CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance *Pseudozyma flocculosa* strain ATTC 64874[1]

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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 the Netherlands, for the pesticide active substance *Pseudozyma flocculosa* strain ATTC 64874 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 *Pseudozyma flocculosa* strain ATTC 64874 as a fungicide on cucumber and roses in glasshouses. 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

Pseudozyma flocculosa strain ATTC 64874, peer review, risk assessment, pesticide, fungicide

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SUMMARY

Pseudozyma flocculosa strain ATTC 64874 is a new active substance for which in accordance with Article 2 of Commission Regulation (EU) No 188/2011 the Netherlands (hereinafter referred to as the 'RMS') received an application from Maasmond Westland b.a. for approval. Complying with Article 4 of Commission Regulation (EU) No 188/2011, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2002/305/EC.

The RMS provided its initial evaluation of the dossier on *Pseudozyma flocculosa* strain ATTC 64874 in the Draft Assessment Report (DAR), which was received by the EFSA on 11 March 2004. The peer review was initiated on 16 April 2004 by dispatching the DAR for consultation of the Member States and the applicant Maasmond Westland b.a. (The peer review was interrupted after the expert meeting.) In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant Atechno SA, who took over the responsibility from Maasmond Westland b.a. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received in March 2014 (Netherlands, 2014). The peer review was continued on 13 March 2014 by dispatching the updated DAR to Member States and the applicant Atechno SA for consultation and comments.

Following consideration of the comments received on the updated DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should adopt a conclusion on whether *Pseudozyma flocculosa* strain ATTC 64874 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.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of *Pseudozyma flocculosa* strain ATTC 64874 as a fungicide on cucumber and roses in glasshouses as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis data gaps were identified for batch analysis data on secondary metabolites/toxins, a full data package for the chemical compounds involved in the mode of action and for methods of analysis.

In the area of non-dietary exposure and mammalian toxicology, no detailed analysis of the batches used in the toxicity studies was available and data gaps were identified on the content of contaminating micro-organisms in the technical material leading to an issue that could not be finalised. The operator and worker risk assessment to the microorganism cannot be finalised until reliable information on respiratory toxicity, pathogenicity and infectiveness is available. The risk assessment for secondary metabolites/toxins cannot be finalized either until the issues identified in Section 1 and 4 with regard to the compounds involved in the mode of action and other secondary metabolites/toxins is addressed.

For residues and consumer exposure the risk assessment cannot be finalised until the issues identified in Section 1 with regard to the compounds involved in the mode of action and with regard to other secondary metabolites are resolved.

The level of reporting on the available investigations on the competitiveness of *Pseudozyma flocculosa* strain ATCC 64874 in growing media and water was not that needed for the results reported to be considered reliable for regulatory use, thus results in an assessment not finalised. The assessment of the potential for *Pseudozyma flocculosa* strain ATCC 64974 to produce metabolites, that would trigger environmental exposure and risk assessments including a groundwater exposure assessment, could not be finalised with the available information in the dossier.

A low risk for birds, mammals, bees, non-target arthropods, earthworms, soil microorganisms and non-target plants was concluded. However, the assessment of infectivity and pathogenicity of *Pseudozyma flocculosa* strain ATCC 64874 to aquatic organisms could not be finalised with the available information. Pending on the outcome of the data gaps for the identification of secondary metabolites and toxins which may either be present in the formulated product or formed in the environment, further information may be required to address the risk to aquatic organisms and to address the potential for bioaccumulation in fish.

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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 up to 8 months (where additional information is required to be submitted by the applicant) in accordance with Article 8(3).

In accordance with Article 2 of Commission Regulation (EU) No 188/2011 the Netherlands (hereinafter referred to as the 'RMS') received an application from Maasmond Westland b.a. for approval of the active substance *Pseudozyma flocculosa* strain ATTC 64874. Complying with Article 4 of Commission Regulation (EU) No 188/2011, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2002/305/EC.[6]

The RMS provided its initial evaluation of the dossier on *Pseudozyma flocculosa* strain ATTC 64874 in the DAR, which was received by EFSA on 11 March 2004 (Netherlands, 2004). The peer review was initiated on 16 April 2004 by dispatching the DAR to Member States and the applicant Maasmond Westland b.a for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by 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 peer review was interrupted after the M 01 expert meeting in January 2007. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant Atechno SA, who took over the responsibility from Maasmond Westland b.a. for the active substance. The RMS's evaluation of the additional information was provided in the format of an updated DAR, which was received in March 2014 (Netherlands, 2014). The peer review was continued on 13 March 2014 by dispatching the updated DAR to Member States and the applicant Atechno SA for consultation and comments.

