Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

FORMITOX

Product type(s) 18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-FP049658-15

Evaluating Competent Authority: CZ

Date: 3.4.2023

Table of Contents

1 CONCLUSION

The biocidal product Formitox is an insecticide (PT18) in a form of a ready-to-use contact powder that contains 0.25% w/w of the active substance permethrin and it is intended to be used to control adults of ants. The product can be used indoor by non-professional users. It is a light blue crystalline powder with unidentified odour like raw starting materials/components. The biocidal product is a solid and it is not intended to be applied as an aqueous dilution or dispersion.

Physico-chemical properties and analytical methods
Formitox physicochemical properties are considered acceptable taking into account the given and intended purpose of use. According to the accelerated storage stability tests, the biocidal product is considered to be stable and compatible with the commercial packaging for the shelf-life period of 2 years. Long-term stability testing is denoted by the applicant as ongoing. The light, temperature and humidity have no influence on the content of the active substance and on the stability of the biocidal product itself. The recommended storage is in tightly closed original containers in dry, dark and well-ventilated areas at the temperature from 0°C to 30°C only, i.e. under the defined conditions described on the product packaging label. The product is neither expected to have explosive or oxidising properties, nor to be self-heating or flammable. Thus has no classification according to CLP criteria. The product is not intended to be applied with any other substances or other biocidal products.

Efficacy assessment
The product was shown to be efficacious against ants (*Lasius niger*) in a simulated use test indoors on hard surfaces when applied 1 g in 1 cm wide and approx. 35 cm long line. The residual efficacy of the product is 3 weeks after application and the treated surfaces cannot be cleaned (dry or wet) during that period.

Risk assessment for human health
The risk is acceptable for both non-professional users and general public when the product is used in accordance with the directions for use specified in this assessment report.

Risk assessment for the environment
The risk is acceptable for the environment providing that the product is used in accordance with the directions for use specified in this assessment report.

General conclusion
According to Article 19(1) the product Formitox can be authorized for the indoor use against ants under the conditions specified in this assessment report.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Formitox	Czech Republic

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Papírna Moudrý, s.r.o.
	Address	Nádražní 56, 66701 Židlochovice, Czech Republic
Authorisation number	CZ-0031042-0000	
Date of the authorisation	7.6.2023	
Expiry date of the authorisation	7.6.2033	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Papírna Moudrý, s.r.o.
Address of manufacturer	Nádražní 56, 66701 Židlochovice, Czech Republic
Location of manufacturing sites	Nádražní 56, 66701 Židlochovice, Czech Republic

2.1.1.4 Manufacturer(s) of the active substance(s)

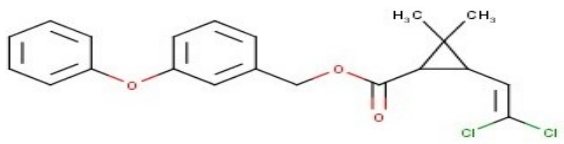
Active substance	Permethrin Technical 25/75
Name of manufacturer	Tagros Chemicals India Ltd
Address of manufacturer	"Jhaver Centre" 4th Floor, R. A. Building, 72, Marshalls Road, Egmore, Chennai – 600008 INDIA
Location of manufacturing sites	-
LIMARU NV, located at Business Center Mezzo, Paalsesteenweg 170 Bus 7, 3583 Beringen, Belgoum has the right to grant access to the complete Tagros dossier.	

2.1.2 Product composition and formulation

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	permethrin (ISO)
IUPAC or EC name	3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity/content	>=93% purity of active substance/ content in biocidal product: 0.25%
Structural formula	

2.1.2.2 Candidate(s) for substitution

According to Biocidal Products Committee (BPC), 2014 (Opinion of the Biocidal Products Committee on the application for approval of the active substance permethrin for product type 18), permethrin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

However, according to the BPC-40 minutes from January 18, 2022, permethrin meets the T and the P criteria, and subsequently, it meets the conditions of Article 10(1)(d), and comparative assessment will be needed for products containing permethrin. Furthermore, it was concluded during the BPC meeting that a statement would be included in the Assessment Report that data to conclude on the B criterion has to be submitted for renewal. Considering the submission date for the concerned application for the product Formitox, the implication of the decision formulated in the minutes to the BPC meeting in January 2022, i.e., the requirement for a comparative assessment, will be applicable only at the renewal stage.

2.1.2.2.1 Qualitative and quantitative information on the composition of the biocidal product

The full composition of the product is provided in the confidential annex of the PAR.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.25

2.1.2.3 Information on technical equivalence
The active substance declared for the product authorisation is identical with substance listed in the Union list of approved active substances under Regulation No. 528/2012.

2.1.2.4 Information on the substance(s) of concern
In the biocidal product there is one coformulant under assessment as PBT classified as SoC present in the amount of less than 0.0005, which is totally negligible. For further details, see the confidential annex of the PAR.

2.1.2.5 Assessment of endocrine disruption (ED) properties of the biocidal product
The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product was performed according to the Regulation (EU) 528/2012. Based on the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the formulation of the biocidal product. For further details, see the confidential annex of the PAR.

2.1.2.6 Type of formulation

CP Contact powder

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects

Classification	
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of contents/container in accordance with local/national regulations for dangerous waste disposal
Additional labelling	EUH208: Contains permethrin. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Insecticidal product for the control of ants in the form of crystalline powder for indoor applications

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticidal product for the control of ants in the form of crystalline powder for indoor applications.
Target organism (including development stage)	Ants (*Lasius niger*), adult
Field of use	Indoor use
Application method(s)	Spreading
Application rate(s) and frequency	For indoor use on hard porous and non-porous surfaces. Formitox crystal powder should be applied to the surface where ants were observed at the dose of 1 g in 1 cm wide and approx. 35 cm long line. Use the enclosed measuring spoon to dose the product. One levelled measuring spoon corresponds to one dose (1 g) of the product. Ants are reduced within 14 days after application. The product is capable of producing effect 3 weeks after application. The product can be reapplied with a maximum of 9 treatments per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	120g/200g Talcum powder container (type of container with open/close lid) from paper, cardboard. The

	bottom is metallic and the inner layer of the box is covered with aluminium. The pour spout lid is plastic. Enclosed measuring spoon is plastic.

2.1.4.1.1 Use-specific instructions for use

Remove all food sources near the product application.

There is a sliding open/close button on the lid of the container. Open it and apply 1 g of the product directly onto the surface in a line 1 cm wide and approx. 35 cm long on the pathway of ants and the site which is inaccessible to children and domestic animals, particularly cats. Use the enclosed measuring spoon to dose the product. One levelled measuring spoon corresponds to one dose (1 g) of the product.

The treated surfaces cannot be cleaned (dry or wet).

Use biocides safely. Always read the label and product information before use. Collect product residues mechanically and dispose of in a certified hazardous waste facility!

2.1.4.1.2 Use-specific risk mitigation measures

When using the product, the directions for use must be followed. Prevent the access to the areas treated with Formitox by children, domestic and farm animals, particularly cats due to their high sensitivity to pyrethroids (permethrin).
Remove or cover terrariums, aquariums and animal cages before application.

Protect food, beverages and feed from contamination.

2.1.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Avoid release to the environment. Stop leak if you can do it without risk. Do not allow to contaminate soil, sewage and surface/ ground water. Notify authorities if product enters sewers or public waters. Dry product take-up mechanically. Collect in a suitable, sealed and labelled container. Dispose according to regulations, dispatch for disposal to collect hazardous waste.

After inhalation: Remove the victim into a fresh air.
If on skin, wash with soap and water.
IF SWALLOWED: Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
Call a POISON CENTER/doctor/…/if you feel unwell.

2.1.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

Dispose of unused product or empty C/PAP packaging in a certified hazardous waste facility! The reuse of packaging is prohibited. The remain of used product take up mechanically and dispose of in a certified hazardous waste facility!

2.1.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Store in tightly closed original containers in a dry, dark and well-ventilated areas at 0°C to 30° C. Shelf-life: 24 months from the date of manufacture. Warranty: 24 months from the date of manufacture in original packaging and at recommended storage conditions.

2.1.4.2 General directions for use
2.1.4.2.1 Instructions for use

For indoor use only. Remove all food sources near the product application There is a sliding open/close button on the lid of the container. Open it and apply the product directly onto the surface. When the work is finished, close the container. Pour 1 g of the product onto the site where ants occur in a line 1 cm wide and 35 cm long. Use the enclosed measuring spoon to dose the product. One levelled measuring spoon corresponds to one dose (1 g) of the product.When the work is finished, close the container. The time required for the biocidal effect: 30 minutes after contact of ants with the product. Effective period: 21 days after application of the product. More than 90% of ants die within 14 days after application. Use biocides safely. Always read carefully the label and comply with the instructions for use. The remain of used product take up mechanically and dispose of as a hazardous material in accordance with national regulation.

2.1.4.2.2 Risk mitigation measures

The product must not be used other than that specified in the manual. Prevent the access to the areas treated with Formitox by children, domestic and farm animals, particularly cats, due to their high sensitivity to pyrethroids (permethrin). Remove or cover terrariums, aquariums and animal cages before application. Protect food, beverages and feed from contamination.

2.1.4.2.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Avoid release to the environment. Stop leak if you can do it without risk. Do not allow to contaminate soil, sewage and surface/ ground water. Notify authorities if product enters sewers or public waters. Dry product take-up mechanically. Collect in a suitable, sealed and labelled container. Dispose according to regulations, dispatch for disposal to collect hazardous waste.

After inhalation: Remove the victim into a fresh air
If on skin, wash with soap and water.
IF SWALLOWED: Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
If medical advice is needed, have product container or label at hand.

Call a POISON CENTER/doctor if you feel unwell.

2.1.4.2.4 Instructions for safe disposal of the product and its packaging

Dispose of unused product or empty C/PAP packaging in a certified hazardous waste facility! The reuse of packaging is prohibited.
The remain of used product take up mechanically and dispose of in a certified hazardous waste facility!

2.1.4.2.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in tightly closed original containers in dry, dark and well-ventilated areas at 0°C to 30° C.
Shelf-life: 24 months from the date of manufacture.
Warranty: 24 months from the date of manufacture in original packaging and at recommended storage conditions.
Keep out of reach of children and non-target animals/pets.

2.1.4.3 Other information

The product is not intended to be used with other biocidal products.

