Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Penflufen

Product type: 8

ECHA/BPC/184/2017

Adopted

14 December 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the acive substance penflufen for product type 8

In accordance with Article 8(4) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 8 of the following active substance:

Common name:	**Penflufen**
Chemical name:	5-fluoro-1,3-dimethyl-N-{2-[(2RS)-4-methylpentan-2-yl]phenyl}-1H-pyrazole-4-carboxamide
EC No.:	N/A
CAS No.:	494793-67-8
New active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by LANXESS DEUTSCHLAND GMBH on 7 July 2015, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to ECHA on 28 February 2017. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-23) and it's Working Groups (WG IV 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance penflufen in product type 8 was adopted on 14 December 2017.

The BPC opinion was adopted by consensus. The opinion is published on ECHA webpage:

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval**]**

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the penflufen in product type 8 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of penflufen in product type 8. Penflufen acts via inhibition of the enzyme succinate dehydrogenase (complex II) within the fungal mitochondrial respiratory chain, thus blocking electron transport. Penflufen (5-fluoro-1,3-dimethyl-N-{2-[(2RS)-4-methylpentan-2-yl]phenyl}-1H-pyrazole-4-carboxamide) is a racemic mixture (1:1) of the two optical isomers R and S. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal products.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices (soil, sediment, water and air).

Penflufen has been evaluated as a pesticide active substance under Directive 91/414/EEC (EFSA Journal 2012;10(8):2860).

No current harmonised classification is available for penflufen. A classification proposal was submitted to ECHA by the UK on 7th December 2016.

The proposed classification and labelling for penflufen according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

(Proposed) Classification according to the CLP Regulation	
Hazard Class and Category Codes	Carcinogen Category 2 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GSH08 GSH09
Signal Word	Warning
Hazard Statement Codes	H351 – Suspected of causing cancer H410 – Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1 (acute and chronic)
Justification for the proposal	
<u>Carcinogen Category 2 consideration</u> Small increases in the incidences of liver tumours in rat and mice and tumours of the ovary, haematopoietic system and brain in rat have been observed. <u>Aquatic Acute 1 consideration</u> Fish are the most acutely sensitive trophic group. With the lowest acute value for 96-hour LC50 of 0.103 mg a.s./l.	

Aquatic Chronic 1 consideration
The NOEC for Fathead Minnow was identified to be within the range of 0.01 to 0.1 mg/l relevant for classification. Additionally, the substance is considered non-rapidly degradable.

b) Intended use, target species and effectiveness

Penflufen is an active substance used for the control of wood rotting fungi. Products containing penflufen are used for the industrial pre-treatment of wood by penetrative methods (vacuum pressure, double vacuum pressure, vacuum pressure with supercritical CO_2) and by superficial application methods (automated spraying, flow coating, automated and manual dipping and brush/roller) by industrial users, professional users and non-professional users, as appropriate.

Two representative products containing penflufen have been considered in this assessment, one aqueous-based and one solvent-based. The aqueous-based product is intended for application by vacuum impregnation, automated spraying, automated and manual dipping and brush/roller in use classes 1 – 4a. The solvent-based product is intended for application by automated and manual dipping and brush/roller in use classes 1 – 3.

The data on penflufen and the representative biocidal products have demonstrated sufficient efficacy against wood rotting fungi.

Penflufen is a new active substance for biocidal purposes, so information on the occurence of resistance from the use in wood preservation is not available. However, in the plant protection area resistances are controlled and managed by the FRAC (Fungicide Resistance Action Committee). Penflufen is listed under FRAC Code No. 7 (SDHI (Succinate dehydrogenase inhibitor) fungicide). FRAC reports that no cases of field resistance have been reported to date although resistance to SDHIs is a known phenomenon.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Penflufen is well absorbed by oral administration, extensively metabolised, and rapidly excreted. It is of low acute toxicity via all routes of administration, and not irritating to eyes or skin and with no skin sensitising potential. It was negative for genotoxicity both *in vitro* and *in vivo.* In repeat dose studies in rats, mice and dogs the main target organ was identified as the liver. Penflufen showed no neurotoxic or immunotoxic effects, and no effects on fertility or development.