[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 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 L 53, 26.2.2011, p. 51-55.

[6] Commission Decision 2002/305/EC of 19 April 2002 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of clothianidin and *Pseudozyma flocculosa* in Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market. OJ L 104, 20.4.2002, p. 42-43.

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 14 July 2014. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and there was no need to conduct an expert consultation.

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 and the additional information to be submitted by the applicants, 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 August 2015.

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 on cucumber and roses in glasshouses 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, 2015) 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 and the revised DAR,
- the Reporting Tables (10 December 2004 and 21 July 2014),
- the Evaluation Tables (1 February 2017 and 9 September 2015)
- the report(s) 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 August 2015 containing all individually submitted addenda (Netherlands, 2015)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE IDENTITY OF THE MICROORGANISM AND THE PROPERTIES OF THE FORMULATED PRODUCT

The strain under review is ATCC 64874. It was isolated from the leaves of white clover in Canada in 1986.

The representative formulated product for the evaluation was 'Sporodex L' a suspension concentrate formulation (SC) containing 3 x 10^{11} CFU/L.

The representative use evaluated is on glasshouse cucumbers and roses. Full details of the GAP can be found in the list of end points in Appendix A.

Psedozyma flocculosa strain ATCC 64874 was discussed in the PRAPeR M01 meeting of experts in January 2007.

CONCLUSIONS OF THE EVALUATION

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

Strain ATCC 64874 is kept in the following culture collections American Type collection (ATCC), Rockville, Maryland ATCC 64874 (Type culture), National Collection of fungus Cultures, Canada Dept of Agric. (DAOM), Ottawa ON DAOM 196992 (Type culture), University of Alberta Mold Herbarium (UAMH), Edmonton AL UAMH 5743, Centraal bureau voor Schimmelcultures (CBS), Delft, The Netherlands (Yeast Division) CBS 167.88, Agric. Research Service Culture Collection (NRRL) USDA (communicated bij CBS) Nat. Center Agric. Utilization Research, Peoria Illinois NRRL Y-17627

Batch data were not provided for microbial contamination to show compliance with the OECD position paper. Acceptable data were also not available for the production of secondary metabolites/toxins in both the fermentation process and on plants. It was also noted that the mode of action is by the production of fungicidal chemicals and as such a full chemical data package would be needed. Data gaps have been identified for the above mentioned issues.

The claimed storage period for the formulation is 3 months at -18 °C and this is supported by the available storage data. There is no information on the stability of the chemical compounds that are involved in the mode of action.

No data gaps were identified for the formulation 'Sporodex L'.

Methods of analysis for residues of the chemicals involved in the mode of action are not available for plants, environmental matrices and body fluids and tissues.

2. Mammalian toxicity

The applicant submitted a basic set of valid acute toxicity studies to evaluate the risk of the microorganism *Pseudozyma flocculosa* strain ATTC 64874. However, no detailed analysis of the batches used in the toxicity studies is available and data gaps have been identified in Section 1 on the content of contaminating micro-organisms in the technical material leading to an issue that could not be finalized.

In these acute toxicity studies, performed with the product or active substance *Pseudozyma flocculosa* strain ATTC 64874, there was no clear indication for acute toxicity of *Pseudozyma flocculosa* strain ATTC 64874 following oral or intraperitoneal administration of high dose levels to rats. *Pseudozyma flocculosa* strain ATTC 64874 did not show the potential to invade the body of the rats and did not proliferate therein excluding the risk of infection following oral or intraperitoneal administration.

Following intratreacheal administration two acute toxicity studies were available. In the main study that included pathogenicity and infectiveness the high mortality raised concerns. In the second study, where pathogenicity and infectiveness were not investigated no mortalities were observed. Because of the limitations and inconsistencies in and between the studies no conclusion could be drawn on respiratory toxicity, pathogenicity and infectiveness and a data gap was identified.