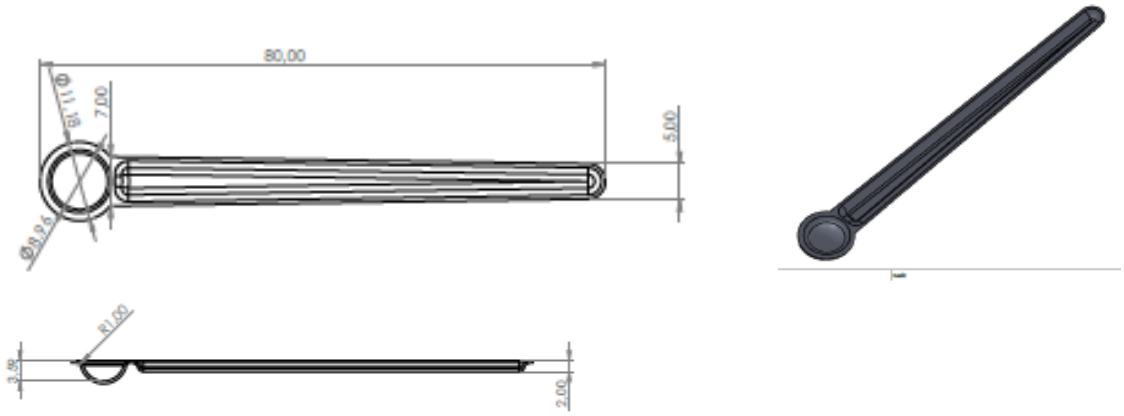
2.1.5 Packaging of the biocidal product

Type of packaging	Size/ volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
talcum powder container	120g	paper, cardboard The bottom is metallic and the inner layer of the box is covered with aluminium	Plastic (05-PP) close/open lid.	non-professional	yes
talcum powder container	200g	paper, cardboard The bottom is metallic and the inner layer of the box is covered with aluminium.	Plastic (05-PP) close/open lid.	non-professional	yes
measuring spoon	1 ml	plastic pharmaceutical spoon	Plastic PET	Non-professional	yes

Talcum powder container (type of container with open/close lid) from paper cardboard. The bottom is metallic and the inner layer of the box is covered with aluminium. The pour spout lid is plastic. See the pictures below.

Picture 1: Pictures of the container for biocidal product Formitox





2.1.6 Documentation

2.1.6.1 Data submitted in relation to the product application

- Letter of Access was submitted in IUCLID dossier (section 13 Summary and evaluation) of biocidal product
- The safety data sheets for each components of biocidal product are attached in IUCLID file (section 13 Summary and evaluation)
- The pictures and schematic drawn of packaging are attached in IUCLID dossier (section 12.3 Packaging) of biocidal product.
- The safety data sheets for the biocidal product in Czech and Slovak language are attached in IUCLID dossier (section 13 Summary and evaluation) of biocidal product.
- Explanation of the presence of sugar in the Formitox formula is attached in confidential annex of the PAR.
- Technical specification for sugar (sucrose) is attached in IUCLID dossier (section 13 Summary and evaluation) of biocidal product.
- Please refer to the list of references for physico-chemical and efficacy part (Annex 3.1).

2.1.6.2 Access to documentation

The applicant submitted the Letter of access to the AS CAR.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – Insecticidal spreading product for the control of ants in form of crystalline powder for indoor applications

Product Type(s)	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticidal spreading product for the control of ants in form of crystalline powder for indoor applications
Target organism (including development stage)	Ants (*Lasius niger*), adult
Field of use	Indoor use
Application method(s)	Spreading
Application rate(s) and frequency	For indoor use. There is a sliding open/close button on the lid of the container. Open it and apply the product directly onto the surface. When the work is finished, close the container. Sprinkle 3 g / 100 cm2 of Formitox crystal powder on the place where you have observed the ants. At the chosen place we recommend to spread out a 0.5 - 1 cm thick line with a maximum length of 35 cm. Remove all food sources near the product application. The time required for the biocidal effect: 30 minutes after contact of ants with biocidal product. Effective period: 21 days after application of the product More than 90% of ants die within 14 days after application.
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	120g/200g Talcum powder container (container with open/close lid) from paper, cardboard. The bottom is metallic and the inner layer of the box is covered with aluminium. The pour spout lid is plastic.

2.2.2 Physical, chemical and technical properties

Physico-chemical properties of the active substance were evaluated during the process of its inclusion in Annex I of the BPD and their detailed description can be found in the CAR. The data can be used on behalf of the applicant based on the Letter of access from the data owner.

Related to the physico-chemical properties of the biocidal product Formitox, the applicant submitted Particle size distribution Test Report, complete Stability Tests Reports, or, where applicable, provided a waiver or justification. A brief overview of the physico-chemical properties for the biocidal product and all the justifications are given in the Table below.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual observation	BP product 0.25% AS with a min. purity 93%	crystalline powder	Vilímková, V., 2019
Colour at 20 °C and 101.3 kPa	Visual observation	BP product 0.25% AS with a min. purity 93%	bluish	Vilímková, V., 2019
Odour at 20 °C and 101.3 kPa	Olfactory inspection	BP product 0.25% AS with a min. purity 93%	unidentified odour like raw materials, components	SDS
Acidity / alkalinity	The biocidal product is a ready-to-use contact powder and will not be applied as aqueous dilutions or dispersions. The pH of 1 % solution is within the range from 4 to 6.			Vilímková, V., 2019
Relative density / bulk density	CIPAC MT 186 (Bulk Density), OECD No. 109, Density of liquids and solids	BP product 0.25% AS with a min. purity 93%	Tap density: 1.052 g/cm^3.	Vilímková, V., 2019
Storage stability test – **accelerated storage**	In accordance with ECHA Guidance Volume I: Parts A+B+C and Technical Monograph n°17, 2nd Edition	BP product 0.25% AS with a min. purity 93%	The between-bottle AS average mass concentration value in the biocidal product before accelerated storage procedure, i.e. in T(0), arising from 15 inter-packing replicate measurements under repeatability conditions, was 0.289 w/w. The inter-packing overall	Vilímková, V., 2019

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	Storage for 14 days at 54°C±2°C CIPAC: MT46.3		mean mass concentration value of the AS in the BP for the same 15 samples measured after the accelerated storage procedure was 0.297 w/w. The increase of the AS permethrin content is within the general limit given by the appropriate Guidances. **Summary:** **T(0) = 0.289 ± 5.7*** **T (14d.) = 0.297 ± 10.2*** both mass values in % w/w *RSD in percent relative **Conclusion:** Results showing statistically practically non-significant increase of the AS content in the biocidal product measured. Based on the accelerated tests results biocidal product is considered to be stable for 2 years.	
Storage stability test – **long term storage at ambient temperature**	In accordance with ECHA Guidance Volume I: Parts A+B+C and Technical Monograph n°17, 2nd Edition (GIFAP)	BP product 0.25% AS with a min. purity 93%	The biocidal product Formitox manufactured in 2015 was packed in a paper packaging without printing. The paper inside was laminated by an aluminium foil, the bottom of the packaging was made from a metal of a gold colour and the top was equipped with a	Vilímková, V., 2019

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	Storage for 3 years under ambient conditions and strictly in accordance with the conditions declared on the label. For further details see the Long term stability and shelf-life justifications below the Table.		red plastic cover with the movable perforated part for the BP dosing. The storage conditions were maintained in accordance with the instructions provided by the applicant on the label of the common commercial packaging of the BP. The between-bottle AS average mass concentration value in the BP obtained within 10 parallel measurements under repeatability conditions was 0.265 w/w. This AS permethrin mass concentration value measured after 3 years of storage compared to the value of the AS measured in totally comparable BP samples within the accelerated stability testing as well as compared to the AS nominal mass concentration value declared by the applicant and arising from the manufacturing process under good manufacturing practice was not significantly changed. **Summary:** **(T0) = 0.250 ± 0.019**** **(T 3yrs.) = 0.265 ± 5.2*** (both values in % w/w)	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			*RSD in percent relative **Declared mass value for the AS is min. 93%, thus the maximum content could be of 0.019 % w/w higher. **Conclusion:** Statistically non-significant change in the AS content in the BP manufactured in 2015 and measured in 2018 after the long term storage procedure in accordance with the requirements declared on the label of the product packaging was observed. However, in fact, active's mass concentration value in T(0), i.e. in 2015, was not determined. For further details and conclusions related to the long-term stability measurement see the discussion below the Table.	
Storage stability test – **low temperature stability test for liquids**		BP product 0.25% AS with a min. purity 93%	Not required. The product is not liquid. The biocidal product is a ready-to-use contact powder.	
Effects on content of the active substance and technical characteristics	Not relevant. The packaging is stable and compatible with the biocidal product. The recommended storage is in tightly closed original non-transparent lightproof containers/packaging in dry, dark and well-ventilated areas at 0 °C to 30 °C only, thus this endpoint is not relevant.			

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
of the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		BP product 0.25% AS with a min. purity 93%	The recommended storage is in tightly closed original containers in dry, dark and well-ventilated areas at 0°C to 30° C only, from this point of view this endpoint is not relevant.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		BP product 0.25% AS with a min. purity 93%	The packaging is stable and compatible with the biocidal product. Visual inspection/assessment was done after the 3 years storage within the stability testing. After the storage period of 3 years, no corrosion, damages or any other changes compared to the original containers before the formulation filling were observed.	Vilímková, V., 2019
Wettability		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is not the formulation to be dispersed in water. Biocidal product is a ready-to-use contact powder.	
Suspensibility, spontaneity and dispersion stability		BP product 0.25% AS with a min. purity 93%	Not relevant. The biocidal product is a ready-to-use contact powder.	
Wet sieve analysis and dry sieve test		BP product 0.25% AS with a	Not relevant. The product is neither wettable powder, suspension or dispersible	Peciar, M., Fekete, R., Peciar, P., 2019

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		min. purity 93%	concentrate, water dispersible or soluble granules or powder, aqueous capsule suspension, nor suspo-emulsion. The product is a ready-to-use contact powder. On the other hand, physico-chemical tests, particle size distribution tests and crystallographic analyses, were realised and provided. See the conclusion later.	
Emulsifiability, re-emulsifiability and emulsion stability		BP product 0.25% AS with a min. purity 93%	Not relevant. The biocidal product is not intended to form or maintain in a form of stable emulsion. The product is a ready-to-use contact powder.	
Disintegration time		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is not intended to be used as a soluble or dispersible tablet. The product is a ready-to-use contact powder.	
Particle size distribution, content of dust/fines, attrition, friability	The particle size distribution in the BP samples were analysed using the equipment Mastersizer 3000, Malvern, i.e. laser diffraction particle size analyser. Accurate	BP product 0.25% AS with a min. purity 93%	No particles in the size below 11.2 μm in the biocidal product Formitox were identified. The particle size ranging from 11.2 μm to 51.8 μm in the volume of 3.03% were found and measured. The particle size ranging from 11.2 μm to 76 μm in the biocidal product Formitox in the volume of 4.17% were found and measured.	Peciar, M., Fekete, R., Peciar, P., 2019

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
	particle size distribution were estimated for dry formulation.		The active substance permethrin is an oily substance that will certainly stick to bigger particles. The biggest particles in the biocidal product formulation are mainly carrier* crystals. The other additive is limestone in its powder form. It could be assumed and concluded that the fine fraction of the formulation is preferably limestone, which is not classified as a dangerous substance and the limestone dust is not explosive. *For further details related to the use of carrier in the biocidal product mixture, see the conclusion in the Confidential annex.	
Persistent foaming		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is not intended to be applied in water for use. The product is a ready-to-use contact powder.	
Flowability/Pourability/Dustability		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is neither suspension concentrate, capsule suspension, nor emulsion. The product is a ready-to-use contact powder.	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Burning rate — smoke generators		BP product 0.25% AS with a min. purity 93%	Not applicable. The product is not a smoke generator.	
Burning completeness — smoke generators		BP product 0.25% AS with a min. purity 93%	Not applicable. The product is not a smoke generator.	
Composition of smoke — smoke generators		BP product 0.25% AS with a min. purity 93%	Not applicable. The product is not a smoke generator.	
Spraying pattern — aerosols		BP product 0.25% AS with a min. purity 93%	The biocidal product does not form aerosols. The product is a ready-to-use contact powder.	
Physical compatibility		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is not intended to be used or stored with any other products.	
Chemical compatibility		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is not intended to be used, stored or mixed with any other products.	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Degree of dissolution and dilution stability		BP product 0.25% AS with a min. purity 93%	Not relevant. The product is neither soluble bag, tablet, nor solid to be diluted in water. The product is a ready-to-use contact powder.	
Surface tension	The study does not need to be conducted because surface tension/activity is not a desired property of the biocidal product. The authorised biocidal product is a solid ready-to-use contact powder and will remain in the solid state within all the stages of use. The biocidal product is not intended to be applied as aqueous dilutions or dispersions. The water solubility of permethrin (active substance) is below 1 mg/L.			
Viscosity	The study does not need to be conducted because the biocidal product is a solid ready-to-use contact powder. The authorised biocidal product is a solid and will remain in the solid state within all the stages of use. The biocidal product is not intended to be applied as aqueous dilutions or dispersions.			

