CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941)[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, Austria, for the pesticide active substance *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of *Aureobasidium pullulans* as a fungicide and bactericide on pome fruit. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

Aureobasidium pullulans strain DSM 14940 and strain DSM 14941, peer review, risk assessment, pesticide, fungicide, bactericide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Aureobasidium pullulans is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC Austria (hereinafter referred to as the 'RMS') received an application from bio-ferm Biotechnologische Entwicklung und Produktion GmbH for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2008/953/EC.

The RMS provided its initial evaluation of the dossier on *Aureobasidium pullulans* in the Draft Assessment Report (DAR), which was received by the EFSA on 17 December 2009. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR. The peer review was initiated on 27 February 2012 by dispatching the DAR for consultation of the Member States and the applicant bio-ferm Biotechnologische Entwicklung und Produktion GmbH.

Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct an expert consultation in the area of ecotoxicology and EFSA should adopt a conclusion on whether *Aureobasidium pullulans* can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of *Aureobasidium pullulans* strain DSM 14940 and strain DSM 14941 as bactericides on pome fruit as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No data gaps were identified for the section identity, physical and chemical properties and analytical methods.

In the mammalian toxicology section no data gaps or areas of concern were identified.

No data gaps or areas of concern were identified in the residue section. *Aureobasidium pullulans* could be considered a candidate for annex IV of Commission Regulation (EC) No 396/2005.

From the available scientific literature, the ubiquitous presence of *Aureobasidium pullulans* in the environment can be considered demonstrated. The level of natural occurrence of *Aureobasidium pullulans* strains DSM14940 and DSM14941 in soil is not precisely defined in the literature supplied in the dossier. The current soil exposure assessment is based on worst case assumptions and therefore new data would only be needed in case the soil exposure assessment needs refinement. None of the *ad hoc* studies presented to address the fate and behaviour of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in water can be considered representative of naturally occurring environmental conditions. Available scientific literature demonstrated the presence of *Aureobasidium pullulans* in various natural aquatic environments (fresh, marine and subglacial ice). The risk assessment is based on worst case PEC SW and no further data will be needed on the fate and behaviour for those risk assessment that can be concluded without further refinement.

A low risk was concluded for birds, wild mammals, fish, aquatic invertebrates, aquatic plants, bees and non-target arthropods. Data gaps were concluded for information to address the risk to algae, earthworms and soil microorganisms.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC Austria (hereinafter referred to as the 'RMS') received an application from bio-ferm Biotechnologische Entwicklung und Produktion GmbH for approval of the active substance *Aureobasidium pullulans*. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2008/953/EC.[6]

The RMS provided its initial evaluation of the dossier on *Aureobasidium pullulans* in the DAR, which was received by the EFSA on 17 December 2009. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR (Austria, 2012). The peer review was initiated on 27 February 2012 by dispatching the DAR to Member States and the applicant bio-ferm Biotechnologische Entwicklung und Produktion GmbH for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 2 July 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2008/953/EC of 8 December 2008 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of Aureobasidium pullulans and disodium phosphonate in Annex I to Council Directive 91/414/EEC. OJ No L 338, 17.12.2008, p. 62-63.

concluded that additional information should be requested from the applicant, and that the EFSA should organise an expert consultation in the area of ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in March 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide and bactericide on pome fruit, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (28 June 2012),
- the Evaluation Table (26 March 2013),
- the report of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of March 2013 containing all individually submitted addenda (Austria, 2013)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Aureobasidium pullulans strains DSM 14940 and DSM 14941 are fungi deposited at the culture collection of the German Collection of Microorganisms and Cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941 respectively. The strain DSM 14940 as well as strain DSM 14941 of *A. pullulans* were isolated at the university of Konstanz in 1989 from apple leaves of an untreated apple plantation.

The representative formulated product for the evaluation was 'Blossom Protect', a water dispersible granule (WG) containing 2.5 x 10^9 CFU/g (typical content of 250 g/kg for each strain) of each strain of *Aureobasidium pullulans* (DSM 14940 and DSM 14941).

The representative uses evaluated comprise field applications by spraying as a bactericide to control fire blight, *Erwinia amylovora,* on pome fruit. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance document was followed in the production of this conclusion: OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, Series on Pesticides No. 65, ENV/JM/MONO(2011)43 (OECD, 2011).