No study on the sensitisation potential of *Pseudozyma flocculosa* strain ATTC 64874 was submitted. However, microorganisms in general are considered sensitising unless there is sufficient experimental evidence that there is no concern. The product is not an eye irritant but is a skin irritant.

Based on the lack of significant toxicity, infectivity or pathogenicity in the available toxicological studies via the oral route, the setting of dietary reference values for the microorganism *Pseudozyma flocculosa* strain ATTC 64874 is not needed. However, reliable information on respiratory toxicity, pathogenicity and infectiveness was not available, so a conclusion cannot be drawn for operator and worker risk assessment to the microorganism leading to an issue that could not be finalised.

Concerning **secondary metabolites/toxins** that could be present in the formulated product or formed in the environment relevant data gaps were set in Sections 1 and 4. *Pseudozyma flocculosa* strain ATTC 64874 is known to be capable of producing certain secondary metabolites/toxins (i.e. fungitoxic unsaturated C-17 fatty acids and acyclic norterpenes). Although the RMS considered these metabolites of no toxicological concern, EFSA considered the information on the toxicity of these metabolites very limited to reach any conclusion on the toxicity profile. The EFSA BIOHAZ Panel could not recommend *Pseudozyma flocculosa* for the qualified presumption of safety (QPS) list because the body of knowledge was insufficient (EFSA BIOHAZ Panel, 2013). Overall, the dietary and non-dietary risk assessment to secondary metabolites/toxins cannot be finalised until the issues identified in Sections 1 and 4 with regard to the compounds involved in the mode of action and other secondary metabolites is addressed.

3. Residues

For residues and consumer exposure the risk assessment cannot be finalised as the levels of secondary metabolites/toxins in plants has not been elucidated.

4. Environmental fate and behaviour

Satisfactory information has been provided in relation to potential interference of *Pseudozyma flocculosa* strain ATTC 64874 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC[7] (see specific Annex for decision making criteria in Council Directive 2005/25/EC[8]). As these methods require pathogenic bacteria to be identified and confirmed as absent, it was considered unlikely that a yeast-like fungus would interfere with methodologies used for such determinations.

Being a mitotic asexual basidiomycete yeast like fungus (no sexual recombination or meiosis having been observed in its life cycle), in which plasmids are absent from the cell cytoplasm (only mitochondrial plasmids are known), *Pseudozyma flocculosa* strain ATTC 64874 would not be expected to have the potential for transfer of genetic material to other organisms.

4.1. Fate and behaviour in the environment of the microorganism

Specific studies on the **persistence and multiplication in a sterilised peat moss based medium** of *Pseudozyma flocculosa* strain ATTC 64874 were reported to indicate that 5 days after application it was undetectable using a PCR technique. These data provide indications that *Pseudozyma flocculosa*

[7] 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.

[8] 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.

strain ATTC 64874 may respect the uniform principles criterion of not being expected to persist in soil in concentrations considerably higher than the natural background levels, taking into account repeated applications over the years.

With respect to the **persistence and multiplication in water** specific studies in the dossier indicated that *Pseudozyma flocculosa* strain ATTC 64874 was not able to survive in aquatic environments (glasshouse hydroponic nutrient media) under favourable conditions. However EFSA considers that the reporting of these studies (both those on peat moss and on hydroponic nutrient media) was insufficiently detailed to provide the necessary confidence to use the results in a regulatory assessment. Decision makers should be aware that these investigations were not carried out in quality assured officially recognised testing facilities or GLP / GEP facilities. This has been identified as a data gap (see Section 7). PEC surface water were calculated considering emission through drainage of a hydroponic nutrient solution from a glasshouse to an adjacent surface water body (see Appendix A).

Regarding **mobility**, the available poorly reported studies described above in relation to persistence and multiplication indicated that *Pseudozyma flocculosa* strain ATTC 64874 had restricted potential to grow in soil and water. Horizontal spread over the soil and to above ground plant parts by conidia was indicated to occur via rain splash but to a limited extent, with travel distances being 1-2m.