Conclusion on the physical, chemical and technical properties of the product

Biocidal product Formitox, use, basic APCP properties:
The biocidal product Formitox is an indoor insecticide used for the control of ants with the concentration of 0.25% of the active substance (permethrin, CAS No.: 52645-53-1, EC No.: 258-067-9). The biocidal product is a light blue crystalline powder with an unidentified odour like raw starting materials/components. The biocidal product is a solid, ready-to-use contact powder, and will not be applied as an aqueous dilutions or dispersions. The pH of 1% solution is in range from 4 to 6 units. The tap density of the biocidal product is 1.052 g/cm^3. According to the Storage Stability Tests (CIPAC MT 46.3), i.e. two weeks accelerated storage tests, biocidal product is stable and compatible with the commercial packaging. For further details related to the stability tests, see the conclusion below. The light, temperature and humidity have no influence on the content of the active substance and on the stability of the biocidal product itself. The recommended storage is in tightly closed original containers in dry, dark and well-ventilated areas at 0 °C to 30 °C only.

Conclusion related to the stability testing, shelf life of the BP:
All the samples analysed within the stability tests were delivered to the laboratory on June 28, 2018. Samples were marked as Formitox 12/03/2015 (10 samples), the mass concentration of the AS was measured, and Formitox PE 28/05/2018 (15 samples), accelerated storage stability testing was performed. Based on the accelerated stability tests results, biocidal product is considered to be stable for 2

years. However, in fact, the samples manufactured in 2015 should have been stored under defined conditions as well as the active's mass concentration value in the 3 years aged samples at the beginning of the long-term stability testing, i.e. in 2015, T(0), should have been determined. As discussed above (Table in the Chapter 2.2.2., storage stability test, long term storage at ambient temperature), based on the nominal active's mass concentration value declared by the applicant and arising from the manufacturing process, biocidal product is most likely stable for 3 years. However, strictly in accordance with the relevant Guidances, active's mass value in T(0) was not measured and determined. As eCA, we were informed by the applicant that the long-term stability testing based strictly on the relevant procedure and Guidances were managed, started and are ongoing. Once the results available, shelf-life of the biocidal product could be changed later. As a conclusion, based on the relevant accelerated tests results, shelf-life of 2 years is proposed and could be granted.

Conclusion related to the particle size distribution analyses:
The samples were analysed using the laser diffraction particle size analyser. Accurate particle size distribution was measured for dry dispersions. No particles in the size below 11.2 μm in the biocidal product Formitox were identified. The particle size ranging from 11.2 μm to 51.8 μm in the volume of 3.03% were found and measured. The particle size ranging from 11.2 μm to 76 μm in the biocidal product Formitox in the volume of 4.17% were found and measured. The active substance permethrin is an oily substance that will certainly stick to the bigger particles. The biggest particles in the biocidal product formulation are mainly the carrier crystals. The other additive is limestone in its powder form. It could be assumed and concluded that the fine fraction of the formulation is preferably limestone, which is not classified as a dangerous substance and the limestone dust is not explosive.

*For further details related to the use of carrier in the biocidal product mixture, see the conclusion in the Confidential annex.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Differential scanning calorimetry Guidelines: UN-MTC (2019), section 20.3.3.3; TAB APCP (v. 3.0), section 5.4.1 Equipment: Setaram SENSYS	Product tested as received	One exothermic event observed: onset temperature 203 °C, peak at 213 °C, enthalpy change -118 J/g No mass change The DSC curve is attached in Annex 3.6 to this document	VSB-TUO, 2023

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	EVO TG/3D DSC High Pressure calorimeter Crucible: incoloy alloy, high pressure (up to 50 MPa), 0.13 ml, closed (lid with crucible screwed) Heating rate: 3 °C/min Temperature range: 25-600 °C Sample weight: 10.1 mg Test atmosphere: air			
	Conclusion on classification: Since the exothermic decomposition energy is less than 500 J/g, the acceptance procedure does not need to be applied. The product is not considered explosive.			
Flammable gases	Not relevant. Biocidal product is a ready-to-use contact powder.			
Flammable aerosols	Not relevant. Biocidal product is a ready-to-use contact powder.			
Oxidising gases	Not relevant. Biocidal product is a ready-to-use contact powder.			
Gases under pressure	Not relevant. Biocidal product is a ready-to-use contact powder.			
Flammable liquids	Not relevant. Biocidal product is a ready-to-use contact powder.			
Flammable solids	This ready-to-use contact powder is neither readily combustible, nor may cause or contribute to fire through friction. A mixture need not be classified for flammable properties directly provided that none of the substances in the mixture possesses properties related to flammability and, on the basis of the information available to the supplier, the mixture is unlikely to present hazards of this kind.			
Self-reactive substances and mixtures	Since the exothermic decomposition energy is less than 300 J/g (DSC analysis by VSB-TUO, 2023, described under 'explosives' above), the classification procedure does not need to be applied. The product is not considered self-reactive.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Pyrophoric liquids	Not relevant. Biocidal product is a ready-to-use contact powder.			
Pyrophoric solids	According to the additional classification considerations in the CLP Guidance the classification procedure for pyrophoric solids need not be applied when the experiences in the manufacture or handling showing that the biocidal product formulation does not ignite spontaneously on coming into contact with air at ambient temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)). This ready-to-use contact powder is stable at the recommended and declared conditions within the shelf-life period of storage.			
Self-heating substances and mixtures	Self-heating is the result of an exothermic reaction of a substance or mixture with the oxygen in the air. The phenomenon can occur only where a large surface of substance or mixture is in contact with air or oxygen. The surface area of a solid substance or mixture exposed to air increases with decreasing particle size. Particle size distribution study was performed. The small amount of fine fraction are of the component (see the confidential annex) which is not expected to be self-heating. From the chemical point of view study does not need to be conducted because there are no chemical groups present in the mixture and/or formulation which are associated with self-heating properties as well as none of the components is liable to undergo oxidative self-heating. Therefore the classification procedure for this biocidal product does not need to be applied.			
Substances and mixtures which in contact with water emit flammable gases	Biocidal product is known not to emit flammable gases in contact with water. Therefore, this test is not necessary to be conducted. Moreover, the biocidal product is not intended to be used in contact with water. The recommended storage of the BP is in tightly closed original containers in dry, dark and well-ventilated areas at 0°C to 30° C only. The chemical structure of the substance or mixture does not contain metals or metalloids and experiences in handling and use shows that the substance or mixture does not react with water.			
Oxidising liquids	Not relevant. Biocidal product is a ready-to-use contact powder.			
Oxidising solids	The components in the biocidal product are not oxidising as well as none of the components is liable to undergo oxidative self-heating. A mixture need not be classified for oxidising properties as referred to in Part 2 of Annex I of the CLP provided that none of the substances in the mixture possesses oxidising properties and, on the basis of the			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	information available to the supplier, the mixture is unlikely to present hazards of this kind. For organic substances or mixtures, the classification procedure for this hazard class need not be applied if the mixture does not contain oxygen, fluorine or chlorine or does contain oxygen, fluorine or chlorine chemically bonded to carbon or hydrogen atoms only. This is fulfilled.			
Organic peroxides	The study does not need to be conducted because none of the substances in the biocidal product falls under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. The biocidal product contains neither organic peroxides nor their precursors.			
Corrosive to metals	The biocidal product is neither a liquid nor a solid that may become liquid during the transport. Therefore the data is not necessary to be provided. The biocidal product does not contain components corrosive to metals. Moreover, visual inspection/assessment of the inner layer of the packaging was done after the storage period of 3 years. No corrosion, damages or any other changes after this storage period compared to the original packaging were observed.			
Auto-ignition temperatures of products (liquids and gases)	Not relevant. Biocidal product is a ready-to-use contact powder.			
Relative self-ignition temperature for solids	Biocidal product contains no components with an auto-ignition temperature below 100°C. The auto-ignition temperature of the active substance permethrin and limestone is more than 400°C. The main components of the mixture are known not to be flammable and therefore it could be strongly assumed that the product will not self-ignite.			
Dust explosion hazard	Based on the Particle size distribution tests, see the conclusion in the relevant section above, the fine fraction in the biocidal product is considered to be limestone dust. Limestone is not classified as a dangerous substance and the limestone dust is neither explosive nor associated with any potential explosive properties.			

Conclusion on the physical hazards and respective characteristics of the product
No physical hazards were identified and all the data waivers related to relevant tests were justified properly. All justifications and clarifications are based on the professional assessment supported by several years of experiences with manufacture, use, handling and/or storage showing no indications related to physical hazards properties. A DSC test is also available, confirming the absence

of explosive or self-reactive properties. Biocidal product is considered to have no physical hazards. It is considered to be relatively inert, with no expected explosive, flammable, oxidising, self-heating, self-reacting or self-ignition hazards.

