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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Product identifier in R4BP	ENDURLED TFT
Product type(s):	18 - Insecticides, acaricides and products to control other arthropods
Active ingredient(s):	Transfluthrin
Case No. in R4BP	BC-TJ054979-06
Asset No. in R4BP	DE-0031904-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00026 710-05-18-00026-00-00-00-0000
Date	13.12.2023

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product ENDURLED TFT with the active substance transfluthrin (0.719 % w/w) is used as an insecticide (product-type 18) for the control of mosquitoes (Culicidae) indoors by the general public.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Dutch Assessment Report for the approval of the active substance transfluthrin including the “elements to be taken into account by Member States when authorising products” as requested by the Dutch CA.
2. The specific provisions from Commissioin Implementing Regulation (EU) No 407/2014 of 23 April 2014 approving transfluthrin as an existing active substance for use in biocidal products for product type 18.

Approval of the active substance
The active substance transfluthrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
- Authorisations are subject to the following condition: In view of the risks for water, sediment and soil compartments, transfluthrin shall not be used in vaporisers for indoor use or insecticidal coils

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

Composition and formulation

The ready-to-use liquid ENDURLED TFT to be used in a vaporising device contains the active substance transfluthrin.

The biocidal product contains the active substance transfluthrin, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. Based on the available information at the moment, the biocidal product should be considered not to have endocrine-disrupting properties. More information is available in section 2.2.3 of the PAR and in the confidential annex.

The non-active substance 2,6-di-tert-butyl-p-cresol (BHT) has been identified as substance of concern. Please refer to chapter 2.2.4 for further information.

Please refer to chapter 2.2 (Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has shown to be efficacious for the use appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.

A human health risk assessment has been carried out for non-professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

According to Annex VI of Regulation (EC) No 1272/2008, transfluthrin has a harmonised classification for skin irritation category 2, H315. During active substance approval, transfluthrin has been classified for acute oral toxicity category 4, H302 only (CAR NL, 2014).
In 2019, a CLH-Dossier has been submitted by the Netherlands, proposing a change in the harmonised classification of transfluthrin. In March 2021, a RAC opinion with a new harmonised classification and labelling of transfluthrin was adopted by consensus. According to the draft of the 21st ATP, the resulting entry in Annex VI of Regulation (EC) No 1272/2008 would change to classification and labelling with Acute Tox. 4, H302, Carc. 2, H351 and STOT SE 1, H370 (nervous system), as well as labelling with EUH066.
However, given the transfluthrin concentration in the biocidal product of ≤ 1 %, these differences in classification do not change the classification and labelling of ENDURLED TFT and thus, do not affect the outcome of the corresponding risk assessment for human health.
Based on the risk assessment it is unlikely that the intended use causes any unacceptable acute or chronic risk to non-professional users, bystanders and residents. Regarding non-professional users health protection, there are no objections against the intended use if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since the non-active substance BHT has been identified as substance of concern, the risk assessment for the environment for this product is based on the active substance and the substance of concern.
A risk assessment for the environment has been carried out for non-professional indoor use of the product (see chapter 3.8) for the intended use (see chapter 3.1).
Based on the risk assessment it is unlikely that the intended use causes any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Comparative Assessment

Since the active substance transfluthrin has not been identified as a candidate for substitution (see also chapter 2.2.5) a comparative assessment has not been necessary (see chapter 3.10).

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

ENDURLED TFT

2.1.2 Manufacturer(s) of the product

Name of manufacturer	ENDURA S.p.A.
Address of manufacturer	Viale Pietramellara, 5 40121 Bologna Italy
Location of manufacturing sites	ZOBELE HOLDING SPA Via Fersina 38100 Trento Italy
	CTR – Consultoria Técnica e Representacoes LDA Loteamento Industrial da Murteira Rua de Moçambique, Lotes 23-24-25 2135-325 Samora Correia Portugal

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

Active substance	Transfluthrin
Name of manufacturer	2022 ENVIRONMENTAL SCIENCE FR SAS (Acting for Environmental Science US LLC (US))
Address of manufacturer	Lyon Vaise Business Center 3 Place Giovanni Da Verrazzano 69009 Lyon France
Location of manufacturing sites	Bayer Vapi Private Limited* Plot No.306/3 Phase II G.I.D.C.

	396195 Vapi Gujarat India

*formerly: Bilag Industries Pvt. Ltd.

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	0.719
2,6-di-tert-butyl-p-cresol (BHT)	4-methyl-2,6-bis(2-methyl-2-propanyl)phenol	Non-active substance	128-37-0	204-881-4	1.0

- Information on the full composition is provided in the confidential[3] annex (see chapter 5).

- 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 ☒

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐

[3] Access level: “Restricted” to applicant and authority

2.2.3 Information on endocrine disrupting properties

The biocidal product contains the active substance transfluthrin, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.
Based on the available information at the moment, the biocidal product should be considered not to have endocrine-disrupting properties.
More information is available in sections 3.6.4.4 and 3.8.5.6 of the PAR and in the confidential annex.

2.2.4 Information on the substance of concern

The following substance of concern was identified:

- 2,6-di-tert-butyl-p-cresol (BHT) (CAS 128-37-0, EC 204-881-4)
  For the environment, the non-active substance BHT was identified as a substance of concern. According to the SDS, BHT is classified as H400 and H410, but no M factors are given there. In the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975), M factors of 1 for both acute and chronic are reported that can be confirmed considering the data reported there. Based on the content in the biocidal product, BHT would lead to the classification of the product as aquatic chronic 3 (H412) and has thus to be considered as substance of concern.

2.2.4.1 Information on 2,6-Di-tert-butyl-p-cresol (BHT)

Common name	2,6-Di-tert-butyl-p-cresol
IUPAC name	4-methyl-2,6-bis(2-methyl-2-propanyl)phenol
CAS number	128-37-0
EC number	204-881-4
Concentration (minimum and maximum, g/kg or g/l)	10 g/kg
Classification and Labelling according to Regulation (EC) No 1272/2008	H400, H410 according to the SDS. (C&L is provided by companies to ECHA in REACH Registration process, no harmonised classification)
Relevant toxicological/eco-toxicological information	s. REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975)

Other grounds for concern	no

- (Further) information on the substance(s) of concern is provided in chapter 3.6.2.8.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type of formulation

The product is a RTU liquid that is used in a vaporizing device. LV liquid vaporizer

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance transfluthrin and the substance of concern BHT, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance transfluthrin is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):

Skin Irrit. 2, H315

Moreover, the classification from the Assessment-Report (RMS NL (2014)) was taken into account:

Acute Tox. 4 H302

According to the draft of the 21st ATP to amend Annex VI to the CLP Regulation, the following classification is foreseen for transfluthrin:

Acute Tox. 4, H302

Carc. 2, H351

4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

STOT SE 1, H370 (nervous system)

EUH066

Aquatic acute 1 (H400) and aquatic chronic 1(H410). However, no M factors are given. Based on the available effect values, a M factor of 1000 (for both acute and chronic) can be derived.
In addition to the active substance transfluthrin, the antioxidant BHT was identified as substance of concern for the environment. According to the SDS BHT is classified as aquatic acute 1 (H400) with M factor 1) and aquatic chronic 1 (H410) with M factor 1.

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required. The content of the a.s. transfluthrin triggers the classification of the product with hazard classes aquatic acute 1 (H400) and aquatic chronic 1 (H410).