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

Pseudozyma flocculosa has been reported as producing antibiotic metabolites. In the dossier, originally it was indicated that fungitoxic unsaturated C-17 fatty acids and acyclic norterpenes cause the same symptoms of antagonism as the organism when tested alone on mildew. Subsequently it has been hypothesisied that the metabolite flocculosin is responsible for the antagonism and that the conditions of handling exogenous compounds in the earlier peer reviewed scientific literature investigations had led to the formation of the identified unsaturated C-17 fatty acids and acyclic norterpenes from flocculosin. Experiments reported in the more recent peer reviewed scientific literature (that followed gene expression of genes that code flocculosin) have indicated that flocculosin is not produced when the organism is being antagonistic to powdery mildew. Therefore whilst flocculosin (and unsaturated C-17 fatty acids and acyclic norterpenes) exhibit antibiotic activity against mildew, it appears that *Pseudozyma flocculosa* strain ATTC 64874 is antagonistic to mildew without producing flocculosin.

Regarding flocculosin it may be that it does not fulfil the criteria according to Part B Section 7 (iv) of Directive 91/414[9] namely:

- the relevant metabolite is stable outside the micro-organism;
- a toxic effect of the relevant metabolite is independent of the presence of the micro-organism;
- the relevant metabolite is expected to occur in the environment in concentrations considerably higher than under natural conditions.

However as a systematic literature review regarding microbial metabolites of *Pseudozyma flocculosa* that included the search term flocculosin as well as toxin and metabolite more generally was not available, EFSA considers the potential for *Pseudozyma flocculosa* strain ATTC 64874 to produce metabolites in relation to these criteria remains an open issue in relation to the need for further data requirements and the corresponding risk assessment according to Commission Regulation (EU) No 544/2011, part A, Section 7 (standard data requirements and assessment mandatory for chemical plant protections active substances). See Section 7 of this conclusion regarding this data gap. The issue is also still open whether the product contains metabolites, present consequent to the manufacturing process (see Section 2 and Section 7).

[9] Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC). OJ L 230, 19.8.1991, p.1 ff

5. Ecotoxicology

As the representative use of *Pseudozyma flocculosa* strain ATTC 64874 is to cucumbers and roses grown in glasshouses a low risk for birds, mammals, bees, non-target arthropods, earthworms, soil microorganisms and non-target plants was concluded.

The available literature search did not reveal any references suggesting that *Pseudozyma flocculosa* strain ATTC 64874 is infectious/pathogenic to aquatic organisms. However, no data were available to assess the possibility of infectivity or pathogenicity of *Pseudozyma flocculosa* strain ATTC 64874 to fish, aquatic invertebrates and algae. As exposure to surface water cannot be excluded, a data gap was identified for suitable data. Therefore, the assessment cannot be finalised. The RMS does not agree on the need for data as they suggest that the lack of indications of infectivity and pathogenicity in the available literature search is sufficient to conclude a low risk.

Data gaps were identified for the identification of secondary metabolites and toxins which are either present in the formulated product (see Section 1) or formed in the environment (see Section 4). Pending on the outcome of these data gaps further information may be required to address the risk to aquatic organisms and to address the potential for bioaccumulation in fish.

For the representative uses exposure of sewage treatment organisms cannot be excluded. A data gap was therefore identified for information to address the risk to sewage treatment processes from exposure to *Pseudozyma flocculosa* strain ATTC 64874 and any relevant secondary metabolites and toxins. The RMS does not agree on the data gap as they consider that the presence of *Pseudozyma flocculosa* strain ATTC 64874 will only add to the numerous microorganisms already present in sewage treatment plants.

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**
Pseudozyma flocculosa strain ATCC 64874	Not competitive in the soil environment, though there is a data gap relating to the extent of reporting and quality of the available information	No data, not required for the representative use.
No metabolites identified, though there is a data gap in relation to metabolites and toxins, see Section 7.	-	-

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**
None identified, though there is a data gap in relation to metabolites and toxins, see Section 7.	-	-	-	-	-

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Pseudozyma flocculosa strain ATCC 64874	Data gap to assess the potential for infectivity and pathogenicity of *Pseudozyma flocculosa* strain ATCC 64874 to aquatic organisms.
No metabolites identified, though there is a data gap in relation to metabolites and toxins, see Section 7.	Pending on the outcome of the data gaps for the identification of secondary metabolites and toxins, further information may be required to address the risk to aquatic organisms.

6.4. Air

Compound (name and/or code)	**Toxicology**
Pseudozyma flocculosa strain ATCC 64874	No reliable information available (data gap).