2.2.4 Methods for detection and identification

For determination of the mass concentration of Permethrin, CAS No. 52645-53-1, in the biocidal product Formitox the GC-MS analytical method, including all required validation parameters (i.e. Linearity, Specificity, Precision explained as relative standard deviation of repeatability and Accuracy explained and stated as Recovery), was developed and all relevant results submitted by the laboratory. The analytical method for relevant environmental compartment is described in the dossier for the active substance (Letter of access was submitted by the applicant). More in detail as follows.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analyte (type of analyte e.g. AS)	**Method**	**Fortification range Number of replicates**	Linearity 6 points calibration curve	Specificity	Validation parameters: Accuracy (as recovery) Precision (as rel. std. deviation of repeatability) Values in % relative.			**LOD LOQ (AS)**	**Reference**
					Recovery		Precision		
					Range	Mean	RSD		
Permethrin, CAS No. 52645-53-1	GC-MS	n=8 (RSD) Recovery: conc. level 0.30% AS	**y=kx+q** k=254125 q= −167679 R^2=0.9985	See the conclusion below the Table	96.8-100.9	average 98.9	3.6	LOD 0.004 LOQ 0.012	Vilímková, V., 2019

Conclusion on the methods for detection and identification of the product

The purpose of the study was the development of a fully validated analytical method including all required validation parameters (Linearity, Specificity/Selectivity, Precision explained as relative standard deviation of Repeatability and Accuracy covered by Recovery) for determination of the mass concentration of the active substance Permethrin, CAS No. 52645-53-1, in the biocidal product Formitox. The analytical method suitable for this given purpose was found as GC-MS equipped with Rx5 SIL MS 60m column. Before the AS determination the analytical standard was dissolved and diluted as well as the samples were extracted and diluted in methanol. For the external 6 points calibration the analytical standard of Permethrin, 45614-250MG; LOT # SZBE 188 XV, supplied by Fluka, declared purity (COA) of 98.8% AS, was used. The correction to the purity declared by the RM supplier has been used in all calculations. The acceptable recovery values for the AS nominal value of 0.1-1.0% are within the range of 95-105 %. Permethrin coformulant mix of the 0.30 w/w AS concentration level using an external calibration was measured as well as in the same time 4-point standard addition method was applied. The average AS mass concentration value measured by an external calibration was 0.3028 % w/w, the AS mass concentration value obtained by the standard addition method was 0.2905 % w/w meaning the recovery 98.9 %. Limit Of Quantitation (LOQ) for the

AS in the matrix as it is, i.e. with all coformulants, is 0.012% and Limit of Detection (LOD) is 0.004%. Linearity was evaluated at the relevant concentration level in accordance with the expected AS mass concentration in the biocidal product. The correlation coefficient is higher than 0.99. The parametric equation of the calibration curve and the correlation coefficient are presented in the Table above. The precision of the method used, explained as relative standard deviation of repeatability (RSD), is 3,6 % relative. The number of replicate measurements under the repeatability conditions was set to n=8. The measurement was provided using Permethrin analytical standard in matrix, i.e. in the mixture of the same ratio of the coformulants as in the formulation assessed. Related to the specificity / selectivity, the biocidal product formulation neither contains any other active substances nor components which interfere with Permethrin. The method used for Permethrin determination is therefore specific/selective. This was clearly shown and declared by the completely described and evaluated spectra for the analytical standard of the AS as well as for real matrix of the sample and blank sample measured which are an integral part of the relevant Test Report Vilímková, 2019.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use
The product Formitox is intended to be used indoor as a powder insecticide product with concentration 0.25% of active substance permethrin (CAS: 52645-53-1, EC: 258-067-9) by non-professional users.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected
The biocidal product Formitox is used for the control of ants (*Lasius niger*).
Organisms (to be protected) or treated materials: man, and households.

2.2.5.3 Effects on target organisms, including unacceptable suffering
Direct contact with product has lethal effect for test organism.

2.2.5.4 Mode of action, including time delay
Active substance of the biocidal product is permethrin, which belongs to pyrethroid family. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetive discharges in motor and sensory axons.
According to Assessment report permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. It is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole-body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisa-ged**	**Test subst.**	**Test orga-nism**	**Test metho d**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Refe-rence**
Insecti-cide	Used for the control of ants	BP Formitox (AS: Permethrin 0.25%)	*Lasius niger*	Labora-tory test	The amount 3g of the biocidal product was placed onto 10 × 10 cm beech plywood squares (representing a porous surface) and ceramic tiles (a non-porous surface). 20 ant workers per replicate Porous surface with biocidal product (5 replicates) Non-porous surface with biocidal product (5 replicates) The test was performed 24 hours and 21 days after application Untreated controls: 20 ant workers per replicate, 5 replicates on porous surface without biocidal product and 5 replicates on non-porous surface without biocidal product	The results on porous surface show 100% knock down effect (lethal effect) in 7 min. 24 hours after application of biocidal product and 11 minutes 21 days after application. The results on non-porous surface show 100% knock down effect (lethal effect) in 7 min. 24 hours after application of biocidal product and 10 minutes 21 days after application. No recovery effect was observed within 24 hours. No mortality was observed in the controls.	Kulma, M., 2019, study report numbe r: 19133 6
insecticid e	Used for the control of ants	BP Formitox (AS: Permet-hrin 0.25%)	*Lasius niger*	Simula-ted use test	Three glass chambers of 100cm × 100cm × 15cm (L × W × H) were used. One gram of the biocidal product was applied in a 33 × 1 cm line. Furthermore, several shelters of accordion-folded filter paper, glass drinking fountains, sugar cubes and crushed flies were placed on the bottom of the	The simulated use test was performed simulating normal use immediately after application and 21 days after the application. During these tests a significant mortality (90.6% and 98.6%) of the workers of the ants was observed within 14 days.	Kulma, M., 2019, study report numbe r: 19133 6

					chambers. The upper edges of the containers were treated with fluon (Sigma-Aldrich, USA) to limit the escape of ants. 20 and more individuals (ant workers) per one chamber Number of replicates: 3 Untreated controls: 3 replicates (chambers) The test was performed during 14 days. After 14 days the dead and live ants was removed. The test was repeated after 21 days from biocidal product application to check the residual efficacy. The duration of the test for residual efficacy was again 14 days.		

Conclusion on the efficacy of the product

The laboratory and simulated use tests were submitted to prove efficacy of the biocidal product Formitox that claim to kill ants that are in contact with the biocide.

The results of the laboratory test on porous surface show 100% knock down effect (lethal effect) in 7 min. tested 24 hours after application of biocidal product and 11 minutes 21 days after application.
The results of the laboratory test on non-porous surface show 100% knock down effect (lethal effect) in 7 min. tested 24 hours after application of biocidal product and 10 minutes 21 days after application.
The amount 3g of the biocidal product was placed onto 10 × 10 cm area in the laboratory test. It corresponds to the intended use, when the product is applied in the amount 1g in the line of 1 cm x approx. 35 cm.
The simulated use test simulating normal use was performed immediately after application and 21 days after the application. During this test, significant mortality (90.6 % and 98.6 %) of antworkers was observed within 14 days.

During the test, the behavior of the workers was observed: the test organisms were not prevented from coming into contact with the treated area, but neither did they search for it - they came across it accidentally while they were moving around the test chamber. Workers were not observed to eat or carry the product from the application site.
Based on the efficacy tests submitted and the requirements of the Transitional Guidance on PT18+PT19 (ECHA, September 2016), the insecticide contact powder product Formitox is considered efficacious against ants (*Lasius niger*) at the application of 1 g per a line 1 cm wide and approx. 35 cm long.
Please note that the efficacy of the hard non-porous and porous surfaces can be impacted by cleaning, therefore it must be highlighted that the treated surfaces cannot be cleaned (dry or wet) during the effective period.

2.2.5.6 Occurrence of resistance and resistance management
Resistance to Permethrin has been documented in wide varieties of insects (see Assessment report for active substance, 2014).
In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects.
Resistance to Permethirn in ant has not been recorded yet.
Because of the anticipated low level of selection pressure from the proposed use, no specific strategy for management of the development of resistance is required.

2.2.5.7 Known limitations
No cleaning (dry or wet) of treated area.

2.2.5.8 Evaluation of the label claims
Evaluation on the label claims are in accordance with legislative requirements.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)
The product is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Data waiving	
Information requirement	***Skin corrosion and irritation*** Iuclid section 8.1.1
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP). The biocidal product is not classified as a skin irritant or corrosive as none of its components is classified for skin corrosive/irritating potential.

Eye irritation

Data waiving	
Information requirement	***Eye irritation*** Iuclid section 8.1.2
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not classified as an eye irritant as none of its components is classified for eye corrosive/irritating potential.

Skin sensitization

Data waiving	
Information requirement	***Skin sensitization*** Iuclid section 8.3.1
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not classified as skin sensitising, but contains permethrin in a concentration that triggers labelling with EUH208. Contains permethrin. May cause an allergic reaction".

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	**Acute toxicity: oral** Iuclid section 8.5.1
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not classified as an acute toxic mixture for oral route of exposure. Though, the active substance permethrin (CAS: 52645-53-1) is classified as Acute Tox. 4, H302, its concertation in the product is below the limit triggering its classification as a whole.

Acute toxicity by inhalation

Data waiving	
Information requirement	**Acute toxicity: inhalation** Iuclid section 8.5.2
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not classified as an acute toxic mixture for inhalation route of exposure. Though, the active substance permethrin (CAS: 52645-53-1) is classified as Acute Tox. 4, H332, its concentration in the product is below the limit triggering its classification as a whole.

Acute toxicity by dermal route

Data waiving	
Information requirement	**Acute toxicity: dermal** Iuclid section 8.5.3
Justification	There are valid data available on each of the components in the biocidal product sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not classified as an acute toxic mixture for dermal route of exposure as none of its components is classified for acute toxicity via this exposure route.

Information on dermal absorption

Data waiving	
Information requirement	**Dermal absorption** Iuclid section 8.6
Justification	The data for active substance are available and are covered by Letter of Access

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

There are no substances of concern in the biocidal product Formitox.

Available toxicological data relating to a mixture

There are no data available.

2.2.6.2 Exposure assessment

The assessment of human exposure to the active substance permethrin follows the recommendations of TNsG on Human Exposure, 2002.
The main pathways of human exposure to permethrin from its use in biocidal product FORMITOX are shown in Table 3.

Table 3: Main paths of human exposure to permethrin as Repellent and Attractants

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	Yes	n.a.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Direct exposure: Application of product by amateur (indoor application)	Primary exposure during application and removal of the product in the form of powder. Only indoor application is allowed.	non-professionals
2.	Indirect exposure: Post-application - exposure to child 10.5 months	Secondary exposure during contact with the product in the post application period.	non-professionals

Industrial exposure
There is no industrial use of the FORMITOX.

Professional exposure
There is no professional use of the FORMITOX.

Non-professional exposure

Non-professional exposure is calculated below:

Scenario [1]

Description of Scenario [1]
Application of product by amateur The biocidal product FORMITOX is intended to be used by non-professional users. Only indoor application is allowed. The FORMITOX BP is a ready-to-use product applied by spreading onto the surface at the ant sites/paths. At the chosen place the recommendation is to spread 1/3 g of product over 1 cm wide line with a maximum length of 35 cm. No harmonized value is provided for the number of ant sites/paths in a household or other type of building. As a worst case CZCA considers two paths per room and 5 rooms per dwelling place (house, apartment). Thus, 10/30 g of the product are consumed per one application. As the applicant did not provide measurements quantifying exposure during the product application, an available model had to be chosen for this purpose. Of the available models the model for exposure to contact powder provided in User Guidance to Human Exposure to Biocidal Products is considered as suitable. This model provides a very conservative estimate of exposure to Formitox as it is derived for contact powders used against rodents mainly outdoors where it is usually blown directly into the burrows by dust blowers. However, it is also used at limited spaces indoors. Typically, 250 g of product is used per application. As no dustblower is used in Formitox application, inhalation exposure is considered as negligible.

Description of Scenario [1]

On application an estimate of the dermal exposure is suggested at 1% of the applied amount without protection.