Strains DSM 14940 and DSM 14941 belong to *Aureobasidium pullulans* var. *pullulans.* The strains DSM 14940 and DSM 14941 are very closely related. Differentiation from each other can only be achieved by molecular biological methods focusing on the whole genome, such as random amplification of polymorphic DNA polymerase chain reaction (RAPD PCR) or by PCR using strain-specific primers. The microorganism content in the granular technical material used to produce the plant protection product should be between 5 x 10^9 CFU/g and 5 x 10^{10} CFU/g MCPA for both strains.

There is no evidence of direct relationships of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 to known plant, animal or human pathogens. Optimal growth temperatures for these strains are 29ºC (DSM 14940) and 27º C (DSM 14941). The strains are not able to grow at or above 35°C.

The MPCA dried granules as well as the supernatant from the fermentation, were analysed for toxins with a multi-mycotoxin screening method based on HPLC-ESI-MS/MS analysis and no toxins were detected.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity and technical properties of the active substance or the representative formulation. It should be noted that the spraying suspension should be stirred during application and that the active substance loss is 50% after one year storage at ambient temperature.
Acceptable methods are available for the determination of the microorganism in the technical material, formulated product and for the determination of the content of contaminating microorganisms.

For *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 no MRLs are required, there is no need for residue monitoring methods.

2. Mammalian toxicity

Toxicity studies

MPCA

No evidence of toxicity, infectivity or pathogenicity was observed in an acute oral toxicity study in rats after administration of one single oral dose of 4x10^8 colony forming units (CFU) per animal by

gavage; *Aureobasidium pullulans* did not cause any relevant effects in the acute pulmonary toxicity study in rats after intratracheal administration of $0.8x10^8$ CFU. The subcutaneous LD50 was estimated to be > $1.95x10^7$ CFU/rat (*Aureobasidium pullulans* DSM 14940) and > $1.12x10^7$ CFU/rat (*Aureobasidium pullulans* DSM 14941).

Aureobasidium pullulans DSM 14941 was negative in an *in vivo* mammalian erythrocyte micronucleus test. *Aureobasidium pullulans* strain DSM 14940 and 14941 were shown not to grow at 35°C or higher. Production of antibiotics or bactericidal substances is considered unlikely based on the available data. Microorganisms may have the potential to provoke sensitising reactions (in addition the MPCP showed sensitising potential).

MPCP

Acute oral toxicity is low (LD50 > 2000 mg/kg bw or 10^{10} CFU/kg bw; the same value was derived for an acute intraperitoneal study), as well as the acute inhalation toxicity (LC_{50} > 5.17 mg/L or $2.6x10^7$ mg/L).

Medical data

Some clinical cases are reported in the open literature for immunosuppressed, neutropenic, or predisposed patients depending on dialysis, malformations and multiples traumas. *Aureobasidium pullulans* is widespread in the environment and can be isolated from human hair, nails, and nasal fluid of healthy persons. To date, sensitisation or allergenic responses of workers handling the fungus have not been observed.

Reference values

Based on the results of the toxicity studies, no Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) or Acceptable Operator Exposure Level (AOEL) were derived.

Exposure estimates

The currently available exposure models are not appropriate for microorganisms. However, as *Aureobasidium pullulans* DSM 14940 and DSM 14941 did not elicit any signs of toxicity, infectivity and pathogenicity, an assessment of the operator, worker and bystander exposure is not necessary.

3. Residues

Based on the toxicity studies it was concluded that the setting of dietary toxicological values are not required, and therefore a quantitative risk assessment is not necessary for *Aureobasidium pullulans*. Moreover, the available data show that after application to pome fruit the density of *Aureobasidium pullulans* is still in the range of natural occurring densities. Hence an application of *Aureobasidium pullulans* at flowering according to the proposed GAP is not expected to increase the level of the natural population.

Aureobasidium pullulans could be considered a candidate for annex IV of Commission Regulation (EC) No 396/2005[7].

4. Environmental fate and behaviour

No information has been provided in relation to the potential interference of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 with the analytical systems for the control of the quality of

[7] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p.1-16

drinking water provided for in Directive 98/83/EC[8] (see specific Annex VI decision making criteria in Directive 2005/25/EC[9]). However, as these methods require pathogenic bacteria to be identified and confirmed as absent, it is probably unlikely that filamentous fungi or their conidia would interfere with methodologies used for such determinations.