In line with the outcome of the e-consultation relating to the inclusion of precautionary statements in section 5 of the SPC (CG-44), the spirit of P101-P103 has been added to section 2.5 in the PAR.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Aquatic acute 1	H400
Aquatic chronic 1	H410

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS09	
Signal word	-	Warning
Hazard statements	H410	Very toxic to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P273	Avoid release to the environment
	P 501	Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site.
Note	-	-

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation

2.4.1 Use 1 appropriate for authorisation – Indoor mosquito control

Product Type(s)	18
Where relevant, an exact description of the use	Not relevant.
Target organism(s) (including development stage)	Scientific name: *Culicidae* (e.g. *Aedes spp.*, *Culex spp.*) Common name: Mosquitoes (e.g. *Aedes* mosquitoes, House mosquitoes) Development stage: Adults
Field(s) of use	Indoor
Application method(s)	Open system: diffusion The biocidal product is a RTU liquid insecticide formulation contained in a bottle designed to fit a suitable heater unit.
Application rate(s) and frequency	max. 10 h per day One unit lasts 45 days (with 10 h vaporisation/day). Maximum room size: 30 m³.
Category(ies) of users	General public
Pack sizes and packaging material	30 mL PP bottles

2.4.1.1 Use-specific instructions for use

See chapter 2.5.1 “Instructions for use”.

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5.2 “Risk mitigation measures”.

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

See chapter 2.5.3 “Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment”.

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

See chapter 2.5.4 “Instructions for safe disposal of the product and its packaging”.

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

See chapter 2.5.5 “Conditions of storage and shelf-life of the product under normal conditions of storage”.

2.5 General directions for use

2.5.1 Instructions for use

1) Comply with the instructions for use. 2) Effect might take more than 45 minutes after activation of the product. 3) Remove the protection cap from the bottle. 4) Insert the bottle in the appropriate seat of the electric diffuser; then, turn and screw it. 5) Wash hands after handling the bottle. 6) Make sure that the device is in vertical position; if necessary, turn the plug. 7) Insert the diffuser into the socket to activate the anti-mosquito action. Maximum use: 10 hours per day. 8) The heater usually has a button to switch on and off the power, but some versions might not have the button and heating starts directly when the heater is plugged into the power socket.

9) After use, remove the diffuser from the power outlet. It is not necessary to remove the bottle from the electric diffuser when the product is not in operation. When the bottle is empty, replace it to renew the anti-mosquito efficacy.
10) For optimal efficacy, windows should be kept closed during the use of the product.

2.5.2 Risk mitigation measures

1) To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.
2) Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.
3) Place vaporiser unit out of the reach of children.
4) Contains transfluthrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
5) For use only in areas that are inaccessible to pets and non-target animals.
6) Do not apply in rooms where fish tanks and/or terrariums are present.
7) Keep cats away from treated areas. Due to their particular sensitivity to transfluthrin, the product can cause severe adverse reactions in cats.
8) If the infestation persists, contact a professional pest control operator.

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

1) If medical advice is needed, have product container or label at hand.
2) Transfluthrin may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.
3) IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
4) IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
5) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
6) IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site.

2) Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

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

1) Shelf-life: 36 months 2) Keep out of reach of children and non-target animals/pets.

2.5.6 Other information

1) Efficacy has been demonstrated in a 30 m^3 room (floor area: 12 m^2, height: 2.5 m).

2.6 Packaging

Table 4

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Bottle	30 mL	PP Outer packaging: cardboard	Wick: Fiber material is bonded polyester (PET/PP). Stopper: PP. Cap: PE.	General public (non-professional)	Yes

Since the storage tests were conducted by using PP bottles, only PP bottles and PP stoppers are eligible for authorisation (and PET bottles and PBT stoppers as additionally applied for are not).

3 Assessment of the product

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

3.1.1 Intended use 1 – Indoor mosquito control

Product Type(s)	18
Where relevant, an exact description of the use	The product is intended for use indoors as insecticide by non-professional users to control mosquitoes in private houses.
Target organism(s) (including development stage)	House mosquitoes, Culex quinquefasciatus (adults) Asian tiger mosquitoes, Aedes albopictus (adults)
Field(s) of use	Indoor
Application method(s)	Application method(s) Open system: diffusion The biocidal product consists of a liquid insecticide formulation in a bottle designed to fit a suitable heater unit. The refill bottle is inserted into the suitable heater, which is plugged into a power socket. The heater usually has a button to switch on and off the power, but some versions might not have the button and heating starts directly when the heater is plugged into the power socket. The application can be stopped by switching of the heater and/or by disconnecting the heater from the power supply.
Application rate(s) and frequency	max. 10 h per day one unit lasts 45 days (with 10 h vaporisation/day) In areas of hot climate (like Italy, Spain, Greece and southern France): The biocidal product can be used from beginning of June until mid-September on a daily basis. In other areas/in case of low mosquito pressure: A usage for 2 months per year on a daily basis can be expected.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	30 mL PET/PP bottles

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Organoleptic inspection	Transfluthrin-based LED LGECT05, batch no. R321/17	Homogeneous liquid	BioGenius GmbH (Germany), Study No Mo5978
Colour at 20 °C and 101.3 kPa	Organoleptic inspection	Transfluthrin-based LED LGECT05, batch no. R321/17	Clear, colourless	BioGenius GmbH (Germany), Study No Mo5978
Odour at 20 °C and 101.3 kPa	Organoleptic inspection	Transfluthrin-based LED LGECT05, batch no. R321/17	Weak synthetic	BioGenius GmbH (Germany), Study No Mo5978
Acidity / alkalinity	CIPAC MT 75.3	Transfluthrin-based LED LGECT05, batch no. R321/17	1 % w/v dispersion in water Before accelerated storage: pH 6.25 After accelerated storage: pH 6.2 Due to the pH no test of acidity resp. alkalinity necessary.	BioGenius GmbH (Germany), Study No Mo5978

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Relative density / bulk density	EU method A.3 Oscillating density meter	Transfluthrin-based LED LGECT05, batch no. R321/17	Relative density: 0.968 at 20°C 0.951 at 40°C	BioGenius GmbH (Germany), Study No Mo5978
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Transfluthrin-based LED LGECT05, batch no. R321/17	2 weeks at 54°C The tests was conducted using PP bottles. Before: 0.703 % After: 0.697 % Active substance decrease of 0.9% Active substance concentration was analysed with method described in section 5.1 The physical state, colour, odor and integrety of packaging did not change during storage. No leakes no paneling or ballooning and by that no deformation was observed at any time. The weight loss of the eight test items after storage ranges from 0.19 – 0.61%.	BioGenius GmbH (Germany), Study No Mo5978

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			The weight loss was determined by weighting the test item (bottle including the biocidal product) before storage and as well as after reaching room temperature after storge. For results on pH and viscosity please refer to individual enpoints in this table.	
Storage stability test – **long term storage at ambient temperature**		Transfluthrin-based LED LGECT05, batch no. R321/17	36 months at 20°C The tests was conducted using PP bottles. **Active substance content:** Before: 0.703 % After 12 months: 0.694 % Active substance decrease of 1.3 % After 24 months: 0.654 % Active substance decrease of 7.0 % After 36 months: 0.680 % Active substance decrease of 3.2 %	BioGenius GmbH (Germany), Study No Mo5978