The total amount to which the skin is exposed is estimated by the following equation:

$$A_{der} = \frac{Q_{prod} \times Fc_{prod}}{V_{prod} \times D} \times TH_{der} \times AREA_{der} \quad (mg)$$

Where TH_{der} is the thickness of the powder layer in contact with skin, 0.01 cm
D- product density
$AREA_{der}$ – skin area in contact with the powder
Q_{prod} - the applied amount of the product (mg)
V_{prod} - volume of the applied product (cm^3)
Fc_{prod}- fraction of the a.s. in the product.
Assuming that 1% of 10/30 g (cf. above) with 0.0025 a.s. and a density of cca. 1 g/cm^3, gets into contact with hands and forearms (2000 cm^2) then the dermal load in contact with the skin is 0.25/0.75 mg a.s..(i.e all the loaded product (100 mg) is contained within the layer thinner than 0.01 cm on the exposed skin area and it is available for dermal absorption).
The weight of an adult handling the product is 60 kg, the default dermal absorption is 50% (EFSA guidance 2017). The absorbed dose is: 0.0021/0.0063 mg/kg bw/d for doses of 10/30 g, respectively.

On disposal: Removal by brooming is considered as a worst case (as opposed to vacuum cleaning) may disperse the dust into the air resulting in inhalation and dermal and even oral exposures.
Inhalatory exposure and dermal exposures are estimated at 1% of the residual amount, assuming 50% residues still present. As the worst case, all above amount is considered to be taken via inhalation route (i.e. 100% of pulmonary uptake): The absorbed dose is 0.0021/0.0063 mg/kg bw.

Thus, the use of the product as proposed results in 0.0042/0.0126 mg/kg bw/d

Oral: n.a.

Alternatively, for comparison and confirmation, HEAd hoc recommendation no.6, page 33., Scattering powder against ants from a hand held flexible duster/hand held canister can be used for inhalation exposure. Duration of exposure is 1 hour and, inhalation rate is 1.25 m3/hr, product airborne concetration is 2.47 mg/m3. Exposure via inhalation is:
1*1.25*2.47 *0.0025*/60 = 0,00013 mg/kg bw.
Dermal exposure : Duration- 1hour, hands and forearms - 2.73 mg/min; legs feet and face -2.74 mg/min,
Dermal exposure is : (2.73*60 +2.74*60) * 0.0025*0.5/60 = 0.0068 mg/kg bw/d
Total exposure = 0.00013 + 0.0068 = 0.0069 mg/kg bw/d

Further information and considerations on scenario [1]

Chronic risks were considered for non-professional users. However, as non-professional users are expected to use the biocidal product only intermittently for a few events per year, comparison of exposure to limits for short term exposure are considered to be more reasonable.

Exposure of the general public

In the case of indirect exposure as a result of use (secondary exposure) two scenarios are proposed: dermal and oral scenarios.

Scenario [2]

Description of Scenario [2]
Secondary exposure should be prevented by RMM described in the proper labelling. This should lead to the product being placed in places not accessible by children (under cupboards etc.) As a realistic worst-case, exposure of infant is considered to take place by accident no more than several times per year. The applicant used CONS expo – post application exposure of infants to dusting powder. This model does not appear suitable for quantifying the secondary exposure due to the Formitox use. This is because it is derived for spraying applications covering larger areas with lower dose/area whereas Formitox use is based on a more spot on application of larger amount of the product/area. Furthermore, the model assumes dislogable amount of 15 g product/m^2. This exceeds 7.5 fold Formitox amount used in one room. Thus, the below approach was used to quantify secondary exposure **Indirect exposure (post-application - exposure to child 10.5 months)** In the absence of a suitable model the following assumptions are made: 1) An infant gets into contact with the powder in one room (i.e. 2/6 g of formitox) 2) 3% of the product is transferred onto the infant skin (USEPA SOP for Residential Exposure to Pesticides Assessment, Table 7-9: Chemical-specific Fraction transferred (Fai) for Hard Surfaces -75th percentile for permethrin) 3) 1% of the product is inhaled (assuming the same inhalation exposure as that for brushing during the product disposal above in scenario 1) 4) The infant body weight is 8 kg (Headhoc opinion 14) 5) Dermal and oral absorption is 100% (it is assumed that the dermal load is either dermally absorbed or licked out and swallowed) and pulmonary absorption is 100 % (Assessment Report for Permethrin, ECHA) The systemic exposure is calculated as follows: For 2 g per room: [(2000*0.0025mg*0.03*1) + (2000*0.0025mg*0.01*1)]/ 8 kg = [0.075 +0.05]/8 = 0.025 mg/kg bw/ day For 6 g per room:

Description of Scenario [2]
[(6000*0.0025mg*0.03*1) + (6000*0.0025mg*0.01*1)]/ 8 kg = [0.225 + 0.15]/8 = 0.075 mg/kg bw/ day

Monitoring data
No data available.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier**	**Estimated total uptake**
1.	Non-professional user Amateur user powder – Primary exposure	1	0.0042 mg/kg bw/d 0.0126 mg/kg bw/d
2.	General population Secondary exposure infants	1	0.025 mg/kg bw/d 0.075 mg/kg bw/d

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for permethrin

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	The 90-day inhalation rat study (Kumar, 2006)	NOAEL = 59.46 mg/kg bw/day	100	-	0.5 mg/kg bw/day
AELmedium-term	The 90-day oral rat study submitted by Applicant 2 (Ramesh, 2002)	NOAEL = 172 mg/kg bw/day	-	-	0.05 mg/kg bw/day
AELlong-term	the 12-month dog study (Kalinowski *et al*, 1982 (key)	NOAEL = 50 mg/kg bw/day	-	-	0.05 mg/kg bw/day
ARfD	-	-	-	-	0.5 mg/kg bw/day

ADI	WHO/FAO JMPR	NOAEL = 5 mg/kg bw/day	-	-	0.05 mg/kg bw

[1] see Assessment Report for permethrin (EU RAR, 2014).

Data are taken from EU RAR, 2014.

Risk for industrial users
There is no industrial use of the FORMITOX.

Risk for professional users
There is no professional use of the FORMITOX.

Risk for non-professional users
Chronic risks were considered for non-professional users. However, as non-professional users are expected to use the biocidal product only intermittently for a few events per year, comparison of exposure to limits for short or medium term exposure are considered to be more reasonable.
The exposure assessment for non-professional users under worst case assumptions yielded a potential dermal exposure leading to a systemic dose of 0.0042 mg/kg bw/d for an unprotected user during application of the ready-to-use powder.
The comparison to the proposed AELs of 0.05 or 0.50 mg/kg bw/day for - medium term and short term exposure shows high level of protection of the Formitox users, provided the instructions for use are followed.

Systemic effects

Task/ Scenario	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Short term exposure (10g/household)	50	0.5	0.0042	0.84	yes
Short term exposure (30g/household)	50	0.5	0.0126	2.52	yes
Medium term exposure	5	0.05	0.0042	8.4	yes

(10g/house hold)					
Medium term exposure (30g/house hold)	5	0.05	0.0126	25.2	yes

Combined scenarios

No combined exposure is foreseen.

Local effects
There is no need to consider local effects separately. Although the biocidal product (BP) Formitox contain active substance permethrin, which is classified as a skin sensitizer, the BP Formitox contain only 0.25 % of permethrin, thus the biocidal product itself is not classified as a skin sensitizer. However, labelling shall contain EUH 208: Contains permethirin, may cause allergic skin reactions.

Conclusion

Risk characterisation for primary exposure took into account the intermittent use of the product, which is used no more than several times per year. Thus reference value for short term exposure appears to be appropriate for this purpose. The comparison of systemic exposure with the short term AEL of 0.5 mg/kg bw/d resulted in 0.84%, showing high level of protection of the user provided instructions for use are followed. Apart from this, the systemic exposure was also compared with the medium term AEL of 0,05 mg/kg bw/d resulting in 8.4 %. This confirms the high level of protection of the consumer using Formitox.
Regarding local risk, it is not assessed as such assessment is not triggered by product classification or any other information contained e.g. in the a.s. AR. However, the content of the a.s. permethirin in the product, which is calssified co a skin sensitizer, calls for the product labelling with EUH208: "Contains permethrin. May causes allergic skin reaction.". The risk is further mitigated by the use of a lid for spreading the biocidal product which is designed to avoid the direct contact with the skin.

Risk for the general public

The secondary exposure refers to the contact with the product during the post application phase.(i.e. between the application and disposal of the product). Such contact should be avoided by risk mitigation measures recommended as part of the labelling. As the worst case, secondary exposure of infant was quantified. As such exposure is assumed to take place no more than several times per year, short term AEL of 0.5 appears to be the appropriate reference value. The calculated systemic exposure of 0.016 mg/kg bw d accounts for 3.2 % of the short term AEL leading.

Thus, the proposed use presents no unacceptable risk in terms of secondary exposure provided the proposed risk mitigation measures shall be followed.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary exposure infants (10.5 months old children) / Scenario [2]						
Short term exposure	TIER 1	50	0.5	0.025	5	yes
Short term exposure	TIER 1	50	0.5	0.075	15	yes

Local effects
See the section for primary exposure risk characterization above.

Conclusion
Secondary exposure of infants who would be in contact, inhale or ingest residues is considered to be very low and the margins of safety are very high and therefore, acceptable following exposure due to the use of relevant Permethrin containing products. Therefore, it can be assumed that very little risk to infants exists in this scenario.
The comparison of the estimated exposure to the proposed AELs results in 3.2/9.4 %, being well below the limits, indicating an acceptable risk.
Risk mitigation measures for secondary exposure was established also on the label such as:

- Keep out of reach of children.
- The product must not be used other than that specified in the manual.
- Prevent the access to the areas treated with Formitox by children, domestic and farm animals. Protect food, beverages and feed from contamination.

Risk for consumers via residues in food
Not relevant.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

2.2.7 Risk assessment for animal health

Not relevant.

There is no harmonised exposure scenario for domestic pets and other non-target animals.

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication is very common and may be lethal. In order to protect these animals, specially cats, the following RMM must be added on the label:

- "Prevent the access to the areas treated with Formitox by children, domestic and farm animals, particularly cats due to their high sensitivity to pyrethroids (permethrin)."
- Protect food, beverages and feed from contamination.

As poikilothermic animals like fish, amphibians and reptiles, are particularly susceptible towards the toxicity of pyrethroids, and as no data were provided for exposure assessment, the risk mitigation measure "Remove or cover terrariums, aquariums and animal cages before application" is set.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment

According to the Assessment Report (April 2014), permethrin is classified as N Dangerous for the Environment and R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Permethrin is assigned R53 as it is not readily biodegradable. Under CLP this translates into H410 (Acute Cat 1, Chronic Cat 1) very toxic to aquatic life with long-lasting effects. This classification is based on the high toxicity to fish (0.0051 mg a.s./L) and to aquatic invertebrates, with Daphnia 0.00127 mg a.s/L, being the most sensitive of the aquatic organisms tested. Chronic toxicity studies resulted in a NOEC of 0.0000047 mg/L for Daphnia magna. Permethrin does not appear to have an endocrine affect in fish. The studies in the Assessment Report (2014) were conducted with permethrin with the isomer composition (cis:trans) of 25:75 or with a mixture of isomers with 50-78% of the trans-isomer.