No information was initially provided on the potential transfer of genetic material from *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 to other organisms. Further justification or data was required during the peer review. Applicant has performed a scientific literature search specifically on *Aureobasidium pullulans* and natural plasmid or horizontal gene transfer. A limited number of hits were obtained, none of which were considered relevant to the transfer of genetic material. The same search strategy applied to *Saccharomyces cereviesae* resulted in the identification of five relevant scientific papers confirming the adequacy of the search strategy employed. Being a fungus, *Aureobasidium pullulans sp*. is not expected to possess plasmids in their cytoplasm (only mitochondrial plasmids are known). Consequently it is not expected to possess the potential for transfer of genetic material.

The studies presented in the fate section that are not scientific peer reviewed literature, have not been performed under GLP. A certificate has been provided by the University of Natural Resources and Applied Life Sciences which self-certified to be an officially recognised testing facility fulfilling the requirements under points 2.2 and 2.3 of the introduction of Annex III of the Directive 91/414/EEC. However, it is not clear whether a self certificate is sufficient to satisfy the requirements of 'Official Recognition' (GEP) in Austria, and therefore a data gap is identified. No document has been presented for other testing facilities (eg. University of Konstanz). A data gap has been identified to provide documentary evidence that all testing facilities involved in the studies presented are officially recognised testing facilities fulfilling the requirements under points 2.2 and 2.3 of the introduction of Annex III of the Directive 91/414/EEC.

4.1. Fate and behaviour in the environment of the microorganism

Aureobasidium pullulans is naturally found throughout a wide range of habitats and temperatures over all kinds of substrates. The level of natural occurrence of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in the soil is not precisely defined in the literature supplied in the dossier (only levels in plant leaves and water are reported).

One study on the **persistence and multiplication in soil** of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in soil is available. According to this study CFU of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 increased over the first 7 d after application up to 182.5 % (at 22°C) of the initial nominal concentration (initial concentrations: 2.9×10^5 to 1.85×10^6 CFU) followed by a rapid decrease of CFU (< 2×10^3 CFU after 120 d). *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 showed higher survival rates in the sandy soil at 10 °C (4×10^3 CFU after 120 d). During the peer review it was noted that this study investigates persistence and multiplication in only two soils with very similar pH. However, the current soil exposure assessment is based on worst case assumptions, and therefore new data would only be needed if the soil exposure assessment needs refinement.

A number of scientific publications are available in the dossier on the occurrence of *Aureobasidium pullulans* in plant leaves. Whereas it is difficult to derive quantitative information on naturally occurring levels its ubiquitous presence can be considered demonstrated.

Levels in soil used for the risk assessment were reported as PEC soil (mg / kg and CFU / kg) considering the increase observed after its application in the laboratory experiments.

[8] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.98, p.32-54

[9] Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms. OJ L 90, 8.4.2005, p.1-34

Scientific literature and two *ad hoc* studies have been provided to address **persistence and multiplication in water** of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941. The two *ad hoc* studies have been performed in water in the absence of sediment. The first study investigated the fate of *Aureobasidium pullulans* in tap water, 0.9 % NaCl solution and sterilised pond water at 10 and 20 °C under indirect light. Proliferation was observed in the pond water system with rapid decline in the experiment incubated at 20 °C and no decline with the experiment performed at 10 °C. Experiments were interrupted after 28 d due to contamination of the control samples. The second study was performed in the dark with tap water and non-sterilised water from Lake Constance. Rapid decline was observed in both systems. None of these laboratory studies can be considered representative of naturally occurring environmental conditions and cannot be used to assess the persistence and multiplication of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in water. The applicant has also provided a number of scientific publications that show the presence of *Aureobasidium pullulans* in various natural aquatic environments (fresh, marine and subglacial ice). In surface water (rivers and lakes) a great stationary variability on the levels of *Aureobasidium pullulans* has been found, being the maximum concentrations usually found in autumn (supposedly due to run off from fallen tree leaves). Maximum levels encountered to naturally occur in fresh water are in the order of 10^4 CFU / L. RMS has calculated worst case PEC SW based on Ganzelmeier drift values. Levels calculated were in the order of 10^5 CFU/L for the single application and in the order of 10^6 for the multiple applications (5 x 7.5 10^{12} CFU / ha). No further data are necessary for risk assessments that can be concluded on basis of these worst case estimations.

Spores of *Aureobasidium pullulans* could be transported through the **air**. In a scientific publication, spores of *Aureobasidium pullulans* are reported to be one of the components of airborne spores in Thailand. *Aureobasidium pullulans* has also been found in the nasal mucus of healthy humans.