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Active substance concentration was analysed with method described in section 5.1 **Appearance / Packaging:** The physical state, colour, odor and integrety of packaging (PP) did not change during storage for 36 months. The integrity of the packaging material was confirmed. The weight loss of three test items after storage for 12 months ranges from 0.34 to 0.37%. The weight loss of three test items after storage for 24 months ranges from 0.46 to 0.47%. The weight loss of 23 test items after storage for 36 months ranges from 0.30 to -0.01%. **pH:** 1 % w/v dispersion in water (20 °C)	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Before storage: pH 6.25 After 12 months: pH 6.20 After 24 months: pH 6.35 After 36 months: pH 6.30 The same method used as reported in the individual enpoints in this table. The pH value did not change significantly. **Viscosity:** dynamic viscosity: Before storage: 5.72 mPa*s (shear rate 20/s) to 7.44 mPa*s (shear rate 100/s) at 20°C. After storage for 24 months: 7.06 mPa*s (shear rate 20/s) to 8.09 mPa*s (shear rate 100/s) at 20°C. After storage for 36 months: 7.54 mPa*s (shear rate 20/s) to 8.00 mPa*s (shear rate 100/s) at 20°C.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			kinematic viscosity: Before storage: 5.90 mm²/s (cSt) (shear rate 20/s) to 7.68 mm²/s (cSt) (shear rate 100/s) at 20°C. After storage for 24 months: 7.29 mm²/s (cSt) (shear rate 20/s) to 8.36 mm²/s (cSt) (shear rate 100/s) at 20°C. After storage for 36 months: 7.79 mm²/s (cSt) (shear rate 20/s) to 8.27 mm²/s (cSt) (shear rate 100/s) at 20°C. **Vaporization rate:** For values, please refer to individual endpoint in this table below. The vaporization rate before storage, after 24 months and 36 months of storage showed an acceptable linear decrease.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC I\IT 39.3	ENDURLED TFT (LGECT05), Batch No. R321/17 (According to test report the product is identical with Transfluthrin-based LED LGECT05 (composition see conf. Annex) and therefore not identical with ENDURLED TFT.	No significant change in the appearance no sediment/separate material or layer observed after storage for 1 weeks at 0 °C.	Endura S.p.A. (Italy), Report No 1127
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Waiving acceptable. The outer packaging of the product is opaque and therefore stored away from light.	Waiving
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Due to its packaging the product is kept away from humidity. The accelerated storage test showed that an elevated temperature has no adverse effects on the product.	BioGenius GmbH (Germany), Study No Mo5978

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	SOP-PR-029		Storage stability test – **accelerated storage** Test Item. 30 ml PP bottle (2 weeks at 54°C) Results: Test Item in sound condition, sealed and without leakages, without paneling or ballooning Weight loss: 0.19 - 0.61%	BioGenius GmbH (Germany), Study No Mo5978
	SOP-PR-029		Storage stability test – **long term storage at ambient temperature** Test Item. 30 ml PP bottle (36 months at 20°C) Results: Test Item in sound condition, sealed and without leakages, without paneling or ballooning Weight loss: - 0,30 – 0.01%	
Wettability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Suspensibility, spontaneity and dispersion stability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Wet sieve analysis and dry sieve test			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Emulsifiability, re-emulsifiability and emulsion stability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Disintegration time			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Particle size distribution, content of dust/fines, attrition, friability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Persistent foaming			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Flowability/Pourability/Dust ability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Burning rate — smoke generators			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Burning completeness — smoke generators			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Composition of smoke — smoke generators			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Spraying pattern — aerosols			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Physical compatibility			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Chemical compatibility			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving
Degree of dissolution and dilution stability			Waiving acceptable. Test need not be conducted for the type of formulation.	Waiving

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Surface tension	EU method A.5 Du Noüy Ring	Transfluthrin-based LED LGECT05, batch no. R321/17	Test on undiluted test item 31.9 mN/m at 20°C	BioGenius GmbH (Germany), Study No Mo5978
Viscosity	CIPAC MT 192 Rotational viscometer	Transfluthrin-based LED LGECT05, batch no. R321/17	dynamic viscosity: 5.72 mPa*s (shear rate 20/s) to 7.44 mPa*s (shear rate 100/s) at 20°C. 1.95 mPa*s (shear rate 20/s) to 3.71 mPa*s (shear rate 100/s) at 40°C. kinematic viscosity: 5.90 mm²/s (cSt) (shear rate 20/s) to 7.68 mm²/s (cSt) (shear rate 100/s) at 20°C. 2.05 mm²/s (cSt) (shear rate 20/s) to 3.90 mm²/s (cSt) (shear rate 100/s) at 40°C	BioGenius GmbH (Germany), Study No Mo5978
Other technical characteristics:		Transfluthrin-based LED LGECT05, batch no. R113/17	In the course of 460 hours 4 test samples were	BioGenius GmbH (Germany), Report No BIO148a-17

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Reference</th></tr>
<tr><td>Vaporization rate</td><td></td><td>Test product ued in storage test:
Batch no. R321/17</td><td>weighted after certain periods of time:
<table>
<tr><td>Time / h</td><td>Mean weight</td></tr>
<tr><td>0</td><td>38.78</td></tr>
<tr><td>10</td><td>37.21</td></tr>
<tr><td>20</td><td>36.10</td></tr>
<tr><td>60</td><td>33.54</td></tr>
<tr><td>100</td><td>31.41</td></tr>
<tr><td>130</td><td>29.91</td></tr>
<tr><td>210</td><td>26.08</td></tr>
<tr><td>220</td><td>25.69</td></tr>
<tr><td>230</td><td>25.07</td></tr>
<tr><td>280</td><td>23.35</td></tr>
<tr><td>350</td><td>20.82</td></tr>
<tr><td>420</td><td>18.29</td></tr>
<tr><td>450</td><td>16.72</td></tr>
<tr><td>460</td><td>16.09</td></tr>
</table>
The weight loss over time showed a linear behaviour and therefore a (almost) constant rate.

After 24 months of storage:
<table>
<tr><td>Time / h</td><td>Mean weight</td></tr>
<tr><td>0</td><td>38.83</td></tr>
<tr><td>10</td><td>37.18</td></tr>
<tr><td>20</td><td>36.22</td></tr>
<tr><td>50</td><td>34.10</td></tr>
<tr><td>60</td><td>33.58</td></tr>
<tr><td>90</td><td>31.85</td></tr>
</table></td><td>After storage of 24 and 36 months:
BioGenius GmbH (Germany), Report No BIO081-21a</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>100</td><td>31.29</td></tr>
<tr><td>120</td><td>30.16</td></tr>
<tr><td>130</td><td>29.68</td></tr>
<tr><td>200</td><td>26.90</td></tr>
<tr><td>210</td><td>25.48</td></tr>
<tr><td>220</td><td>25.00</td></tr>
<tr><td>230</td><td>24.52</td></tr>
<tr><td>270</td><td>22.73</td></tr>
<tr><td>280</td><td>22.24</td></tr>
<tr><td>340</td><td>19.19</td></tr>
<tr><td>350</td><td>18.62</td></tr>
<tr><td>410</td><td>15.81</td></tr>
<tr><td>420</td><td>15.49</td></tr>
<tr><td>450</td><td>14.51</td></tr>
<tr><td>460</td><td>14.26</td></tr>
</table>
The weight loss over time showed a linear behaviour and therefore a (almost) constant rate.