The summary of the effect values (taken from the active substance assessment report, April 2014, IE, and the addendum to the AR, March 2017, IE) for permethrin is provided below:

Permethrin		
Species	**Endpoint (time scale)**	**Toxicity**
O. mykiss	LC50 (96 h), mortality	0.0051 mg a.s./L
D. rerio	NOEC (35 days), reduced survival LC10	0.00041 mg a.s./L 0.00059 mg a.s./L
D. magna	LC50 (48 h) NOEC (21d), reproduction	0.00127 mg a.s./L 0.0000047 mg a.s./L; 0.0001874 mg/L
P. subcapitata	ErC50 (72 h)	> 1.13 mg a.s./L
P. subcapitata	NOEC ErC50 (72 h)	<0.0131 mg a.s./L 0.0023 mg a.s./L
Microorganisms (activated sludge)	EC50 (3h) NOEC	> 1000 mg/l 0.00495 mg/l[2]
Microorganisms (activated sludge)	EC50 (3h) NOEC	> 0.42 mg/l 0.00495 mg/l[2]

C. riparius	LC50 (10-d), adult emergence LC50 (96h), survival	2.110 mg/kg 0.00289 mg/L
C. riparius	NOEC (5d after last emergence), adult emergence	0.1 mg/kg
Earthworm	EC50	371 mg a.s./kg (126 mg/kg dwt converted to artificial soil 3,4% O.M)
Soil microorganisms	EC50	> 9.9 mg/kg dry weight (8.76 mg/kg wwt)

2 According to TM II 06 and TM II 08, for substances with low water solubility and if no effects on microorganisms are observed at the highest tested concentration, then water solubility is set as the NOEC

Metabolites

According to the assessment report for permethrin the major metabolites are 3-(2, 2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

The summary of the effect values for the metabolites (taken from the active substance assessment report) is provided below:

Species	**Endpoint (time scale)**	**Toxicity**
Metabolite: DCVA		
Rainbout trout	LC50 (96 h), mortality	≥ 14.7 mg a.s./L
D. magna	LC50 (48 h)	25 mg a.s./L
Earthworm	NOEC (14 d), mortality LC50 (14 d), mortality NOEC (34 d), reproduction	100 mg/kg converted to artificial soil = 167 mg/kg dwt 400.9 mg/kg converted to artificial soil = 668 mg/kg dwt >316 mg/kg converted to artificial soil = >526 mg/kg dwt
Metabolite: PBA		
C.pyrenoidosa/ S.quadricauda	EC50 (14 d), growth yiled	> 10 mg a.s./L 0.0023 mg a.s./L
Earthworm	NOEC (14 d), mortality LC50 (14 d), mortality NOEC (34 d), reproduction	940 mg/kg converted to artificial soil = 1567 mg/kg dwt > 940 mg/kg converted to artificial soil = > 1567 mg/kg dwt 297 mg/kg converted to artificial soil = 495 mg/kg dwt

Information relating to the ecotoxicity of the biocidal product is sufficient to enable a decision to be made concerning the classification of the product.

The biocidal product is classified as dangerous for the environment: Aquatic Acute 1, H400 Aquatic Acute 1, H410.

Further Ecotoxicological studies

Data waiving	
Information requirement	Toxicity to aquatic organisms IUCLID sections: 9.2.1.1, 9.2.1.2, 9.2.1.3, 9.2.1.5
Justification	There are valid data available on each of the components in the biocidal product. The data are considered to be sufficient to allow classification of the mixture according to the rules laid down in the Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is classified as dangerous for the environment: Aquatic Acute 1, H400 Aquatic Acute 1, H410. Limestone (CAS: 1317-65-3) is not classified as dangerous for human health and the environment. Sucrose (CAS: 57-50-1) is not classified as dangerous for human health and the environment. The colorant EGACIDOVÁ MODŘ K (mixture) and the main component Acid blue 25 (CAS: 6408-78-2) are not classified as dangerous for human health. Acid blue 25 (CAS: 6408-78-2) is classified as: Aquatic Chronic 3, H412. The active substance permethrin (CAS: 52645-53-1) is classified as: Acute Tox. 4, H332, Acute Tox. 4, H302, Skin Sens. 1B, H317, Aquatic Acute 1, H400 Aquatic Acute 1, H410.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No data available.

Supervised trials to assess risks to non-target organisms under field conditions
No data available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No data available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
No data available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

FORMITOX is a powder concentrate formulation that contains 0.25% w/w of the active substance permethrin (in the cis:trans isomeric ratio of 25:75). It is intended to be used indoor by non-professional use in targeted spot applications against ants resting on surfaces. The product is applied as ready–to-use directly from the package with the pour spout lid. The product is applied by spreading 1 gram of crystals directly onto the surface at the insect sites (ants).

More detailed information with regard to the emission pathways is provided in Section *Fate and distribution in the environment.*

Further studies on fate and behaviour in the environment (ADS)
No data available*.*

Leaching behaviour (ADS)
No data available*.*

Testing for distribution and dissipation in soil (ADS)
No data available*.*

Testing for distribution and dissipation in water and sediment (ADS)
No data available*.*

Testing for distribution and dissipation in air (ADS)
No data available*.*

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)
Not relevant.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given, then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)
Not relevant.

2.2.8.2 PBT assessment

PBT assessment of permethrin was during active substance authorization and is available in the Assessment report (2014). The main findings were as follows:
Persistence:

Permethrin as the isomeric mixture 25:75 cis:trans is not persistent in aquatic systems, on the basis that its whole system DT50 (12 ºC) values do not fulfil the P criterion for sediment. However, a constituent of permethrin (the cis isomer) may have the potential to be persistent. Permethrin (25:75) is not considered to fulfil the P or vP criteria.

Bioaccumulation:

The reported Log Pow values for permethrin range from 4.6 to 6.1, indicating it is a fatsoluble molecule with a potential to bioconcentrate. However, experimentally derived BCF values for fish and chironomid ranged from 290 to 620 l/kg. Additionally, these data also indicated that residues were readily eliminated through depuration with approximately 80% of the residues depurated within 14 days.
Permethrin (25:75) is not considered to fulfil the B or vB criteria.

Toxicity:

The most critical long-term aquatic endpoint was the reproductive NOEC of 0.0000047 mg a.s./L for *Daphnia magna*, which is less than 0.01 mg/l trigger. Permethrin (25:75) is considered to fulfil the T criteria.

Conclusion: Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers. Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria.

However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfill the P criteria. Guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that since the cis isomer constituent is present within permethrin at amounts ≥0.1 % w/w then the multi-constituent substance, permethrin, should also be treated as potentially persistent. In this situation permethrin may potentially fulfill the persistency criteria and, hence, fulfill two out of the three PBT criteria. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, permethrin is currently assessed by the ECHA PBT working group. Depending on the outcome of the ECHA PBT working group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10 of Regulation (EU) No 528/2012.

In addition, according to the BPC-40 minutes from January 18, 2022, permethrin meets the T and the P criteria, and subsequently, it meets the conditions of Article 10(1)(d), and comparative assessment is needed for products containing permethrin. Furthermore, it was concluded during the BPC meeting that a statement would be included in the Assessment Report that data to conclude on the B criterion has to be submitted for renewal. Considering the submission date for the concerned application for the product Formitox, the implication of the decision formulated in the minutes to the BPC meeting in January 2022, i.e., the requirement for a comparative assessment, will be applicable only at the renewal stage.

2.2.8.3 Exposure assessment

Exposure assessment was driven by the emission exposure scenario ‘Application of powders by dusting’ under PT18 and the corresponding emission scenario document

for 'Insecticides, acaracides, and products to control other arthropods for household and professional uses'. More information is provided below.

General information

Assessed PT	*PT 18*
Assessed scenarios	Scenario 1: Application of powders by dusting
ESD(s) used	Emission Scenario Document for Product Type 18: Insecticides, acaracides, and products to control other arthropods for household and professional uses
Approach	The assessment was made as the worst-case scenarios.
Distribution in the environment	Calculated based on EUSES (Simple Treat 4.0)
Groundwater simulation	No simulation for leaching to groundwater using a higher tier model was performed.
Confidential Annexes	No
Life cycle steps assessed	Scenario 1.1: Non-professional use – dry cleaning process
	Scenario 1.2: Non-professional use – wet cleaning process

Emission estimation

FORMITOX is applied in a form of powder in indoor applications by general public. The product is intended to be sold in a ready to use form, where no preparation step is needed. No direct application to the environment is expected. In the exposure assessment, two sub-scenarios differing in the proposed cleaning step (dry or wet) were considered. According to the label statement, only the dry cleaning process (Scenario 1.1) is allowed. Nevertheless, since the product is dedicated to non-professionals, the wet cleaning process (Scenario 1.2) is also considered in a separate exposure sub-scenario. For Scenario 1.1 (dry-cleaning process), direct emissions to wastewater are expected to be negligible, and only indirect emissions due to washing of clothes (washable coveralls) are foreseen. For Scenario 1.2, emissions to wastewater are expected through the wet cleaning step. In both sub-scenarios, the STP is the major recipient of the emissions (direct emissions to air are considered to be negligible), while surface water (sediment), groundwater, soil, and air are considered to be the 'final' recipients.

The environmental exposure assessment has been performed by using the model EUSES 2.2.0 in accordance with the emission scenario document for insecticides, acaricides and products to control arthropods (PT 18) for household and professional use (OECD, 2008) and was based on the information related to the use patterns of the product FORMITOX. The area treated with the product was set to 2 m^2 following the explanation in PT 18 (p. 57) on that for social insects, it is not necessary to treat all the floor, the operator has just to apply insecticide on the insect tracks.

The environmental exposure assessment was performed on the basis of physico-chemical properties of permethrin and fate data derived from the Assessment report (2014). The studies in the Assessment Report (2014) were conducted with permethrin with the isomer composition (cis:trans) of 25:75 or with a mixture of isomers with 50-78% of the trans-isomer.