The main adverse finding in animal studies was an increase in tumour incidences such as hepatic carcinomas in male mice, astrocytoma and histiocytic sarcoma in male rats, and liver adenomas and tubulostromal adenoma of ovary in female rats. Mode of action studies on the liver tumours were considered to be insufficient to conclude these tumours were not relevant to humans. No mode of action studies are available for other tumour types. Classification with Carcinogen Category 2; H351 is proposed.

The table below summarises the exposure scenarios assessed for penflufen in both solvent-based and aqueous-based representative products.

Summary table: human health scenarios for aqueous-based product			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Manual dipping of wooden articles	Primary exposure to the biocidal product Concentate: 1.5 % In use concentration: 0.03 % Gloves	Industrial users/professionals	Acceptable with PPE
Automated dipping of wooden articles	Primary exposure to the biocidal product In use concentration: 0.03 % Automated process, gloves	Industrial users	Acceptable with PPE and other RMM
Automated spraying of wooden articles	Primary exposure to the biocidal product In use concentration: 0.04 % Automated process, gloves	Industrial users	Acceptable with PPE and other RMM
Flow coating (deluge) treatment of wooden articles	Primary exposure to the biocidal product In use concentration: 0.03 % Automated process, gloves	Industrial users	Acceptable with PPE and other RMM
Vacuum pressure treatment of wooden articles with supercritical CO_2	Primary exposure to the biocidal product In use concentration: 0.1 % Automated process, gloves, coated coverall (10 % penetration)	Industrial users	Acceptable with PPE and other RMM
Vacuum pressure treatment of wooden articles	Primary exposure the biocidal product In use concentration: 0.005 % Automated process, gloves, coated coverall (10 % penetration)	Industrial users	Acceptable with PPE and other RMM
Double vacuum pressure treatment of wooden articles	Primary exposure the biocidal product In use concentration: 0.1 % Automated process, gloves, coated coverall (10 % penetration)	Industrial users	Acceptable with PPE and other RMM
Cleaning of treatment equipment	Primary exposure to the biocidal product Maximum concentration: 0.1 % Gloves	Industrial users/professionals	Acceptable with PPE
Restacking of treated timber	Primary exposure to preserved wood In use concentration: 0.03 % Gloves	Industrial users	Acceptable with PPE
Mixing & loading/decating prior to brush/roller application	Primary exposure to the biocidal product Concentration:1.5%	Professionals/non-professionals	Acceptable without PPE
Brush/roller application	Primary exposure to the biocidal product	Professionals/non-professionals	Acceptable without PPE

	In use concentration: 0.1 %		
Adult cleaning paint brushes after use	Primary exposure to the biocidal product In use concentration: 0.1 %	Professionals/non-professionals	Acceptable without PPE
Adult sanding treated wood	Primary exposure to preserved wood Concentration in wood: 0.025 mg/m^3	Professionals/non-professionals	Acceptable without PPE
Adult launders contaminated clothing at home	Secondary exposure	Professionals/non-professionals	Acceptable
An infant ingests residues through mouthing treated wood off-cuts	Secondary exposure	General public	Acceptable
Dermal and oral exposure of an infant playing on treated wood structures	Secondary exposure	General public	Acceptable
Inhalation exposure can occur from the treated wood installed indoors	Secondary exposure	General public	Acceptable
Mixing & loading of product, brush/roller application, cleaning brush/roller, and laundering contaminated clothing	Combined exposure	Professionals/non-professionals	Acceptable without PPE

Summary table: human health scenarios for the solvent-based product			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Manual dipping of wooden articles	Primary exposure to the biocidal product Concentrate: 0.1 % In use concentration: 0.04 % Gloves	Industrial users/professional	Acceptable with PPE