No information on *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 **mobility in soil** is available in the dossier. However, no groundwater risk assessment is necessary since *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are neither considered pathogenic nor toxic to humans.

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

No specific secondary metabolites of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 have been identified. The mode of action of the microorganism is considered to be associated with competition for nutrients and changes in the pH.

5. Ecotoxicology

A study was available which investigated the potential for *Aureobasidium pullulans* strain DSM 14941 to be infectious or pathogenic to birds. The data were sufficient to conclude a low risk to birds from infectivity and pathogenicity for *Aureobasidium pullulans* strain DSM 14941 and strain DSM 14940. In addition, a low risk from infectivity and pathogenicity to wild mammals was concluded on the basis of the available information (see Section 2).

Studies, performed with the formulated product (containing both strains), investigating toxicity, infectivity and pathogenicity to fish, aquatic invertebrates and aquatic plants were available. On the basis of the available information a low risk from infectivity and pathogenicity was concluded. A low risk to honey bees from infectivity and pathogenicity was concluded on the basis of a long-term laboratory study which was performed with the formulated product. A low risk to non-target arthropods was indicated with the available data.

No data investigating the effects of *Aureobasidium pullulans* strain DSM 14941 and strain DSM 14940 to soil microorganisms was available. Therefore, a data gap was concluded and the risk assessment for soil microorganisms could not be finalised.

The available earthworm and algae study were not performed under GLP nor were they taken from scientific peer reviewed literature. A certificate has been provided by the University of Natural Resources and Applied Life Sciences (who performed the studies) which self certified to be an officially recognised testing facility fulfilling the requirements under points 2.2 and 2.3 of the introduction of Annex III of the directive 91/414/EEC. However, it is not clear whether a self certificate is sufficient to satisfy the requirements of 'Official Recognition' (GEP) in Austria. Therefore, the data cannot be relied upon for risk assessment and data gaps have been concluded for further information to address the risk to algae and earthworms.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Aureobasidium pullulans strains DSM 14940 and DSM 14941	Data gap	Data gaps to address the risk to earthworms and soil microorganisms.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Not applicable	-	-	-	-	-

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Aureobasidium pullulans strains DSM 14940 and DSM 14941	Low risk indicated. Data gap for information to address the risk to algae.

6.4. Air

Compound (name and/or code)	**Toxicology**
Aureobasidium pullulans strains DSM 14940 and DSM 14941	Not acutely toxic in an acute pulmonary toxicity study

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Documentary evidence that all testing facilities involved in the studies presented are officially recognised testing facilities fulfilling the requirements under points 2.2 and 2.3 of the introduction of Annex III of the Directive 91/414/EEC (relevant for all representative uses evaluated ; no submission date proposed by the applicant; see sections 4 and 5).

- Data to address the risk to algae (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Data to address the risk to earthworms (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Data to address the risk to soil microorganisms (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- None

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The assessment for algae, earthworms and soil microorganisms could not be finalised with the available information.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

None identified.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Pome fruit**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[1]
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Chapter 1 Identity, Biological properties, Details of Uses, Further Information

Active micro-organism	*Aureobasidium pullulans* strains DSM 14940 and 14941
Function (e.g. control of fungi)	Fungicide and bactericide

Identity of the micro-organism (Annex IIM 1)

Name of the organism	*Aureobasidium pullulans* strains DSM 14940 and 14941
Taxonomy Species, subspecies, strain:	

Strain(s)	**DSM 14940 (CF10) and DSM 14941 (CF40)**
Species	***Aureobasidium pullulans* var. *pullulans***
Genus	***Aureobasidium***
Family	***Dothioraceae***
Order	***Dothideales***
Class	***Euascomycetes***
Phylum	***Ascomycota***
Kingdom	**Fungi**
Division	***Eucaryota***

Identification	Biological methods, molecular fingerprint
Culture collection	German Strain Collection for Micro-organisms (DSMZ)

Biological properties of the micro-organism (Annex IIM 2)