7. List of studies to be generated, still on-going 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).

- 5 batch analysis are required complying with the OECD issue paper (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).

- Data on the production of toxins/secondary metabolites both in the fermentation process used for manufacture and on plants or in growing media are insufficient. This data has to be GLP compliant regarding the fermentation process. Furthermore as the mode of actions is reported to be by the production of fungicidal chemicals a full data package including a literature review regarding metabolites reported to be produced by the species is needed. Investigations would then need to identify which chemicals are produced by strain ATTC 64874 and consequently address all areas of the risk assessment for each chemical identified (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1–5).

- Methods of analysis for the compounds responsible for the mode of action in plants, environment matrices and in body fluids and tissues (relevant for all representative uses evaluated ; submission date proposed by the applicant: unknown; see Section 1)

- Reliable information on respiratory toxicity, pathogenicity and infectiveness (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).

- Data on the persistence and viability in soil of *Pseudozyma flocculosa* strain ATCC 64874 and data on potential levels, and viability of conidia and on the ability of *Pseudozyma flocculosa* strain ATCC 64874 to compete with other microorganisms in the drainage water of greenhouses after several applications, reported in sufficient detail, where there was evidence that the work had been carried out in a quality assured officially recognised testing facility or GLP / GEP facility was not available. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).

- Information is required to assess the infectivity and pathogenicity of *Pseudozyma flocculosa* strain ATCC 64874 to fish, aquatic invertebrates and algae (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).

- Pending on the outcome of the data gaps for the identification of secondary metabolites and toxins which are either present in the formulated product (see Section 1) or formed in the environment (see Section 4), further information may be required to address the risk to aquatic organisms and to address the potential for bioaccumulation in fish (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).

- Information to address the risk to sewage treatment organisms from exposure to *Pseudozyma flocculosa* strain ATTC 64874 and any relevant secondary metabolites and toxins (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 proposed.

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 compliance of the batches used in the toxicity studies compared to the technical material for which no information on the content of contaminating micro-organisms is available.

2. The operator and worker exposure to the microorganism cannot be finalised because reliable information on respiratory toxicity, infectiveness and pathogenicity is not available.

3. The non-dietary and consumer risk assessment to secondary metabolites/toxins cannot be finalised due to the data gaps identified in Sections 1 and 4.

4. The level of reporting on the available investigations on the competitiveness of *Pseudozyma flocculosa* strain ATCC 64874 in growing media and water was not that needed for the results reported to be considered reliable for regulatory use.

5. The assessment of the potential for *Pseudozyma flocculosa* strain ATCC 64874 to produce metabolites that would trigger environmental exposure and risk assessments including a groundwater exposure assessment could not be finalised with the information in the applicants dossier.

6. The assessment of infectivity and pathogenicity of *Pseudozyma flocculosa* strain ATCC 64874 to aquatic organisms could not be finalised.

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.

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		**Glass house cucumbers**	**Glass house roses**
Operator risk	Risk identified		
	Assessment not finalised	X[1,2,3]	X[1,2,3]
Worker risk	Risk identified		
	Assessment not finalised	X[1,2,3]	X[1,2,3]
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised	X[3]	X[3]
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		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised	X[4,5,6]	X[4,5,6]
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	X[5]	X[5]
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

Active micro-organism	*Pseudozyma flocculosa*
Function (e.g. control of fungi)	Biocontrol agent with fungicidal action against powdery mildew

Identity of the micro-organism

Name of the organism:	*Pseudozyma flocculosa*
Taxonomy:	The genus *Pseudozyma* belongs to the family Ustilaginales, Basidiomycetes *Pseudozyma flocculosa* is a basidiomycetous yeast-like epiphyte. It is the anamorphic (imperfect) state of a smut-like fungus in the family Ustilaginales.
Species, subspecies, strain:	*Pseudozyma flocculosa* strain ATCC 64874
Identification:	The fungus was first named as *Stephanoascus flocculosa.* Based on physiological, biochemical and molecular studies the fungus was reclassified in the genus *Pseudozyma.*
Culture collection:	The strain is deposited at the following culture collections: • American Type collection (ATCC), Rockville, Maryland *ATCC 64874* (Type culture) • National Collection of fungus Cultures, Canada Dept of Agric. (DAOM), Ottawa ON *DAOM 196992* (Type culture) • University of Alberta Mold Herbarium (UAMH), Edmonton AL *UAMH 5743* • Centraal bureau voor Schimmelcultures (CBS), Delft, The Netherlands (Yeast Division) *CBS 167.88* • Agric. Research Service Culture Collection (NRRL) USDA (communicated bij CBS) Nat. Center Agric. Utilization Research, Peoria Illinois *NRRL Y-17627*