After 36 months of storage:
<table>
<tr><td>Time / h</td><td>Mean weight</td></tr>
<tr><td>0</td><td>38.99</td></tr>
<tr><td>10</td><td>37.24</td></tr>
<tr><td>20</td><td>36.23</td></tr>
<tr><td>50</td><td>33.90</td></tr>
<tr><td>60</td><td>33.09</td></tr>
<tr><td>90</td><td>31.03</td></tr>
<tr><td>100</td><td>30.42</td></tr>
<tr><td>120</td><td>29.21</td></tr>
<tr><td>130</td><td>28.56</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>200</td><td>23.72</td></tr>
<tr><td>210</td><td>23.17</td></tr>
<tr><td>220</td><td>22.62</td></tr>
<tr><td>230</td><td>22.04</td></tr>
<tr><td>270</td><td>19.91</td></tr>
<tr><td>280</td><td>19.39</td></tr>
<tr><td>340</td><td>15.96</td></tr>
<tr><td>350</td><td>15.51</td></tr>
<tr><td>410</td><td>13.83</td></tr>
<tr><td>420</td><td>13.58</td></tr>
<tr><td>450</td><td>13.04</td></tr>
<tr><td>460</td><td>12.93</td></tr>
</table>
The weight loss over time showed a linear behaviour and therefore a (almost) constant rate.</td><td></td></tr>
<tr><td>Other technical characteristics:
Measurement of the surface temperatures of plastic bottles and plastic stopppers</td><td></td><td></td><td>Measurement of the temperature of the plastic stopper and the neck of the bottle were performed during the use of the ENDURLED TFT liquid dispenser. The measured maximum temperature was registered when the measured value reached the plateau and was stable. A temperature of 37.7°C was measured for the PP bottle neck and a temperature of 49.1°C was measured at the PP stopper.</td><td>Endura S.p.A. (Italy), Report No 1309</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			A temperature of 38.0°C was measured for the PET bottle neck and a temperature of 49.9°C was measured at the PBT stopper. The measured values are lower than the temperature at which the respective plastic material starts to deform.	

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. Please refer to the confidential annex for the identity of test product “Transfluthrin-based LED LGECT05” as well as for the read-across justification. The product is a clear, colourless, homogeneous liquid with a weak synthetic odour. The product has a pH of 6.2 and a density of 0.97 at 20°C. The accelerated storage test showed a negligible decrease in active substance concentration. The physical and chemical properties also showed no significant changes. The test for long-term storage at ambient temperature showed an acceptable decrease in active substance content. The physical and chemical properties also showed no significant changes after storage. A shelf life of 36 months is acceptable. No significant change in the appearance, no sediment/separate material or layer were observed during the storage test at low temperatures. The surface tension on undiluted test item is 31.9 mN/m at 20°C. The viscosity shows a slight dependence of the shear rate. After accelerated storage the viscosity increased inconsiderably (e.g. from 5.72 mPa*s (shear rate 20/s) to 6.32 mPa*s (shear rate 20/s) after storage). This might be connected with the weight loss after accelerated storage of - 0.19 – 0.61%. The vaporization rate is regarded constant over a time of 460 h before storage and after storage of 36 months.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	UN test 2(a): UN gap test	ENDURLED TFT (0.719 % w/w Transfluthrin), Batch No. E127/21	The tube remained intact during both tests and no holes were punched through the witness plate. The test result is therefore considered negative (-).	Not classified based on GHS/CLP criteria.	DEKRA (UK), Report No J4028007980R2/2021
	UN test 2(b): Koenen Test	LGECT05 - ENDURLED TFT (0.710 % w/w Transfluthrin), Batch No. E23/21	No explosion observed, limiting diameter < 1 mm. The test result is evaluated as negative (-).		Siemens AG Prozess-Sicherheit (Germany), Report No PS20210081-2
	UN test 2(c): Time/pressure test		None of three tests reached a pressure of 2070 kPa. The test result is evaluated negative (-).		
Flammable gases	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Flammable aerosols	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is no aerosol	Waiver
Oxidising gases	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Flammable liquids	EN ISO 2719	LGECT05 - ENDURLED TFT (0.710 % w/w Transfluthrin), Batch No. E23/21	Flash point: 113.5°C	Not classified based on GHS/CLP criteria	BioGenius GmbH (Germany), Study No Mo7065
Flammable solids	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Self-reactive substances and mixtures	Screening method: DSC measurement	LGECT05 - ENDURLED TFT (0.718 % w/w Transfluthrin), Batch No. E22/21	Heating rate: 3 K/min Sample amount: 16.18 mg Crucible: closed high-pressure crucible Termperature range: ambient – 492°C. At 492°C the crucible burst Atmosphere: inert gas (nitrogen) Sum of exothermic peaks with an onset temperatur below 200 °C: 11.99 J/g	As the exothermic decomposition energy (onset <200 °C) is below 300 J/g, no classification has to be considered.	Siemens AG Prozess-Sicherheit (Germany), Report No PS20210081-1
Pyrophoric liquids				The study does not need to be conducted because the substances in the biocidal product and the biocidal product itself is known to be stable in contact with air at room temperature	Waiver

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				for prolonged periods of time and hence, the classification procedure does not need to be applied.	
Pyrophoric solids				Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Self-heating substances and mixtures	study scientifically unjustified			Waiver: In its packaging as placed on the market as well as during usage, the biocidal product will be present mainly in the form of a bulk liquid inside the bottle, and partly as a little amount of liquid absorbed to an inert carrier (i.e. the wick). The surface of bulk liquids is not large enough for reaction with oxygen in the air. Justification for data waiving for the liquid absorbed to the wick: As pointed out in 2.11.1.1 of the CLP Regulation, Annex 1, Part 2, as well as in 33.4.1.2 of the UN RTDG, Manual of Tests and Criteria, self-heating properties are only relevant when the material is in large amounts (kilograms). The amount of the biocidal product absorbed in the wick is in the order of magnitude of 1-2 grams only. Therefore, due to the small amount of mixture in issue, testing for self-heating properties can be waived.	Waiver

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied.	Waiver
Oxidising liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the organic substances containing oxygen or halogen atoms which are chemically bonded only to carbon or hydrogen and hence, the classification procedure does not need to be applied.	Waiver
Oxidising solids	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	Waiver
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	Transfluthrin-based product, Product ID LGECT05, batch no. E23/21	Test period: 7 days at 53 – 56°C Type of material: Aluminum Non-immersed: weight before test: 5.560g weight after test: 5.560g	Not classified based on GHS/CLP criteria	BioGenius GmbH (Germany), Study No Mo7065

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
			partly immersed: weight before test: 5.499g weight after test: 5.499g fully immersed: weight before test: 5.515g weight after test: 5.515g steel Non-immersed: weight before test: 15.07g weight after test: 15.07g partly immersed: weight before test: 14.89g weight after test: 14.89g fully immersed: weight before test: 15.15g weight after test: 15.15g since the wight loss is 0.0% for all test results, no corrosion and no localised corrosion occures. Corrosion rate: no corrosion		
Auto-ignition temperature (liquids and gases)	EU Method A.15 (following DIN 51794:2003-05)	Transfluthrin-based LED LGECT05	Auto-ignition temperature: 185°C,	The product is a RTU liquid that is used in a vaporizing device, that works at elevated temperatures during use. Because of that an additional test was carried out in which the highest in	Siemens AG Prozess-Sicherheit (Germany),

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		Batch No.: R 321/17 (composition see conf. Annex)		use temperature close to the wick was measured. The measured temperature was 95.7°C so that a safe use of the product was shown.	Report No PS20180095-1
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver
Dust explosion hazard	study scientifically unjustified			Waiver: the study does not need to be conducted because the substance is a liquid	Waiver

Table 8

Conclusion on the physical hazards and respective characteristics
The product ENDURLED TFT is not classified for physical hazards. All hazard classes that can not be waived based on GHS/CLP criteria were addressed by appropriate testing and classification could be excluded.