Origin and natural occurrence	Species *A. pullulans* is a ubiquitous, globally distributed saprophytic fungus (yeast). Strains *A. pullulans* DSM 14940 and 14941 were isolated in 1989 at the University of Konstanz from an untreated apple plantation ('Golden Delicious').
Target organism(s)	*Erwinia amylovora* (fire blight pathogen) on pome fruit
Mode of action	Increased resistance of host plants towards the fire blight pathogen by competition for nutrients and space
Host specificity	Not applicable, ubiquitous saprophytic phylloplane microorganism
Life cycle	Complex polymorphic life cycle consisting of various unicellular forms and a filamentous mycelium. Individual hyphae produce blastospores and chlamydospores. No sexual reproduction stage is known.
Infectivity, dispersal and colonisation ability	Both strains do not replicate at or above 35°C and are therefore not infective to humans

Relationships to known plant, animal or human pathogens	No relationships known
Genetic stability	Stable genotype maintained through standard procedures (stock cultures), mutation rates above the background levels are not expected
Production of relevant metabolites/toxins	No indications for production of toxins or toxic metabolites
Resistance/sensitivity to antibiotics used in human or veterinary medicine	Resistant towards Amphotericine, Fluconazole, Fluorocystine, and Griseofulvine. Sensitive to Itraconazole

Summary of intended uses

Crop and /or situation (a)	Member state or Country	Product name	F G or I (b)	Pest or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of MPCA (i)	method kind (f-h)	growth stage & season (j)	number min max	Interval Between Application (min)	kg MPCA/hl min - max	water l/ha min max	kg MPCA/ha CFU MPCA/ha min - max		
Pome fruit (NNNOK)	EU-North and EU-South	Blossom protect	F	*Erwinia amylovora* (ERWIAM)	WG	DSM 14940: $2.5*10^9$ [b] 50 to 500 g/kg [c] DSM 14941: $2.5*10^9$ [b] 50 to 500 g/kg [c] [a]	overall spray (high volume spray)	BBCH 61 – 69 spring	1 - 5	2 days	DSM 14940 + DSM 14941 [a]: 0.015 - 0.15 kg/hl [c]	1000 [d]	DSM 14940 + DSM 14941 [a]: 0,15 - 1.5 kg/ha [c] $7.5*10^{12}$ cfu/ha	-	Per meter crown height 500 l water should be used.[d]

The application rate is calculated for trees with 2 m crown height. In this case 1.5 kg MPCP (Blossom Protect) are used for 1000 L/ha water.

[a] The MPCP contains both strains in equal cell density.

[b] The specification in cfu (colony forming units)/ha is based on the guaranteed germination number of $5*10^9$ cfu/g ($5*10^{12}$ cfu/kg) in the MPCP.

[c] The MPCP (Blossom protect) contains 100 – 1000 g MPCA per kg.

[d] Usually, 1.5 kg MPCP is diluted in 1000 l/ha water for trees with 2 m crown height. If trees of lower crown height are treated, the spray-volume and product quantity has to be adjusted.

Explanation of a -m

a: The EU classification for crops (90/642/EEC).
b: Outdoor or field use (F), glasshouse application (G) or indoor application (I)
c: e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
d: e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR), water soluble powder (SP)
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, g/l or appropriate term for micro-organisms
j: Growth stage at last treatment (BBCH Monograph, Growth stage of plants, 1997, Blackwell, ISBN 3-8263-3152-4)
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

Further information

Production control	Growth parameters are controlled for initial and main cultures. Microscopic scrutiny enables the identification of possible contaminations. If contaminated cultures are detected they are immediately destroyed and disposed off. In addition to the above mentioned measures samples are taken during the different production steps and plated out on selective media to identify contaminating organisms.
Proposal for classification and labelling	Microorganisms may have the potential to provoke sensitising reactions.

Chapter 3 Effects on Human Health

Effects on human health (Annex IIM 5; IIIM 7)