Biological properties of the micro-organism

Origin and natural occurrence:	*Pseudozyma flocculosa* strain ATCC 64874 is a wild strain and was isolated from the leaves of white clover, *Trifolium pratense* infected with powdery mildew, *Erysiphe polygoni*, collected in rotation plots of the Agriculture and Agri-Food Canada Research Centre at Harrow, Ontario [Essex county] in August 1986. The first description of this fungus was made by Traquair, Shaw and Jarvis in 1988.
Target organism(s):	Several species of powdery mildew.
Mode of action:	The fungus kills the host upon contact by secretion of fungitoxins. Host cells collapse and die rapidly.
Life cycle:	A sexual reproductive state of *Pseudozyma flocculosa* has not been found. The fungus multiplies by budding and extension of pseudomycelial filaments. The fungus colonises leaves in absence of powdery mildew and undergoes rapid reproduction when the host is present.

Host specificity:	*Pseudozyma flocculosa* is found to be a hyperparasite of several species of powdery mildew.
Production of metabolites:	In culture filtrates a number of antifungal fatty acids were isolated. Open for further data.
Resistance:	The development of resistance is not probable.
Production:	The production of *Pseudozyma flocculosa* takes place under sterile conditions in a liquid medium. Open for batch analysis
Production control:	During the production a sterility control and the number of conidia is determined. After the production the number of conidia produced, the absence of human and other contaminants and the integrity and quality of the active ingredient is determined. Open for batch analysis

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 as (i)	method kind (f-h)	growth stage & season (j)	number min max	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Glass-house cucumbers	The Netherlands	SPORODEX L	G	Powdery mildew (*Sphearotheca fuliginea)*	SC	13 g/L (3 x 10^{11} CFU/L)	high volume spraying overall	Application when powdery mildew is present	1-52	1 week	0.0065 (1.5 x 10^{11} CFU/hL)	1000 - 1500	0.065-0.0975 1.5 - 2.25 x 10^{12} CFU/ha	-	
Glass-house roses	The Netherlands	SPORODEX L	G	Powdery mildew (*Sphearotheca pannosa var. rosae)*	SC	13 g/L ((3 x 10^{11} CFU/L)	high volume spraying overall	Application when powdery mildew is present	1-52	1 week	0.0065 (1.5 x 10^{11} CFU/hL)	1000 - 1500	0.065-0.0975 1.5 - 2.25 x 10^{12} CFU/ha	-	

(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 plant - 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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Chapter 2.2 Methods of Analysis

Analytical methods for the micro-organism (Annex IIA, point 4.1)

Manufactured micro-organism (principle of method)	Multiplex PCR-system
Impurities and contaminating micro-organisms in manufactured material (principle of method)	bioassay
Plant protection product (principle of method)	1. Genetic stability monitoring of the mother strain by microsatellite/PCR test. 2. Pre-fermentation sterility control in liquid medium. (method-CQa/001/1). 3. Active ingredient monitoring (method-CQa 009/1) 4.Integrity of production culture (Bioassay and Multiplex PCR) 5. Contaminant monitoring

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (Annex IIA, point 4.2)

of the active micro-organism (principle of method)	Residues of *P. flocculosa* can be detected with: 1. Plate count method (CQa/009/1). 2. PCR test Soil, water, air: not required
of relevant metabolites (principle of method)	Open for methods of analysis for the compounds involved in the mode of action.

