse effects < 25%) [g/ha]	max. Application rate [g/ha]	Risk acceptable [yes/no]
tebuconazole	6250	4 x 150 = 600	yes

6.9.3 Overall conclusions

Based on the worst case application rate of tebuconazole, the risk to soil microbial processes following exposure to tebuconazole according to the GAP of the formulation Bayer Garten Rosen-Pilzfrei Baymat is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

none

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

The applicant has submitted data on the effect of Bayer Garten Rosen-Pilzfrei Baymat (Tebuconazole SE 025) on non-target terrestrial plants.

6.10.2 Toxicity

Table 6.10-1: New endpoints for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference	Internal code
6 species	Tebuconazole SE 025	Vegetative vigour 21 d	ER ₅₀ > 15 L Pr./ha (equivalent to 388 g a.s./ha)	Friedrich, S. 10.02.2011 11 10 48 502 S	84717
6 species	Tebuconazole SE 025	Seedling emergence 21 d	ER ₅₀ > 15 L Pr./ha (equivalent to 388 g a.s./ha)	Friedrich, S. 10.02.2011 11 10 48 501 S	84716

6.10.3 Justification for new endpoints

Please refer to the core assessment.

6.10.4 Risk assessment

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

$$PER_{\text{off-field}} = \text{Maximum } PER_{\text{in-field}} \text{ (including MAF)} \times \% \text{drift}$$

Tebuconazole has a vapour pressure of $< 10^{-5}$ Pa and is therefore classified as non volatile. Hence, deposition following volatilization has not to be considered.

Tier 1 assessment

The assessment of the risk to non-target arthropods due to an exposure to Bayer Garten Rosen-Pilzfrei Baymat is performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{ER50 (L \text{ product} / ha)}{\text{Off - field } PER (L \text{ product} / ha)}$$

The results of the risk assessment are summarized in the following table.

Table 6.10-2: Risk assessment for tebuconazole for non-target plants for the entry route via spray-drift and deposition under the implementation of different risk mitigation measures, group A

Compound:		tebuconazole							
Intended use group:		A (4 x 150 g a.s./ha, interval 7 d; gardening plants > 50 cm (worst case assumed as no height is given))							
Drift-Percentile:		74.							
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PER_{off-field}; conventional and drift reducing technique				
	[m]	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.
3	0.41	1.656	-	-	1.656	n.a.	n.a.	n.a.	n.a.
Relevant toxicity endpoint: ER ₅₀ > 388 g a.s./ha (vegetative vigour, all 6 test species) Relevant TER: 10									
Buffer zone [m]					TER				
3					234.4				
Risk mitigation measures					not required (not applicable for applications in home gardens)				

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

Table 6.10-2: Risk assessment for tebuconazole for non-target plants for the entry route via spray-drift and deposition under the implementation of different risk mitigation measures, group B

Compound:		tebuconazole							
Intended use group:		B (4 x 100 g a.s./ha, interval 7 d, gardening plants > 50 cm (worst case assumed as no height is given))							
Drift-Percentile:		74.							
Buffer zone	Entry via spraydrift		Entry via deposition following volatilization		PER_{off-field}; conventional and drift reducing technique				
	[m]	[%]	[g/ha]	[%]	[g/ha]	0% conv.	90% red.	75% red.	50% red.
3	0.41	1.104	-	-	1.104	n.a.	n.a.	n.a.	n.a.
Relevant toxicity endpoint: ER ₅₀ > 388 g a.s./ha (vegetative vigour, all 6 test species) Relevant TER: 10									
Buffer zone [m]					TER				
3					351.5				
Risk mitigation measures					not required (not applicable for applications in home gardens)				

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

n.a.: not applicable for home gardens

6.10.5 Conclusion

Based on the predicted rates of tebuconazole in off-field areas, the TER values describing the risk for non-target plants following exposure to tebuconazole according to the GAP of the Bayer Garten Rosen-Pilzfrei Baymat achieves the acceptability criteria $TER \geq 10$ according to commission implementing regulation

(EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Bayer Garten Rosen-Pilzfrei Baymat in ornamental plants according to the label.

Consequences for authorization:

none