Medical data and direct observation, e.g. clinical cases (Annex IIM 5.2)	*A. pullulans* DSM 14940 and DSM 14941 are not human or animal isolates (cannot grow at or above 35°C). Other strains of this species can replicate at 37°C and may act as opportunistic pathogens
Medical surveillance on manufacturing plant personnel	Limited database. No adverse health effects observed among laboratory and production plant personnel
Sensitisation/allergenicity observations, if appropriate	Sensitising (Microorganisms may have sensitising potential; in addition Buehler test performed with the MPCP was positive)
Acute toxicity, pathogenicity and infectiveness	Not acutely toxic, pathogenic, or infective
Acute oral toxicity, pathogenicity and infectiveness	*A. pullulans* DSM 14941: $LD_{50} > 4x10^8$ cfu/rat Blossom protect: $LD_{50} > 2000$ mg/kg bw or 10^{10} cfu/kg bw
Acute inhalation toxicity, pathogenicity and infectiveness	*A. pullulans* DSM 14941: $LC_{50} > 0.8x10^8$ cfu/rat (intratracheal) Blossom protect: $LC_{50} > 5.17$ mg/L or $2.6x10^7$ mg/L
Intraperitoneal/subcutaneous single dose	*A. pullulans* DSM 14940: $LD_{50} > 1.95x10^7$ cfu/rat *A. pullulans* DSM 14941: $LD_{50} > 1.12x10^7$ cfu/rat Blossom protect: $LD_{50} > 2000$ mg/kg bw or 10^{10} cfu/kg bw
Genotoxicity (Annex IIM 5.3.5)	Not mutagenic *in vivo* (mouse micronucleus test)
Cell culture studies (Annex IIM, point 5.3.6)	Not provided- not considered necessary
Information on short term toxicity and pathogenicity (Annex IIM, point 5.3.7)	Not provided- not considered necessary
First aid measures, medical treatment (Annex IIM, point 5.2.5)	No specific measures recommended
Specific toxicity, pathogenicity and infectiveness studies (Annex IIM, point 5.5)	Not provided- not considered necessary

Exposure scenarios

Operators	No AOEL was derived - not relevant
Workers	Not relevant at the conditions of application
Bystanders	No AOEL was derived - Not relevant

Chapter 4 Residues

Residues in or on treated products, food and feed (Annex IIM 6; IIIM 8)

Viable residues	The available data show that after application of Blossom Protect to pome fruit the amount of *Aureobasidium pullulans* is still in the range of natural occurring densities. Hence an application of Blossom Protect during flowering is not expected to increase the natural colonisation density of *Aureobasidium pullulans*. Data on potential residues of *Aureobasidium pullulans* are therefore not relevant. Moreover it was considered not necessary to propose toxicological reference values such as an Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD).
Non-viable residues	Not applicable

Chapter 5 Fate and Behaviour in the Environment (Annex IIM 7; IIIM 9)

Persistence and multiplication in soil	*Aureobasidium pullulans* is naturally found throughout a wide range of habitats and temperatures over all kind of substrates (including plant surfaces, in particular on leaves and fruits of apples and pear). The level of natural occurrence of *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 in the soil is not precisely defined in the literature supplied in the dossier (only levels on plant leaves and in water were reported) In soil, *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 increased over the first 7 d after application up to 182.5 % (at 22 °C) of the initial nominal concentration followed by a rapid decrease of CFU. *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 showed higher survival rates in the sandy soil at 10 °C. * The calculated worst-case initial soil PEC_S is 1.83 x 10^7 CFU MPCA kg^{-1} soil (single application) and 9.13 x 10^7 CFU MPCA kg^{-1} soil (5 applications)
Persistence and multiplication in water	*A. pullulans* is a ubiquitously distributed microorganism in aquatic environments (fresh, marine and sub-glacial ice). Maximum levels encountered to naturally occur in fresh water are in the order of 10^4 CFU / l. The calculated worst-case initial surface water PEC_S (drift entry only) is 7.3 x 10^5 CFU MPCA L^{-1} (single application) and 2.89 x 10^6 CFU MPCA L^{-1} (5 applications)
Persistence and multiplication in air	*A. pullulans* is ubiquitously distributed in the environment and frequently found in the atmosphere.
Mobility	No groundwater risk assessment is necessary since *Aureobasidium pullulans* strains DSM 14940 and DSM 14941 are neither considered pathogenic nor toxic to humans

* This information originates from an unpublished study for which the GLP/GEP status has not been demonstrated (data gap identified), however, the information is retained in the list of endpoints since it is potentially adverse for the risk assessment.

Chapter 6 Effects on Non-target Species (Annex IIM 8; IIIM 10)