3.4 Methods for detection and identification

Table 9

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Transfluthrin	HPLC-ESTD UV detection at 235 nm (internal method name: MV179)	Specific for transfluthrin as sum of all isomers not specific to 1R-trans-configuration of the a.s.	0.08 mg/mL – 0.88 mg/mL (n=8) correlation coefficient (r^2) = 1.0	70%, 0.28 mg/mL (n=3)	102.5 – 103.8	103	0.7	LOD: 1.34 µg/mL LOQ: 4.43 µg/mL	BioGenius GmbH (Germany), Study No Mo5977
				100%, 0.4 mg/mL (n=3)	100.4 – 102.0	101.0	0.9		
				130%, 0.52 mg/mL (n=3)	99.6 – 103.3	101.1	2.0		

The study above does not distinguish between the isomers of the active substance. Additionally to this study, the applicant possesses a LoA for the active substance approval dossier. This dossier comprises of a method that distinguishes between the active substance isomers. Together with the study above, a valid analytical method is available.

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	transfluthrin 2,6-di-tert-butyl-p-cresol (BHT)	0.09 mg/kg 0.1 mg/kg	$PNEC_{soil:}$ $PNEC_{soil}$
Drinking water	transfluthrin	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	transfluthrin 2,6-di-tert-butyl-p-cresol (BHT)	0.00175 µg/L 5.3 µg/L	$PNEC_{water}$, based on NOEC *Daphnia magna*, AF: 10 $PNEC_{water}$
Air	transfluthrin	3 µg/m³	$AEL_{long\ -term}$: 0.01 mg/kg bw/d, AR for PT18, list of endpoints, 03/2014
Animal and human body fluids and tissues	not relevant	-	not classified as toxic or very toxic
Food of plant origin	no relevant residues expected	-	AR for PT18, list of endpoints, 03/2014
Food of animal origin	no relevant residues expected	-	AR for PT18, list of endpoints, 03/2014

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Transfluthrin	GC-MS, m/z 207, 209, 211	Monitoring of three fragment ions	1 – 100 ng/mL R≥0.9972	m/z 207: 0.05 µg/L / 10 0.5 µg/L / 10 m/z 209: 0.05 µg/L / 10 0.5 µg/L / 10 m/z 211: 0.05 µg/L / 10 0.5 µg/L / 10	 78 – 128 73 – 108 75 – 127 73 – 116 94 – 121 74 - 122	 103 93 101 93 108 95	 12.3 15.0 13.1 15.0 10.3 15.7	0.05 µg/L LOQ is not sufficient for PNEC water, but sufficient for LC_{50} fish. Therefore, the method was accepted for drinking water and surface water.	CAR, Doc IIIA, 4.2/03 Bayer CropScience AG, Report No M-280731-01-1

Table 12

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Transfluthrin	GC-ECD, DB-1 column	GC-MS, DB-5 column, m/z 163, 165, 335	5 – 2000 ng/mL R^2=0.9997	GC-ECD: 0.005 mg/kg / 5 0.05 mg/kg / 5	 81 – 88 78 – 88	 84 82	 3.6 4.5	0.05 mg/kg	CAR, Doc IIIA, 4.2/01Specht & Partner, Report No MO-01-009826

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				GC-MS: 0.005 mg/kg / 1 0.05 mg/kg / 1		 97 87	 - -		
BHT	GC-MS, HP-5MS column, m/z 177, 205, 220 for BHT	Monitoring of three fragment ions	25–5000 ng/g corresponding to 0.025 – 5 mg/kg r>0.9987	dust 0.044 mg/kg / 3 0.44 mg/kg / 3 2.2 mg/kg / 3 sediment 0.044 mg/kg / 3 0.44 mg/kg / 3 2.2 mg/kg / 3	No data	 88 87 104 81 75 74	 3.8 2.3 1.8 7.5 8.7 3.2	0.044 mg/kg	doi 10.1016/j.scitotenv.2017.11.115

Table 13:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Transfluthrin	GC-MS, DB-5 column, m/z 163, 127, 143	Monitoring of three fragment ions	4 – 2000 ng/mL, R≥0.998	<u>Ambient air</u> m/z 163: 0.49 µg/m³ / 5 4.8 µg/m³ / 5 m/z 127+ m/z 143:	No data	 106 102	 3 4	0.49 µg/m³	CAR, Doc IIIA, 4.2/02 PTRL Europe, Report No MO-05-010149

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				0.49 µg/m³ / 5 4.8 µg/m³ / 5 <u>Warm, humid air</u> m/z 163: 0.49 µg/m³ / 5 4.8 µg/m³ / 5 m/z 127+ m/z 143: 0.49 µg/m³ / 5 4.8 µg/m³ / 5		109 103 104 106 105 106	2 5 5 5 9 4		

Table 14

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
BHT	GC-MS, FS-Supreme-5 column, EI, m/z 220 for BHT	for BHT proposed further mass fragments m/z 205 and m/z 177	No data	0.4 µg/L / 10	No data	92	6	0.4 µg/L	doi 10.1016/S0043-1354(01)00453-5

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	1. An acceptable analytical method for determining the active substance concentration was submitted. The content of the SoC in the family is not expected to change respectively increase during storage of the product. Therefore, additional analytical methods to quantify the content of the SoC are not necessary. 2. 5.2.4. Analytical methods for body fluids and tissues 3. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant
Justification	See justification(s)/annotation(s) in IUCLID dossier Methods for body fluids and tissues are not required since transfluthrin and the SoC BHT are not classified as toxic or very toxic. Residue analytical methods in food of plant and animal origin are not required because occurrence of residues in these matrices is improbable from the intended use.

Table 16

Conclusion on the methods for detection and identification
The method provided regarding the active substance was acceptable. A method regarding the substances of concern was not necessary. The methods provided regarding residues of transfluthrin in drinking and surface water, soil and air are acceptable. The method for determination of transfluthrin in surface water was accepted in the CAR. During the active substance renewal, it should be adressed that a method for monitoring the limit of 0.00175 µg/L based on PNECwater should be provided. The methods provided regarding residues of the substance of concern BHT in soil and surface water are acceptable.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

Main Group 03: Pest Control
Product type 18: Insecticides, acaricides and products to control other arthropods

The biocidal product “ENDURLED TFT” is intended to be used indoors (domestic use) to kill mosquitoes by non-professionals. The product consists of a liquid insecticide formulation in a refill bottle designed to fit into a suitable heater unit (with or without button to switch on and off the power), which is plugged into a power socket. The product contains the active ingredient, transfluthrin, in a concentration of 0.719%.
The submitted studies are suitable to support the claim “kills adult mosquitoes (*Aedes* spp. and *Culex* spp.) starting 45 minutes after product activation and for 45 days at continuous operating the device for 10 hours per day in a room of max. 30 m^3”.