SCENARIO 1

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1.1: *Product Type (18): Insecticides, acaricides and products to control to other arthropods – application of powders by dusting (including the **dry cleaning step**)* Scenario 1.2:			

*Product Type (18): Insecticides, acaricides and products to control to other arthropods – application of powders by dusting (including the **wet cleaning step**)*			
Select formulation/use	Dust/powder - surface		*Targeted application*
Fraction of active substance in product (F_{AI})	0.0025	-	*0.25% permethrin*
Mixing/loading step	No		Ready-to-use product
Quantity of product applied per m^2 (Q_{prod})	1	*g/m²*	Efficacy data (Simulated use test)
Area treated with the product ($AREA_{treated, house}$)	2	*m²*	PT18, p. 57 (targeted application)
Frequency of application ($F_{simultaneity}$)	3-11 times a year $F_{simultaneity}$ = 0.008151		Data set (max. 9 applications/y)
Cleaning efficiency (F_{CE})	0.5	-	Default for dust/powders applied on surfaces
Coveralls	Washable		Data set
Cleaning of treated surfaces	Dry (Scenario 1.1) Wet (Scenario 1.2)		Data set

The output (local emissions) for Scenarios 1.1 and 1.2 were as follows:

Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	
	Scenario 1.1	**Scenario 1.2**
Air	3.26E-06	3.26E-06
Wastewater	1.47E-05	7.99E-05

Fate and distribution in the environment

For the assessment of fate and distribution in the environment, the following physico-chemical properties and fate data reported in the active substance Assessment Report (2014) were considered. The proposes setting should reflect the worst-case scenario since no degradation in STP was proposed.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.3	g/mol	Risk Assessment Report for Permethrin, April 2014 (EU RAR, 2014)
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at 20°C)	2.16E-06	Pa	
Water solubility (at 20°C)	4.95E-03	mg/l	
Log Octanol/water partition coefficient	4.67	Log 10	
Organic carbon/water partition coefficient (Koc)	26 930	l/kg	
Henry's Law Constant (at X C) *[if measured data available]*	4.6E-03	Pa/m3/mol	
Biodegradability	*Not readily biodegradable according to OECD 301; no evidence of inherent ultimate biodegradability*		
Rate constant for STP *[if measured data available]*	0	h^{-1}	EUSES output, worst-case scenario
Rate constant for hydrolysis in surface water (12°C)	6.93E-07	d^{-1}	EUSES output
Rate constant for photolysis in surface water	6.93E-07	d^{-1}	EUSES output
Rate constant for biodegradation in surface water (12°C)	6.93E-07	d^{-1}	EUSES output
Rate constant for degradation in air	0	d^{-1}	EUSES output
DT50 for degradation in soil (12°C)	106	d	Geomean, Assessment Report
BCF (earthworm)	15108	L/kg wwt	Assessment Report
BCF (fish)	570	L/kg wwt	Assessment Report

Following the intended uses of Formitox, i.e., as an insecticide in a form of ready-to-use powder for indoor applications followed by dry or wet cleaning, the concerned environmental compartments were identified to be the STP as the primary compartment and surface water/sediment, air, soil, and groundwater as the secondary compartments. Emissions to STP are expected to occur due to washing of clothing (washable overalls) in Scenario 1.1 and due to the proposed wet cleaning process in Scenario 1.2. Emissions to indoor/outdoor air during application and cleaning steps are generally considered negligible due to the low volatility of permethrin (vapor pressure = 2.155 x 10-6 Pa at 20°C) and the assumed low

percentage of the active compound emitted to air in STP. In addition, permethrin has an atmospheric half-life of 0.701 days (AOPWIN v1.91 software), so neither degradation nor long range transport in the atmosphere in the gaseous phase is expected (Assessment Report, 2014). Due the high OC-water partition coefficient (mean Kfoc 73,441 L/kg, Koc = 26,930, n = 9), the compound is expected to sorb to the solid phase (sludge, sediment) in the aquatic environment and in soil, no significant leaching is expected.

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sed.	Sea-water	Seawater sed.	STP	Air	Soil	Ground-water
Scenario 1.1	Yes	Yes	No	No	Yes	No	Yes	Yes
Scenario 1.2	Yes	Yes	No	No	Yes	No	Yes	Yes

The behavior of permethrin in STP was modelled via EUSES 2.0.0 with integrated Simple Treat 4.0. The distribution in the STP (k = 0 d^{-1}, see below) implies that the highest fraction of permethrin emission will be directed to sludge. The fraction f the active compound directed to air is considered to be negligible. No degradation in STP is proposed.

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1.1	**Scenario 1.2**	
Air	7.67E-04	7.67E-04	EUSES output
Water	15.14	15.14	EUSES output
Sludge	84.85	84.85	EUSES output
Degraded in STP	0	0	EUSES output

Metabolites

According to the assessment report for permethrin the major metabolites are 3-(2, 2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA). The approach used to calculate the PECs for these is based on the assumption that 100% of the parent PEC is converted to metabolite PEC taking into account the relative molar masses. The values will be worst case since degradation studies indicate less than 100% conversion to these metabolites. The molecular weight of DCVA and PBA is 209.1 and 214.2 respectively (based on doc IIB of the final draft CAR for permethrin PT18 of 2014). The molecular weight of permethrin is 391.3. The PECs for each are calculated using these ratios.

For DCVA, PEC = $PEC_{permethrin}$ * 209.1/391.3 = $PEC_{permethrin}$ * 0.53

For PBA, PEC = $PEC_{permethrin}$ * 214.2/391.3 = $PEC_{permethrin}$ * 0.55

Calculated PEC values

Following the two emission sub-scenarios (1.1 and 1.2) and the behaviour of permethrin in STP, the following PEC values were estimated for the relevant compartments. The PEC values represent the worst-case scenario since no degradation in STP is considered. The two sub-scenarios differ in the cleaning process (dry cleaning in Scenario 1.1 and wet cleaning in Scenario 2). PEC_{air} value were calculated to be 9.06E-10 mg/m^3 for the proposed scenarios and corroborates the previous assumption that exposure to the active substance *via* air can be neglected.

Permethrin

Summary table on calculated PEC values (permethrin)						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}[d]**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/L]	[mg/m^3]
Scenario 1.1	1.92E-06	1.85E-07	1.8E-04	2.15E-05[a] 1.28E-05[b] 5.08E-06[c]	2.66E-08	9.06E-10
Scenario 1.2	1.05E-05	1.01E-06	5.89E-04	1.17E-04[a] 6.89E-05[b] 2.76E-05[c]	1.45E-07	9.06E-10

[a] Local PEC in agric. soil (total) after 10y sludge application - initial
[b] Local PEC in agric. soil (total) averaged over 180days
[c] Local PEC in grassland (total) averaged over 180 days
[d] PECgw under agricultural soil (based on PEC in agric. soil averaged over 180 d)

Metabolites
For the two metabolites, the predicted concentrations in the relevant compartments are as follows:

Summary table on calculated PEC values (DCVA)						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/L]	[mg/m^3]
Scenario 1.1	1.02E-06	9.81E-08	5.72E-05	1.14E-05[a]	1.41E-08	Not relevant
Scenario 1.2	5.57E-06	5.35E-07	3.12E-04	6.20E-05[a]	7.69E-08	Not relevant
Summary table on calculated PEC values (PBA)						
	PEC_{STP}	**PEC_{sw}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/L]	[mg/m^3]

Scenario 1.1	1.06E-06	1.02E-07	5.94E-05	1.18E-05[a]	1.46E-08	Not relevant
Scenario 1.2	5.78E-06	5.56E-07	3.24E-04	6.44E-05[a]	7.98E-08	Not relevant

*Local PEC in agric. soil (total) after 10y sludge application - initial

Primary and secondary poisoning

Primary poisoning

Birds
According to data available in the assessment report, permethrin has low acute toxicity to birds (LD50 > 4640 mg/kg bw) and very low dietary toxicity (LC50 > 10000 ppm). Also, for indoor use, it is considered unlikely that birds will enter the buildings and unlikely that they would eat the powder product.

Mammals
According to the assessment report, permethrin may be hazardous to small mammals following acute exposure (Lc50: 480 mg/kg bw). In domestic homes, the most likely non-target mammal at risk to the product would be the cat, because cats are known to be particularly sensitive to permethrin and are usually smaller than dogs, which are also likely to be inside treated properties.

Secondary poisoning

According to the assessment report, permethrin has the potential to bioaccumulate based on its log Pow of 4.67 and a bioconcentration factor of 500-570 L/kg from the 28-day bioconcentration study in bluegill fish, although the rapid depuration (50% in 4.7 days) indicates that any permethrin taken up by aquatic or terrestrial organisms will be rapidly eliminated once exposure ceases, which mitigates potential for biomagnification up the food chain.
A BCF fish of 570 L/kg and a BCF earthworm of 15108 L/kg_{wwt} was applied in the assessment of secondary poisoning through the consumption of fish or earthworms by birds and mammals.

2.2.8.4 Risk characterization

The following sub-scenarios were assessed:

Scenario 1.1:
Product Type (18): Insecticides, acaricides and products to control to other arthropods – application of powders by dusting (including the *dry cleaning* step)

Scenario 1.2:
Product Type (18): Insecticides, acaricides and products to control to other arthropods – application of powders by dusting (including the *wet cleaning* step)

The PNEC values used for risk characterization (PEC/PNEC ratio) were taken from the active compound Assessment Report. The PNEC values for the different compartments were as follows:

Permethrin
$PNEC_{surfacewater}$ = 0.00047µg a.s/l
$PNEC_{microorganisms}$ (STP) = 0.00495 mg a.s/l
$PNEC_{soil}$ (wet weight) = >0.0876 mg a.s/kg soil wwt (AR, April 2014), 0.198 mg/kg dry weight (0.175 mg/kg wwt) (Addendum to AR, March 2017)
$PNEC_{sediment}$ = 0.001mg/kg dwt (2.17E-04 wwt)
$PNEC_{oral\ bird}$ = ≥16.7 mg a.s/kg food
$PNEC_{oral\ small\ mammal}$ = 120mg a.s/kg food

DCVA
$PNEC_{surfacewater}$ = 0.015 mg/l
$PNEC_{soil}$ (wet weight) = 4.6 mg/kg wwt
$PNEC_{sediment}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt)

PBA
$PNEC_{surfacewater}$ = >0.010 mg/l
$PNEC_{soil}$ (wet weight) = 1.44 mg/kg wwt
$PNEC_{sediment}$ = 0.042mg/kg dwt (0.009 mg/kg wwt)

Atmosphere
Permethrin has low vapor pressure (2.155E-06 Pa) and the Henry's Law constant of 4.6E-03 Pa/m^3/mol at 20°C. Therefore, volatilization of the active compound is considered to be negligible and low emission to indoor/outdoor can be expected during product application and cleaning. The PEC_{air} values derived for the intended uses of the product (followed by either dry or wet cleaning step) equals 9.06E-10 mg/m^3. In addition, the estimated half-life of the compound in air is 0.701 d due to reactions with OH radicals, which are assumed to be the main contributor to atmospheric degradation of permethrin. In conclusion, the risks for the atmosphere compartment are considered low.

Conclusion: Direct exposure of the air compartment to the active substance is considered to be negligible for both Scenario 1.1 and Scenario 1.2.

Sewage treatment plant (STP)
Permethrin is considered to be hydrolytically and photochemically stable in water (Assessment Report). It is not readily biodegradable according to OECD 301 studies. In the proposed emissions scenarios, no degradation in STP was considered.

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1.1	3.88E-04
Scenario 1.2	2.17E-03

Conclusion: Results showed that there is no risk from permethrin to STP microorganisms from the indoor spot treatment in houses (non-professional use) in both cases (wet and dry cleaning of treated surfaces).

Aquatic compartment

Permethrin

Summary table on calculated PEC/PNEC values		
Permethrin	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1.1	3.94E-01	4.98E-01
Scenario 1.2	2.15E+00	2.71E+00

**Marine environmental exposure assessment is not relevant because it is assumed that FORMITOX will not be used or released in marine environments in considerable amounts.*

Metabolites

Summary table on calculated PEC/PNEC values		
DCVA	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1.1	6.54E-06	4.77E-03
Scenario 1.2	3.57E-05	2.60E-02
PBA	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
Scenario 1.1	1.02E-05	6.60E-03
Scenario 1.2	5.56E-05	3.60E-02

Conclusion:

Permethrin

The PEC/PNEC ratio for surface water and sediment in Scenario 1.1 is below 1, which indicates no risk to the environment due to the use of the product by non-professionals followed by dry cleaning. For Scenario 1.2 (wet cleaning process), risk have been identified for the aquatic (water, sediment) compartment. In conclusion, according to the results, only Scenario 1.1 (dry cleaning process) can be considered safe for the aquatic environment.