Chapter 2.3 Impact on Human and Animal Health

Medical data, surveillance and observations (Annex IIB, point 5.1)	Limited data: No adverse effects observed among researchers, production workers and field technicians.
Acute toxicity (Annex IIB, point 5.2.1 and 5.2.2)	
Pathogenicity:	No evidence of adverse effects from acute intraperitoneal study. Inconclusive results in intratracheal study; reliable information missing.
Infectivity:	No evidence of adverse effects from acute intraperitoneal study. Inconclusive results in intratracheal study; reliable information missing.
Toxicity:	Rat LD_{50} oral: > 10^8 CFU/animal Rat LD_{50} intratracheal: Inconclusive; reliable information missing Rat LD_{50} i.p.: > $3.5x10^7$ CFU/animal
Irritation, Sensitisation	Rabbit: no irritating effects on the eye Skin irritant.
Genotoxicity (Annex IIB, point 5.2.3, 5.4 and 5.5)	Limited information to conclude on the toxicological profile of secondary metabolites/toxins.
Cell culture studies (Annex IIB, point 5.2.4)	Waiver accepted.
Short term toxicity (Annex IIB, point 5.2.5)	Pending on the final conclusion on acute respiratory toxicity.
First aid measures, medical treatment (Annex IIB, point 5.2.6)	Sufficient data submitted.

Specific toxicity, pathogenicity and infectiveness studies (Annex IIB, point 5.5)	Depending on the results of the requested information on short-term toxicity, more information on chronic toxicity, pathogenicity and infectiveness, carcinogenicity and/or reproductive toxicity may be required.

Acceptable exposure scenarios (including method of calculation)

Operator	Based on the submitted data risk evaluation was not possible.
Workers	Based on the submitted data risk evaluation was not possible.
Bystanders	Exposure considered negligible.

Classification and proposed lab (Annex IIB, point 4)

with regard to toxicological data	All micro-organisms should be regarded as potential sensitisers and be labelled as "Micro-organisms may have the potential to provoke sensitising reactions". Skin irritant. It should be noted that the available data were considered unsuitable for classification for acute inhalation toxicity.

Chapter 2.4 Residues

Residues (Annex IIA, point 6 and Annex IIIA, point 8)

	For residues and consumer exposure the risk assessment cannot be finalised until the issues identified in Section 1 with regard to the compounds involved in the mode of action and with regard to other secondary metabolites/toxins are resolved.

Fate and Behaviour in the Environment

Persistence and multiplication in soil	Under favourable conditions in an experiment using soil growth medium and PCR technology the fungus was undetectable after 5 days. *P. flocculosa* cannot develop in a soil substrate and was also completely degraded (along with its DNA). Note there is a data gap for such an experiment that was appropriately quality assured in the way required by the regulations
Persistence and multiplication in water	In a nutrient solution the population of *P. flocculosa did* not persist or was able to compete with other micro-organisms present in the solution. From an initial population of 5 X 10^6 CFU/ml, *P. flocculosa* residues dropped sharply by more than 50 times in one hour and steadily over time to be completely absent after 72 h based on plate count. PCR analysis confirmed these results whereby no residues could be distinguished after 48 h. This indicates that not only could *P. flocculosa* cannot survive in an aqueous environment for more than 48 h but that it was also completely degraded (along with its DNA). Note there is a data gap for such an experiment that was appropriately quality assured in the way required by the regulations
Persistence and multiplication in air	Conidia of *Pseudozyma flocculosa* are suitable for aerial distribution as conidia are wind dispersed in short distances. Exposure to air following emission from a greenhouse may occur.
Mobility	Conidia of *Pseudozyma flocculosa* will remain in the top layers of the soil due to adherence to soil particles.

Soil exposure

Colony Forming Units [CFU/g soil d.w.] (Annex IIIB, point 7.1.1; Annex IIIB, point 9)

Application rate	Max. 7.5 L/ha corresponding with 2.25 x 10^{12} CFU/ha

Predicted environmental density [CFU/g soil d.w.]

	Single application actual	Maximum predicted CFUs considering	Multiple application actual	Maximum predicted CFUs considering 50% interception
	1	1500	52[1]	$0.78x10^5$

[1] degradation of conidia is not taken into account. Calculations are performed with a worst-case scenario.

Exposure of the soil outside the greenhouse: 0.7 conidia/cm^2

Surface water exposure

Colony Forming Units [CFU/L water] (Annex IIIB, point 7.1.2; Annex IIIB, point 9)

Application rate	Max. 7.5 L/ha corresponding with 2.25 x 10^{12} CFU/ha
Main routes of entry	0.1 % emission from greenhouses

Single application actual	Max. predicted CFU/L
1	5.5 x $10^{41)}$

[1)]degradation of conidia is not taken into account. Calculations are performed with a worst-case scenario.