Effects on birds	No signs of infectivity and pathogenicity of *Aureobasidium pullulans* strains DSM 14941 in birds under laboratory conditions exposed to a mean measured dose of 1.1 x 10^{10} cfu/kg bw/d (5 days administration, 30 days observation) LD50 > 2000 mg/kg bw, equivalent to 1.1 x 10^{10} cfu/kg bw
Risk assessment for birds	Safety factor > 27 (based on an Estimated Theoretical Exposure of 81.12 mg/kg bw equivalent to 4.1 x 10^{8} cfu/kg bw for an insectivorous bird according to the Guidance Document for Birds and Mammals (SANCO/4145/2000 (2002)
Effects on other terrestrial vertebrates (mammals)	No signs of infectivity and pathogenicity of *Aureobasidium pullulans* strains DSM 14941 and DSM 14940 in rats under laboratory conditions exposed to a mean measured dose of 2.8 x 10^{10} CFU/kg bw. LD50 > 2000 mg prod./kg bw, equivalent to > 2.8 x 10^{10} CFU/kg bw based on mean measured concentrations
Risk assessment for other terrestrial vertebrates (mammals)	Safety factor > 3.8 (based on an Estimated Theoretical Exposure of 1480.35 mg prod./kg bw equivalent to 7.4 x 10^{9} CFU/kg bw for an herbivorous mammal according to the Guidance Document for Birds and Mammals (SANCO/4145/2000 (2002); Refined assessment: Safety factor > 6 (based on an Estimated Theoretical Exposure of 886.13 mg prod./kg bw equivalent to 4.4 x 10^{9} CFU/kg bw for an herbivorous mammal taking into account an interception factor of 40 %)
Effects on fish:	No signs of infectivity or pathogenicity of *Aureobasidium pullulans* strains DSM14941 and DSM14940 at concentrations of 2.1 x 10^{6} CFU/L 96 h LC50: >100 mg prod./L equivalent to >2.1 x 10^{6} CFU/L, based on mean measured concentration NOEC 100 mg prod./L equivalent to >2.1 x 10^{6} CFU/L, based on mean measured concentration
Effects on freshwater invertebrates	No signs of infectivity or pathogenicity of *Aureobasidium pullulans* strains DSM14941 and DSM14940 at concentrations of up to 1.3 x 10^{9} CFU/L for 21 days. EC50mortality > 200 mg prod./L NOECmortality 200 mg prod./L EC50reproduction > 200 prod./L

	NOECreproduction > 200 mg prod./L equivalent to 1.3 x 10^9 CFU/L based on mean measured concentrations, based on adverse effects		
Effects on algae	No reliable information available.		
Effects on aquatic plants	E_rC50 and E_yC50 based on frond number and yield all >250 mg/L equivalent to 0.8 x 10^6 CFU/mL based on mean measured concentrations and adverse effects NOE_rC and NOE_yC based on frond number and yield all >250 mg/L equivalent to 0.8 x 10^6 CFU/mL based on mean measured concentrations and adverse effects (positive effects were observed)		
Risk assessment	Species	PEC	Safety factor
	Fish	2.89 x 10^6 CFU/L	> 0.72
		1.88 x 10^6 CFU/L (at 5m Buffer zone)	> 1.1
	Invertebrates (21 d)	2.89 x 10^6 CFU/L	> 450
	Aquatic plants	2.89 x 10^6 CFU/L	> 277
Effects on bees	22 days oral NOED 197.6 µg prod./bee, equivalent to 9.88 x 10^5 CFU/bee (highest tested concentration)		
Risk assessment	QH < 7.6		
Effects on terrestrial arthropods other than bees	*Typhlodromus pyri*: 7 + 7 days for mortality and reproduction LR50 > 3.82 x 10^{13} CFU/ha ER50repr. > 3.82 x 10^{13} CFU/ha		
Risk assessment	TER > 1, based on an in-field rate of 3.75 x 10^{13} CFU/ha.		
Effects on earthworms	No reliable information available.		
Risk assessment	Safety factor > 55, based on a predicted environmental concentration of 9.13 x 10^7 CFU/kg soil		
Effects on soil micro-organisms	No study available		
Risk assessment	No information available.		
Additional studies	No valid study available		
Risk assessment	No adverse effects on terrestrial plants indicated under normal conditions based on mode of action and biological properties.		

ABBREVIATIONS

λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ESI	electrospray ionisation
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
fd	feed
FIR	Food intake rate
FOB	functional observation battery

FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
ITS	internal transcribed spacer
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MATC	maximum allowable toxicant concentration
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MPCP	microbial pest control product
MPCA	active agent of the microbial pest control product
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet

MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OD	oil dispersion
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PCR	polymerase chain reaction
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RAPD PCR	Random Amplification of Polymorphic DNA Polymerase Chain Reaction
RNA	ribonucleic acid
rRNA	ribosomal ribonucleic acid
S	svedberg (10^{-13} s)
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis

UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
WP	wettable powder
yr	year