Automated dipping of wooden articles	Primary exposure to the biocidal product In use concentration: 0.04 % Automated process, gloves, coated coveralls (10 % penetration)	Industrial users	Acceptable with PPE and other RMM
Cleaning of treatment equipment	Primary exposure to the biocidal product In use concentration: 0.04 % Gloves	Industrial users/professionals	Acceptable with PPE
Restacking of treated timber	Primary exposure to 0.04% penflufen on preserved wood In use concentration: 0.04 % Automated process, gloves, coated coveralls (10 % penetration)	Industrial users	Acceptable with PPE and other RMM
Mixing and loading/decanting prior to brush/roller application	Primary exposure to the biocidal product Concentration : 0.1 %	Professionals/non-professionals	Acceptable without PPE
Brush/roller application	Primary exposure to in the biocidal product In use concentration: 0.1 %	Professionals/non-professionals	Acceptable without PPE
Adult cleaning paint brushes after use	Primary exposure to 0.04% penflufen in the biocidal product In use concentration: 0.1 %	Professionals/non-professionals	Acceptable without PPE
Adult sanding treated wood	Primary exposure to preserved wood Concentration in wood: 0.02 mg/m^3	Professionals/non-professionals	Acceptable without PPE
Adult launders contaminated clothing at home	Secondary exposure	Professionals/non-professionals	Acceptable
An infant ingests residues through mouthing treated wood off-cuts	Secondary exposure	General public	Acceptable
Dermal and oral exposure of an infant playing on treated wood structures	Secondary exposure	General public	Acceptable
inhalation exposure can occur from the treated wood installed indoors	Secondary exposure	General public	Acceptable
Decanting, brush/roller application, cleaning of paintbrush/roller & laundering work clothing	Combined exposure	Professionals/non-professionals	Acceptable without PPE

Aqueous–based product

For industrial users, acceptable risks are identified for treatment of wood by vacuum pressure impregnation, automated spraying and automated and manual dipping if PPE and other RMM are available, as appropriate.

For professional users acceptable risks are identified for treatment of wood by manual dipping if appropriate PPE is available. For application by brush/roller, acceptable risks are identified without the need for PPE.

For non-professional users acceptable risks are identified for treatment of wood by brush/roller without the need for PPE.

For secondary exposure scenarios, no unacceptable risks are identified.

A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

Solvent-based product

For industrial users, acceptable risks are identified for treatment of wood by automated and manual dipping if PPE and other RMM are available, as appropriate.

For professional users acceptable risks are identified for treatment of wood by manual dipping if appropriate PPE is available. For application by brush/roller, acceptable risks are identified without the need for PPE.

For non-professional users acceptable risks are identified for treatment of wood by brush/roller without the need for PPE.

For secondary exposure scenarios, no unacceptable risks are identified.

A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

Environment

Penflufen is stable to hydrolysis under environmental conditions. A laboratory aqueous photolysis study indicates that penflufen may undergo photo-degradation. Two water/sediment systems were investigated, with both systems having whole system $DegT_{50}$'s that exceed the criteria for both persistent (P) and very persistent (vP).

For laboratory studies (in the dark) soil $DegT_{50}$ exceed the criteria for vP in 6 out of 6 soils tested (when normalised to 12 °C). In field studies, soil $DegT_{50}$ values exceeded the criteria for P in 6 out of 6 soils and the criteria for vP in 4 out of 6 soils. Penflufen is moderately mobile in soil.

Penflufen has a low bioaccumulation potential (not B or vB), it is not classed as Toxic (T) and there is no indication of bioaccumulation potential for this active substance.

In water/sediment systems, one major metabolite was formed: M01 (BYF 14182-3hydroxy-butyl). In soil degradation studies two major metabolites were seen: M01 (BYF 14182-3hydroxy-butyl) and M02 (BYF 14182-pyrazolyl-AAP).

In aerobic laboratory soil studies the $DegT_{50}$ values suggest that metabolite M01 is persistent (P) in soil and M02 is very persistent (vP) in soil, with M01 being considered to be mobile in soil and M02 slightly mobile.
Penflufen has a low vapour pressure which together with the intended use suggests that emissions to air will be negligible.

The proposed classification of penflufen with Carcinogen Category 2 has the consequence that all metabolites are considered to be toxicologically relevant and must have a concentration in groundwater that is below 0.1 µg/L.

The tables below summarise the exposure scenarios assessed.