Application rate	Max. 7.5 L/ha corresponding with 2.25 x 10^{12} CFU/ha
Main routes of entry	Drainage of hydroponic recirculating solution. Assuming 14000 cucumber plants per ha 50% foliar interception and 10cm^2 rockwool per plant 15.8 x 10^8 CFU are assumed to enter 50M^3 of drainage water, which is diluted in 6.72x10^4 L receiving natural water

Single application actual	Max. predicted CFU/L
52	1.2 x 10^6

[1)]degradation of conidia is not taken into account Calculations are performed with a worst-case scenario.

Air

Colony Forming Units [CFU/m^3 air] (Annex IIIB, point 7.1.3; Annex IIIB, point 9)

Method of calculation	Worst-case scenario
Maximum concentration	In a standard greenhouse of 100 x 100 x 3.5 m^3 maximally 2.25 x 10^{12} CFU/35000 m^3 = 6.4 x 10^7 CFU are present in 1 m^3 of air. With a generic emission percentage of 0.1% the concentration of conidia in the air outside the greenhouse is 6.4 x 10^3 CFU/m^3.

Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIB, point 8.1, Annex IIIB, points 10.1)

Effects on birds	No data

Effects on aquatic organisms (Annex IIB 8.2; Annex IIIB 10.2)

No data. Data gap. A literature search revealed no toxicity, genotoxicity or pathogenicity to, freshwater fish, aquatic invertebrates, and aquatic plants for *Pseudozyma flocculosa* and closely related species of wild yeasts.

Effects on bees and other arthropod species (Annex IIB 8.3; Annex IIIB 10.3 and Annex IIB 8.4; Annex IIIB 10.4)

No data

Effects on earthworms (Annex IIB 8.5; Annex IIIB 10.5)

No data

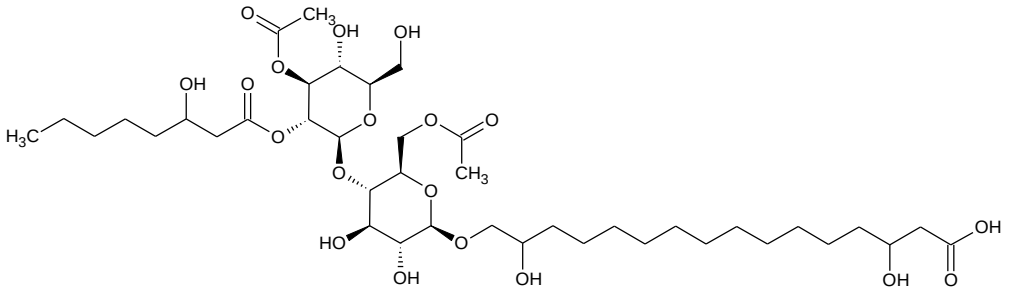
Effects on other soil micro-organisms (Annex IIB 8.6; Annex IIIB 10.6)

No data

Additional studies (Annex IIB 8.7; Annex IIIB 10.7)

Effects on terrestrial plants	No data
Effects on biological methods of sewage treatment	No data, data gap

APPENDIX B – USED COMPOUND CODES

Code/ Trivial name*	Chemical name/SMILES notation	Structural formula
flocculosin	16-({6-O-acetyl-4-O-[3-O-acetyl-2-O-(3-hydroxyoctanoyl)-β-D-glucopyranosyl]-β-D-glucopyranosyl}oxy)-3,15-dihydroxyhexadecanoic acid CCCCCC(O)CC(=O)O[C@@H]2[C@@H](OC(C)=O)[C@H](O)[C@@H](CO)O[C@H]2O[C@@H]1[C@@H](COC(C)=O)O[C@@H](OCC(O)CCCCCCCCCCCC(O)CC(=O)O)[C@H](O)[C@H]1O	

* The metabolite name in bold is the name used in the conclusion.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometre (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
DT_{50}	period required for 50 per cent disappearance (define method of estimation)
DT_{90}	period required for 90 per cent 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
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 Organization 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
IUPAC	International Union of Pure and Applied Chemistry
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
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
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
QPS	qualified presumption of safety
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
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 Organization
wk	week
yr	year