3.5.2 Organisms to be controlled and products, organisms or objects to be protected

The product “ENDURLED TFT” is intended to kill adult mosquitoes (*Aedes albopictus*, *Culex quinquefasciatus*) indoor. The submitted studies support a label claim against adult mosquitoes (*Aedes* spp. and *Culex* spp.

3.5.3 Effects on target organisms, including unacceptable suffering

Knockdown and kill.
Transfluthrin is an insecticide which acts on the nerve function leading to knockdown of the insects, followed by death within a few minutes.

3.5.4 Mode of action, including time delay

Transfluthrin is a synthetic pyrethroid which acts on target organisms by contact. Transfluthrin interferes with nerve function in a manner that is common to the standard pyrethroid mode of action by affecting the insects´ presynaptic voltage gate sodium channels in nerve membranes and causes rapid knockdown. Transfluthrin acts by keeping the sodium channels open for an abnormally long period. This causes

repeated firing of the neurones followed by the blocking of nerve conduction, which leads to hyper-excitation followed by convulsions. Death occurs a few minutes after insecticide absorption.

3.5.5 Efficacy data

For the efficacy assessment a simulated-use test (BioGenius GmbH (Germany), Report No BIO148a-17) with the test product “Liquid Emanator Device TFL LED” (0.716% transfluthrin, composition see chapter 5.1: confidential Annex) has been provided. The content of the active ingredient transfluthrin in the test product is slightly lower (0.716%) than in the product “ENDURLED TFT” under authorization (0.719%) and the co-formulants differ only with regard to the identity of the adjuvant (detailed information on the adjuvant see chapter 5.1). The lower transfluthrin content as well as the slight difference of the adjuvant are negligible, therefore the study (BioGenius GmbH (Germany), Report No BIO148a-17) is acceptable.
In the study the device was activated in the centre of the test chamber (30 m³) and knockdown was determined directly (0 hours) and at different time points (2, 4, 6, 8 and 10 hours) after activation of the product on day 1, 22 and 45 after a continuous operating period of the device for 10 hours per day (for details see table 20).
For *Aedes albopictus* a knockdown of > 80% was observed 30 minutes after activation of the product (0 hours) on day 1, 22 and 45. At all other time points (2, 4, 6, 8 and 10 hours) > 80% knockdown was demonstrated within 15 minutes on all three test days. 100% mortality was shown at all days and time points 24 hours after product activation. The mortality in the untreated controls was ≤ 2%.
For *Culex quinquefasciatus:* a knockdown of > 80% was observed 45 minutes after activation of the product (0 hours) on day 1, 22 and 45. At all other times points (2, 4, 6, 8 and 10 hours) > 80% knockdown was demonstrated within 15 minutes on all three test days. 100% mortality was shown at all days and time points 24 hours after product activation. The mortality in the untreated controls was ≤ 1%.

According to the TNsG (2016, chapter 14.2.1) for a general claim against mosquitoes, efficacy tests with *Culex* spp. and a large mosquito like *Aedes* spp. are required. A knockdown of > 80% was proven within 45 minutes and 100% mortality was reached 24 hours after product activation up to the end of the operating period on day 45 for all time points (0, 2, 4, 6, 8 and 10 hours) for both test species (*Aedes albopictus, Culex quinquefasciatus*) (TNsG 2016, chapter 14.3.1) in 30 m³ rooms. In the simulated-use test the product was placed in the centre of the test chamber, which would not be the case in real use situation. Therefore, it might take a bit longer for the vapor to reach the insects in the room when the product is activated in the periphery of a room, but the vapor from the product will fill up the whole room and will be still efficacious. Therefore, this test set-up is sufficient to show efficacy of the product.

Consequently, a label claim “kills adult mosquitoes (*Aedes* spp. and *Culex* spp.) starting 45 minutes after product activation and for 45 days at continuous operating the device for 10 hours per day in a room of max. 30 m³” is acceptable.

Table 17

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT18	indoor	Liquid Emanator Device TFL LED; 0.716% Transfluthrin	*Culex quinque-fasciatus, Aedes albopictus,* adult females 3-4 day old, fed on sugar water	Simulated-use test	- test chamber: 30m³ (12 m²), no ventilation - insects per replicate and species: 100 - temperature: 21 - 25°C - rel. humidity: 21 - 50% - position of the product: centre of the room at a height of 30 cm - operating time/day: 10 hours - time points: 0, 2, 4, 6, 8 and 10 hours after switching on - every 2 hours (0, 2, 4, 6, 8 and 10 hours) a new set of insects is released in the test chamber, if previous exposure has reached 100% knockdown - knocked down insects were collected in beakers covered with gauze and remained in the test chamber up to 24 hours from product activation	*Aedes albopictus:* >80% knock down was reached on day 1, 22 and 45 directly after product activation (0 hours) after 30 minutes, at all other time points (2, 4, 6, 8 and 10 hours) within 15 minutes 100% mortality was reached on all days after 24 hours controls: mortality ≤ 2% *Culex quinquefasciatus:* >80% knock down was reached on day 1, 22 and 45 directly after product activation (0 hours) after 45 minutes, at all other time points (2, 4, 6, 8 and 10 hours) within 15 minutes 100% mortality was reached on all days after 24 hours controls: mortality ≤ 1%	BioGenius GmbH (Germany), Report No BIO148a-17

					- test criteria: knock down and mortality hours - test days: 1, 22 and 45 days after conditioning - aging in fume hood - replicates: 4 - control: 4		
PT18	indoor	Liquid Emanator Device TFL LED; 0.716% Transfluthrin		Laboratory test	- determination of refills weight (without heater and cap) - operating time/day: 10 hours in fume hood (turned off and kept halfway open during evaporation) - time points: 0, 10, 20, 60, 100, 130, 210, 220, 230, 280, 350, 420, 450 and 460 hours after operation - temperature: 22°C - rel. humidity: 20 - 55% - replicates: 4	mean weight before start (0 hours): 38.78 g mean weight at the end of the operating time (460 hours): 16.09 g daily weight loss after 10 and 20 hours of operation was 1.57 g and 1.11 g, respectively daily weight loss at the following time points (60 to 460 hours of operation) ranged between 0.34 to 0.64 g	Annex to BioGenius GmbH (Germany), Report No BIO148a-17

3.5.6 Occurrence of resistance and resistance management

Transfluthrin is a synthetic pyrethroid, with the same mode of action as other members of the group, and is anticipated to be subject to the same pressures regarding the potential development of resistance as the other synthetic pyrethroids. The resistance to pyrethroids has been found to varying degrees, depending on the pest species and location. A WHO review of Vector Resistance to Pesticides (2012) identified no reports of resistance to pyrethroids in mosquitoes and other blood sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident.
Cross-resistance of pest species within the group of pyrethroids is to be anticipated due to a common mode of action. Instances of cross-resistance (or multiple resistances) between pyrethroids and organochlorine insecticides also have been reported.
Therefore, a resistance management advice for non-professional use on the label and in the SPC must be as follows:

- If the infestation persists, contact a professional pest control operator.