Summary table: environment scenarios: aqueous-based product		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Industrial application and storage	Application by automated spraying, automated and manual dipping and vacuum pressure impregnation and subsequent storage of treated wood. Compartments assessed: Sewage treatment plant (STP), surface water, sediment, soil.	Penflufen Acceptable for STP, surface water, sediment. Unacceptable for soil. Metabolite M01 Acceptable for surface water. Unacceptable for soil. Metabolite M02 Acceptable for soil.
Noise barrier (UC 3)	Compartments assessed: Sewage treatment plant (STP), surface water, sediment, soil.	Penflufen Acceptable for STP, surface water, sediment, soil. Metabolite M01 Acceptable for surface water, soil. Metabolite M02 Acceptable for soil.
Bridge over pond (in service) (UC 3)	Compartments assessed: Surface water, sediment.	Penflufen Acceptable for surface water, sediment. Metabolite M01 Acceptable for surface water.
Bridge over pond (in situ application) (UC 3)	Compartments assessed: Surface water, sediment.	Penflufen Acceptable for surface water, sediment. Metabolite M01 Acceptable for surface water.
Fence (in service) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.
Fence (in situ application) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.

House (in service) (UC 3)	Compartments assessed: Soil, groundwater.	Penflufen Acceptable for soil, groundwater. Metabolite M01 Acceptable for soil. Unacceptable for groundwater in all models assessed apart from Porto and Sevilla, for wood treated by automatic spraying and automated and manual dipping. Metabolite M02 Acceptable for soil, groundwater.
House (in situ application) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.
Transmission pole (UC 4a)	Compartments assessed: Soil.	Penflufen Unacceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.
Fence post (UC 4a)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.

Summary table: environment scenarios: solvent-based product		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Industrial application and storage	Application by automated and manual dipping and subsequent storage of treated wood. Compartments assessed: Sewage treatment plant (STP), surface water, sediment, soil.	Penflufen Acceptable for STP, surface water, sediment. Unacceptable for soil. Metabolite M01 Acceptable for surface water. Unacceptable for soil. Metabolite M02 Acceptable for soil.
Noise barrier (UC 3)	Compartments assessed: Sewage treatment plant (STP), surface water, sediment, soil.	Penflufen Acceptable for STP, surface water, sediment, soil. Metabolite M01 Acceptable for surface water, soil. Metabolite M02 Acceptable for soil.
Bridge over pond (in service) (UC 3)	Compartments assessed: Surface water, sediment.	Penflufen Acceptable for surface water, sediment. Metabolite M01 Acceptable for surface water.
Bridge over pond (in situ application) (UC 3)	Compartments assessed: Surface water, sediment.	Penflufen Acceptable for surface water, sediment. Metabolite M01 Acceptable for surface water.
Fence (in service) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.
Fence (in situ application) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.

House (in service) (UC 3)	Compartments assessed: Soil, groundwater.	Penflufen Acceptable for soil, groundwater. Metabolite M01 Acceptable for soil. Unacceptable for ground water in all models assessed apart from Porto and Sevilla, for wood treated by brush/roller. Metabolite M02 Acceptable for soil, groundwater.
House (in situ application) (UC 3)	Compartments assessed: Soil.	Penflufen Acceptable for soil. Metabolite M01 Acceptable for soil. Metabolite M02 Acceptable for soil.

An unacceptable risk to soil is identified for the aqueous-based and solvent-base products following industrial application and storage. This risk can be mitigated by preventing emission of penflufen and its metabolites to soil by ensuring application of the products is conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber is stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, and that any losses from the application of the product shall be collected for reuse or disposal.

Emmissions to the environment following application of the aqueous-based and solvent-base products biocidal products indoors and from wood in service (ie use classes 1 and 2) are considered to be negligible and so risks to the environment are considered to be acceptable.

For use class 3, acceptable risk to groundwater is identified only in the Porto and Sevilla models for:

- wood treated with the aqueous-based product by automatic spraying and automated and manualdipping; and
- wood treated with the solvent-based product by brush/roller application.