Metabolites

Permethrin metabolites DCVA and PBA pose no risk to aquatic compartment (surface water, sediment) since the respective PEC/PNEC values are below 1.

Terrestrial compartment

Permethrin

Calculated PEC*/PNEC$_{soil}$ values	
Permethrin	**PEC*/PNEC$_{soil}$**
Scenario 1.1	2.45E-04**/1.23E-04***
Scenario 1.2	1.34E-03**/6.69E-04***

Metabolites

Calculated PEC/PNEC$_{soil}$ values	
DCVA	**PEC*/PNEC$_{soil}$**
Scenario 1.1	2.48E-06
Scenario 1.2	1.35E-05
PBA	**PEC*/PNEC$_{soil}$**
Scenario 1.1	8.21E-06
Scenario 1.2	4.47E-05

*Local PEC in agric. soil (total) after 10y sludge application – initial
** PNECsoil (wet weight) of 0.0876 mg a.s/kg soil wwt used in accordance with the assessment report from April 2014
*** PNECsoil (wet weight) of 0.175 mg/kg wwt used in accordance with Addendum to AR, March 2017

Conclusion:

Permethrin

Results showed that there is no risk to soil organisms from the indoor spot treatment in houses (non-professional use) in the concerned cases (wet and dry cleaning of treated surfaces).

Metabolites

Metabolites DCVA and PBA pose no risk to the soil compartment.

Groundwater, primary and secondary poisoning

Groundwater

The predicted environmental concentration (PEC) of permethrin in groundwater under agricultural soil for Scenario 1.1 (dry cleaning process) and Scenario 1.2 (wet cleaning process) was estimated to be 2.66E-08 mg/L and 1.45E-07 mg/L, respectively. Thus, in both scenarios, the groundwater concentrations are less than the EU trigger value of 0.1 g/L. The same applies to the metabolites DCVA and PBA, for which the PEC_{gw} values also were below the trigger value.

Primary poisoning

Birds

The product is intended to be applied indoor, and therefore primary poisoning is not considered as a relevant scenario for birds.

Conclusion: There is no concern from primary poisoning of birds from use of Formitox in accordance with the use instructions.

Mammals

In households, the most likely non-target mammal at risk to the product would be the cat because cats are known to be particularly sensitive to permethrin and are usually smaller than dogs. However, according to ESD for PT18, the ESD for PT18 states that for primary poisoning, it is not believed that powder is a form that could be sufficiently appetizing to birds or mammals that there they would be a risk.

Conclusion: As a precautionary measure, the instructions for use should specify that cats should be prevented from the contact with the product.

Secondary poisoning

A BCF fish of 570 L/kg and a BCF earthworm of 15108 L/kg_{wwt} was applied in the assessment of secondary poisoning through the consumption of fish or earthworms by birds and mammals. The resulting concentrations in fish and earthworms (= $PEC_{oral,\ predator}$) are summarized in the table below. The $PNEC_{oral\ bird}$ of ≥16.7 mg a.s./kg food and the $PNEC_{oral,\ mammal}$ of 120 mg a.s./kg food were used for the determination of risks of secondary poisoning and were taken from the Assessment Report.
Marine water and marine sediment compartments were not considered to be relevant compartments for the risk assessment.
The relevant secondary poisoning PEC/PNEC values are reported in the tables below:

Summary table on secondary poisoning (permethrin) of birds						
Scenario	**Concentration**		**PNEC** [mg a.s/kg food]		**PEC/PNEC (birds)**	
	fish (freshwater) [$mg.kg_{wwt}^{-1}$]	earthworms [$mg.kg^{-1}$]	fish-eating birds (freshwater)	worm-eating birds	fish-eating birds (freshwater)	worm-eating birds
Scenario 1.1	5.26E-05	1.81E-04	16.7	16.7	3.15E-06	1.08E-05
Scenario 1.2	2.87E-04	9.86E-04	16.7	16.7	1.72E-05	5.90E-05

Summary table on secondary poisoning (permethrin) of mammals						
Scenario	**Concentration**		**PNEC** [mg a.s/kg food]		**PEC/PNEC (mammals)**	
	fish (freshwater) [$mg._{kgwwt}^{-1}$]	earthworms [mg.kg-1]	fish-eating mammals (freshwater)	worm-eating mammals	fish-eating mammals	worm-eating mammals
Scenario 1.1	5.26E-05	1.81E-04	120	120	4.38E-07	1.51E-06
Scenario 1.2	2.87E-04	9.86E-04	120	120	2.39E-06	8.22E-06

Conclusion: According to the results for permethrin, there is no risk for secondary poisoning *via* the food chain for either birds or mammals. The same conclusion can be derived for the two metabolites DCVA and PBA because they are expected to be present in fish and earthworms at even lower concentrations. No further assessment of secondary exposure via the food chain is therefore considered necessary.

Mixture toxicity

Not relevant. There is only one substance with biocidal activity in the product.

Overall conclusion on the risk assessment for the environment of the product
The environmental exposure was assessed for two exposure sub-scenarios, which differed in the way of cleaning the treated surfaces. In Scenario 1.1, the dry-cleaning process was considered while in Scenario 1.2, the wet-cleaning process was taken into account. According to the label statement, only the dry-cleaning process should be applied. *Scenario 1.1: Non-professional use – dry cleaning process* *Scenario 1.2: Non-professional use – wet cleaning process.* **For Scenario 1.1, no risks have been identified for any of the relevant environmental compartments providing that the application dose is 1 g/1m^2. Since the highest PEC/PNEC ratio identified (for sediment) was 0.49, the application dose of 2g/1m^2 is also expected to be acceptable with regard to the environmental risks. However, the detailed environmental risk assessment provided above was tailored to the use of the dose 1g/1m^2.**

For Scenario 1.2, risks were identified for surface water and sediment. The wet cleaning process is therefore not allowed as it poses unacceptable risks to the aquatic environment.

The instructions in SPC should specifically target: i) the dosing, ii) the cleaning process, iii) instructions that contact with pets (cat) should be prevented.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of biocidal product

Keep in tightly closed original containers. Store in a dry, dark and well-ventilated areas at 0°C to 30° C. Protect from direct sunlight and heat sources. Keep away from acids, alkalis and oxidizing agents. Keep separate from food, beverages and animal feed. Keep out of reach of children.

Recommended methods and precautions concerning handling and transport

Avoid contact with eyes, skin and mucous membranes. Use suitable protective clothing. Ensure good ventilation. Handle in accordance with good industrial hygiene and safety practice. Avoid leakage. When handling dry preparations, avoid dust swirl. Avoid creating and inhalation of dust. After work, thoroughly wash your hands and face with water and soap.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.

The mixture is not flammable. In the event of fire, thermal decomposition or incomplete combustion, toxic, irritating and flammable decomposition products could arise. Prevent further leakage or spillage if safe to do so. Always use self-contained breathing apparatus and chemical impermeable protective clothing. Fire-fighting should be done from the windward side. Keep as much distance as possible. Prevent further leakage or spillage if safe to do so. Avoid water contamination. Move product containers away from fire or keep cool with water spray as a protective measure, where feasible. Do not allow run-off from fire-fighting to enter drains or water courses.

First aid instructions, antidotes

After inhalation: Remove the victim into a fresh air.

If on skin, wash with soap and water.
IF SWALLOWED: Rinse mouth.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
Call a POISON CENTER/doctor if you feel unwell.

Instructions to protect non-target animals:
Prevent the access to the areas treated with Formitox by children, domestic and farm animals, particularly cats, due to their high sensitivity to pyrethroids (permethrin).
Remove or cover terrariums, aquariums and animal cages before application. Protect food, beverages and feed from contamination.

Emergency measures to protect the environment in case of accident
Stop leak if you can do it without risk. Do not allow to contaminate soil, sewage and surface/groundwater. Notify authorities if product enters sewers or public waters.
Take-up dry product mechanically into a suitable container. Try to avoid dust formation and swirling. Collect in a suitable, sealed and labelled container. Dispose according to regulations, dispatch for disposal to collect hazardous waste. Clean the affected area with water and detergent - water used for cleaning should not be discharged into sewers, surface and ground water - discard contaminated water as hazardous waste.

Possibility of reuse or recycling
Dispose unused product or empty C/PAP packaging in a certified hazardous waste facility! The reuse of packaging is prohibited.

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)
Only for consumer uses. Dispose of contents/container in accordance with local/national regulations for the disposal of hazardous waste. The reuse of packaging is prohibited. The remain of used product take up mechanically and dispose of as hazardous material. Do not allow product to reach drains/sewage systems.

Procedures, if any, for cleaning application equipment (relevant for biocidal products only)
Only dry-cleaning process is allowed.

2.2.10 Assessment of a combination of biocidal products

Not relevant.

3 Annexes

3.1 List of studies for the biocidal product

- Safety data sheet, 2018: In Slovak and Czech languages
- Vilímková, V., 2019: TEST REPORT ref. No. 462101957-01 replacing test report ref. No. 462101957-01 issued on November 23, 2018, Institut pro testování a certifikaci, a.s, Study sponsor: Papírna Moudrý s r.o.

  Full test report is attached in IUCLID section 3.3, section 3.4.1 and section 5.
- Peciar, M., Fekete, R., Peciar, P., 2019: Analýza distribúcie veľkosti častíc látky Formitox. Posúdenie vplyvu úpravy na distribúciu veľkosti častíc, Ústav procesného inžinierstva Strojnícka fakulta STU v Bratislave Námestie slobody 17812 31 Bratislava 1, Study sponsor: Papírna Moudrý s r.o.

  Full test report is attached in IUCLID section 3.5.
- Kulma, M., 2019: Test biocidního účinku přípravku „Formitox" na mravence *Lasius niger*, Státní zdravotní ústav, Centrum epidemiologie a mikrobiologie, Národní referenční laboratoř pro dezinsekci a deratizaci, Šrobárova 48, 100 42 Praha 10, study report number: 191336, Study sponsor: Papírna Moudrý s r.o., in Czech

  Full test report is attached in IUCLID section 6.7.
- VSB-TUO, 2023: Formitox DSC study. VSB – Technical University of Ostrava, Centre for Energy and Environmental Technologies, Ostrava, Czech Republic. Study Sponsor: Papírna Moudrý, s.r.o
- EU RAR, 2014: Assessment Report, Permethrin, Product-Type 18 (Insecticides, acaricides and products to control other arthropods), Rapporteur: Ireland, April 2014
- Biocidal Products Committee (BPC), 2014: Opinion of the Biocidal Products Committee on the application for approval of the active substance permethrin for product type18, ECHA/BPC/004/2014

3.2 New information on the active substance

Not relevant. There is no new information on the active substances.

3.3 Residue behaviour

Not relevant, please see the dossier for active substance. Letter of Access was submitted.

3.4 Summaries of the efficacy studies (B.5.10.1-xx)

The IUCLID file is available, please see section 6 of IUCLID file.

3.5 Confidential annex

The full composition of the product is provided in the confidential PAR document.

3.6 DSC analysis

The figure below shows the DSC curve of Formitox as reported by VSB-TUO (2023). The endothermic event just below 200 °C probably corresponds to melting of sucrose. The exothermic event with a peak at 213 °C was not accompanied by mass loss (weight decrease 0.08 mg, considered negligible).