3.5.7 Known limitations

The product was only tested in the centre of a room, which does not correspond to the real use situation, therefore usage in sockets in the periphery of a room could affect the efficacy. It might take a bit longer for the vapor to reach the insects in the room when the product is activated in the periphery of a room, but the vapor from the product will fill up the whole room and will be still efficacious.
The efficacy of the product was not tested in ventilated rooms. For optimal efficacy, windows should be kept closed during the use of the product.

3.5.8 Evaluation of the label claims

The biocidal product “ENDURLED TFT” is a vaporizer for indoor use. The efficacy has been proven against adult mosquitoes (*Aedes* spp. and *Culex* spp.) starting 45 minutes after product activation and for 45 days at continuous operating the device for 10 hours per day in a room of max. 30 m^3.

3.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not reported.

3.5.10 Data waiving and conclusion

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	Not relevant.

Table 19

Conclusion on the efficacy
A claim „kills adult mosquitoes (*Aedes* spp. and *Culex* spp.) starting 45 minutes after product activation and for 45 days at continuous operating the device for 10 hours per day" is supported by the efficacy study. As the efficacy study was conducted in a room of 30 m³, the application is limited to a room size of max. 30 m³. The product was only tested in the centre of a room, which does not correspond to the real use situation, therefore usage in sockets in the periphery of a room could affect the efficacy. It might take a bit longer for the vapor to reach the insects in the room when the product is activated in the periphery of a room, but the vapor from the product will fill up the whole room and will be still efficacious.

3.6 Risk assessment for human health

The biocidal product ENDURLED TFT contains the active substance transfluthrin (CAS No. 118712-89-3). According to Annex VI of Regulation (EC) No 1272/2008, transfluthrin has a harmonised classification for skin irritation category 2, H315. During active substance approval, transfluthrin has been classified for acute oral toxicity category 4, H302 only (CAR NL, 2014).
In 2019, a CLH-Dossier has been submitted by the Netherlands, proposing a change in the harmonised classification of transfluthrin. In March 2021, a RAC opinion with a new harmonised classification and labelling of transfluthrin was adopted by consensus. According to the draft of the 21st ATP, the resulting entry in Annex VI of Regulation (EC) No 1272/2008 would change to classification and labelling with Acute Tox. 4, H302, Carc. 2, H351 and STOT SE 1, H370 (nervous system), as well as labelling with EUH066. However, given the transfluthrin concentration in the biocidal product of ≤ 1 %, these differences in classification do not change the classification and labelling of ENDURLED TFT and thus, do not affect the outcome of the corresponding risk assessment for human health.

3.6.1 Assessment of effects of the active substance on human health

Table 20

Transfluthrin	Value	Study	Safety factor
AEL long-term	0.01 mg/kg bw/d	2-year study, rat (AR PT18, NL 2014)	100
AEL medium-term	0.01 mg/kg bw/d	2-year study, rat (AR PT18, NL 2014)	100
AEL acute oral	0.15 mg/kg bw	Developmental toxicity, rabbit (AR PT18, NL 2014)	100
AEL acute dermal	1 mg/kg bw	3-week dermal study, rabbit (AR PT18, NL 20147)	100
AEC acute inhalation	0.5 mg/m³ air (17 mg/kg bw/d)	14-week inhalation study, rat (6h/day) (AR PT18, NL 2014)	100
ADI [1]	0.01 mg/kg bw/d	2-year study, rat (AR PT18, NL 2014)	100
ARfD [1]	0.15 mg/kg bw	Developmental toxicity, rabbit (AR PT18, NL 2014)	100

[1] No residues in food or feed expected

Table 21

Transfluthrin	Value	Reference
Inhalative absorption	100 %	Default value: Assessment-Report (RMS NL (2014) and CAR (Doc IIIA, Section 6.2)
Oral absorption	100 %	Default value: Assessment-Report (RMS NL (2014))
Dermal absorption	see Chapter 3.6.2.7 Information on dermal absorption	

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 22

Data waiving was acceptable for the following information requirements	
Information requirement	8.1 Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 23

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	The biocidal product contains the active substance transfluthrin, which is currently classified for skin irritation category 2, H315 based on the information from the corresponding SDS and Annex VI of Regulation (EC) No 1272/2008[1)]. However, the concentration of this substance is below the generic concentration limit of 10 % and thus, according to Regulation (EC) No 1272/2008, not relevant for classification and labelling of the biocidal product.
Classification of the product according to CLP	Classification for skin corrosion/irritation is not required.

[1)] Note: Though not yet legally binding, a RAC opinion with a new harmonised classification and labelling of transfluthrin was adopted by consensus in March 2021. In the proposal, H315 has been removed and EUH066 is added. These changes do not affect the conclusion on classification for skin corrosion/irritation.

3.6.2.2 Eye irritation

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 25

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eyes.
Justification for the value/conclusion	The biocidal product does not contain components classified for eye damage or eye irritation. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for eye damage/irritation is not required.

3.6.2.3 Respiratory tract irritation

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.10 Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product family has to be made according to the rules of the Regulation (EC) No 1272/2008.

Table 27

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory irritation. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	The biocidal product does not contain components classified for skin sensitisation. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 31

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components that are known to have sensitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute toxicity by oral route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral) > 2000 mg/kg bw Not acutely toxic by oral route.
Justification for the selected value	According to the active substance approval (CAR, NL, 2014), transfluthrin is classified for acute oral toxicity category 4, H302 with a derived LD_{50} (oral) of 583 mg/kg.[1)] For all other co-formulants the LD_{50} (oral) is expected to be above 2000 mg/kg bw, based on the information from the corresponding SDS and other technical data sources. Hence, according to Regulation (EC) No 1272/2008 classification for acute oral toxicity is not required.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

[1)] Based on the Guidance Note on classification and labelling of biocidal products (CA-May13-Doc.5.4; CA/35/2013), a biocidal product (submitted for national authorisation) should not be classified if this classification is based on a new classification for the active substance, identified during the active substance approval and if this classification has not yet been adopted to a RAC opinion. However, though not yet legally binding, H302 has been included in a new harmonised classification and labelling of transfluthrin proposed by the RAC and adopted by consensus in the opinion in March 2021.

3.6.2.6.2 Acute toxicity by inhalation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 35

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation) > 5 mg/L Not acutely toxic by inhalation route.

Value used in the Risk Assessment – Acute inhalation toxicity	
Justification for the selected value	The biocidal product does not contain components classified for acute inhalation toxicty. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 36

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute toxicity by dermal route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal) > 2000 mg/kg bw Not acutely toxic by dermal route.
Justification for the selected value	The biocidal product does not contain components classified for acute dermal toxicty. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Specific information on the dermal absorption of the active substance was not provided. In the absence of product-specific data, defaults according to the EFSA Guidance on Dermal Absorption (2017) have to be applied.

Table 39

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Biocidal product, application, secondary exposure
Value(s)	70 %
Justification for the selected value(s)	Default for solvent-based formulations according to EFSA Guidance on Dermal Absorption (2017). The default of 10 %, as proposed by the applicant, is based on conditions (log P_{ow} < -1 or > 4, MW > 500 g/mol) laid down in the EFSA Guidance on Dermal Absorption (2012). The active substance transfluthrin has a molecular weight of 371 g/mol and thus is not fulfilling this criteria. Furthermore, evaluations performed within the scope of the currently valid EFSA Guidance on Dermal Absorption (2017) could not confirm the predictive relationship of these variables. Hence, setting dermal absorption default values based on partition coefficient and molecular weight is not anymore included in this recent guidance document and therefore not applicable.