For all other groundwater scenarios assessed, the PEC_{GW} of metabolite M01 is greater than 0.1 µg/L, i.e. an unacceptable risk to groundwater is identified for:

- wood treated with the aqueous-based product by vacuum impregnation and brush/roller; and
- wood treated with the solvent-based products by automated and manual dipping

For use class 4a, only application with the aqueous-based product was assessed and an unacceptable risk to the soil is identified. Risk to groundwater was not assessed but an unacceptable risk is assumed based on the outcome for soil. Risk mitigation measures such as top coating have not been considered as part of this assessment.

Overall conclusion

A safe use has been identified for industrial, professional and non-professional application for both human health and the environment for use classes 1 and 2 when appropriate risk mitigation measures are in place, for the aqueous-based and solvent–based products.

A safe use has been identified in use class 3 for human health and the environment (Porto and Sevilla models only) for:

- wood treated with aqueous–based products by automated spraying and automated and manual dipping
- wood treated by solvent-based products by brush/roller.

No safe use has been identified for use class 4a.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	Cat 2 proposed	Penflufen does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Penflufen is vP in fresh water, sediment and soil. Metabolite M01 is vP in fresh water and sediment. Metabolite M02 is vP in fresh water and soil	Penflufen does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	Penflufen is not considered to have endocrine disrupting properties. Penflufen does not fulfil criterion (d) of Artcile 5(1).		
Respiratory sensitisation properties	No classification required. Penflufen does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Penflufen is not considered to have concerns linked to critical effects and therefore it does not filfil criterion (e) of Article 10 (1).		
Proportion of non-active isomers or impurities	Penlfufen does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Penflufen does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Penflufen does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1 - Final - Principles for substance approval.doc)

BPR"[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Owing to the short DT_{50} in air, penflufen is not expected to be subject to long range transport. Penflufen does not trigger the criteria for B/vB or T, therefore requires no further consideration in this regard.

2.3. BPC opinion on the application for approval of the active substance penflufen in product type 8

In view of the conclusions of the evaluation, it is proposed that penflufen shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 980 g/kg (1:1 (R:S) ratio of enantiomers)

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. industrial and professional users

        ii. soil and groundwater for wood in service that will be exposed to frequent weathering.

    c. In view of the risks identified for soil, labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

3. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance penflufen shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012. The substance is proposed for classification according to Regulation (EC) No 1272/2008 as a carcinogen of category 2 and as toxic to aquatic life, acute category 1.

[2] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4 - Final - Further guidance on Art10(1).doc)

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. If an unacceptable risk is identified for industrial and/or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

    b. An unacceptable risk for groundwater has been identified for use of wood not in contact with the ground exposed to frequent weathering, treated with aqueous-based products by vacuum impregnation and brush/roller application. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

    c. An unacceptable risk for groundwater has been identified for use of wood not in contact with the ground exposed to frequest weathering, treated with solvent-based products by automated and manual dipping. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

    d. An unacceptable risk for soil and groundwater has been identified for use of wood in contact with the ground exposed to frequest weathering, treated with aqueous-based products. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

    e. An unacceptable risk for groundwater has been identified for use of wood not in contact with the ground exposed to frequest weathering, treated with aqueous-based products by vacuum impregnation and brush/roller. Labels and where provided safety data sheets of biocidal products shall indicate that wood treated in this way shall not be used in situations where frequent weathering is expected to occur, unless it can be demonstrated at product authorisation that risks to the environment can be reduced to an acceptable level by other means.

    f. An unacceptable risk for groundwater has been identified for use of wood not in contact with the ground exposed to frequent weathering, treated with solvent-based products by automated and manual dipping. Labels and where provided safety data sheets of biocidal products shall indicate that wood treated in this way shall not be used in situations where frequent weathering is expected to occur, unless it can be demonstrated at product authorisation that risks to the environment can be reduced to an acceptable level by other means.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of penflufen.

However, further data on the active substance are required and should be provided to the evaluating Competent Authority (UK) as soon as possible but no later than the date of approval of the active substance:

- **Chemistry:** As the metabolite M01 is included in the residue definition for groundwater, a data gap is identified for a method of analysis.