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

Please refer to section 5.2.1 in the Confidential Annex.

3.6.2.9 Available toxicological data relating to a mixture

Not available.

3.6.2.10 Other

In March 2021, a RAC opinion with a new harmonised classification and labelling of transfluthrin was adopted by consensus. If agreed by the COM, the resulting entry in Annex VI of Regulation (EC) No 1272/2008 would include classification and labelling with Carc. 2, H351 and STOT SE 1, H370 (nervous system), amongst others.
However, given the transfluthrin concentration in the biocidal product of ≤ 1 %, classification of the biocidal product with Carc. 2, H351 or STOT SE 1, H370 (nervous system) according to Regulation (EC) No 1272/2008 is not required.

3.6.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on the available information on the intrinsic properties of the single components, classification for skin corrosion and irritation is not required.
Eye irritation	Based on the available information on the intrinsic properties of the single components, classification for eye irritation is not required.
Respiratory tract irritation	Based on the available information on the intrinsic properties of the single components, classification for respiratory tract irritation is not required.
Skin sensitisation	Based on the available information on the intrinsic properties of the single components, classification for skin sensitisation is not required.
Respiratory sensitisation (ADS)	Based on the available information on the intrinsic properties of the single components, classification for respiratory tract sensitisation is not required.
Acute toxicity by oral route	LD_{50} (oral) > 2000 mg/kg bw Based on the available information on the intrinsic properties of the single components, classification for acute toxicity by oral route is not required.
Acute toxicity by inhalation	LC_{50} (inhalation) > 5 mg/L Based on the available information on the intrinsic properties of the single components, classification for acute toxicity by inhalation is not required.
Acute toxicity by dermal route	LD_{50} (dermal) > 2000 mg/kg bw Based on the available information on the intrinsic properties of the single components, classification for acute toxicity by dermal route is not required.
Information on dermal absorption	In the absence of valid information on dermal absorption for the biocidal product a default value of 70 % for solvent-based formulations, as proposed according to the EFSA Guidance on Dermal Absorption (2017) should be used.
Available toxicological data relating to non-active substance(s)	Please refer to the Confidential Annex.
Available toxicological data relating to a mixture	Not available.
Other relevant information	Based on the available information on the intrinsic properties of the single components, classification for carcinogenicity and specific target organ toxicity is not required.

3.6.3 Exposure assessment

3.6.3.1 Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Table 41

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	/	/	yes	/	/	yes	n.a.
Dermal	/	/	yes	/	/	yes	n.a.
Oral	/	/	n.a.	/	/	yes	no

List of scenarios

Table 42

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
BfR1	Loading	Primary exposure: Dermal and inhalation exposure to transfluthrin during removal and insertion of a bottle into vaporiser unit (LED)	Non-professionals
BfR2	Application - Exposure during operation	Secondary exposure: Inhalation exposure to transfluthrin during operation of the LED	General public
BfR3	Application - Exposure during operation	Secondary exposure: Dermal exposure to volatilised transfluthrin depositing on body surface during operation of the LED	General public
BfR4	Post-application - Exposure after operation	Secondary exposure: Dermal and oral exposure to transfluthrin from contact to surface contaminations in treated rooms	General public
BfR5	Post-application - Exposure after operation	Secondary exposure: Inhalation exposure to transfluthrin re-volatilised from surface contaminations after operation of the LED	General public

3.6.3.1.1 Professional exposure

Not relevant.

3.6.3.1.2 Non-professional exposure

The biocidal product ENDURLED TFT is intended for non-professional use indoors, as insecticide to control mosquitoes in private houses. ENDURLED TFT is a liquid insecticide formulation, containing the active substance transfluthrin (0.719 % (w/w)), packed in a 30 mL PP bottle designed to fit a suitable

heater unit (liquid emanator device – LED). The (refill) bottle is inserted into the heater and plugged into a power socket. Depending on the type of heater unit, heating starts directly when the heater is plugged into the power socket or after pressing a button to switch on the power. The application can be stopped by switching off the heater and/or by disconnecting the heater from the power supply. ENDURLED TFT is intended to operate for 10 h per day on a daily basis during mosquito season (2-4 months/ year). One unit lasts 45 days, when operated for 10 h per day. In-between daily uses, the removal of the bottle from the LED is not necessary. According to the label, one device is sufficient for a room volume of up to 30 m³.

- **Scenario BfR1**

Table 43

Description of Scenario BfR1		
Primary exposure - Removal and insertion of a bottle into vaporiser unit (LED) This scenario considers dermal and inhalation exposure of a non-professional user (adult), when handling the biocidal product by replacing a spent bottle with a new full one. According to the applicant, one bottle lasts for 45 days when the intended operation duration of the LED of 10 h/d is followed. Therefore, primary exposure from loading and activating the LED is considered to be acute. To activate the device, a new bottle needs to be uncapped, then inserted and screwed in the appropriate seat of the LED and plugged in a socket. As the device is supposed to be in a vertical position, dermal contact to the active substance during loading and activating of the product is considered low, if the user is informed accordingly and follows the instructions of use. However, accidental exposure may occur occasionally and therefore, as a worst-case assumption dermal contact to 5 % (expert judgement) of the content of a bottle during its removal and insertion are assessed. Since there is no information available on how much of the b.p. remains in a bottle at the end of the 45-day operation period, an additional reverse scenario on acute dermal exposure has been included below. Regarding the vapour pressure of transfluthrin of 9 x 10^{-4} Pa at 20 °C and the short exposure duration of approx. 5 min (expert judgement), inhalation exposure during loading is considered low. Nevertheless, primary exposure from refilling and activating the device was assessed, assuming that the saturated vapour concentration represents the highest possible concentration of the active substance during application as presented in the HEEG opinion No. 13 (Assessment of inhalation exposure of volatilised biocide active substance, 2013).		
	Parameters	**Value**
Tier 1	Concentration a.s. in biocidal product (Applicant)	0.719 % (w/w)
	Amount in one bottle (Applicant)	30 mL
	Density of the b.p. (Applicant)	0.9679 g/cm³
	Amount a.s. in one bottle (= Conc. a.s. / density x amount in one bottle)	208.8 mg (= 6.96 mg a.s./mL)
	Amount of b.p. from one bottle available for dermal contact (Expert judgement)	5 % (= 1.5 mL)
	Amount of a.s. from one bottle available for dermal contact (1.5 mL x 7.428 mg a.s.)	10.44 mg
	Vapour pressure (CAR, 2014)	9 x 10^{-4} Pa (20 °C)

	Gas constant (HEEG opinion No. 13, Atkins Physical Chemistry, 5th Edition)	8.31451 J mol^{-1} K^{-1}
	Application temperature (default)	20 °C (293 K)
	Saturated vapour concentration (= molecular weight x vapour pressure / (gas constant x application temperature) (HEEG opinion No. 13)	1.37 x 10^{-1} mg/m^3
	Inhalation duration (Expert judgement)	5 min
	Inhalation rate adult, short-term (HEAd hoc Recommendation No. 14)	1.25 m^3/h = 0.02083 m^3/min
	Dermal absorption (EFSA Guidance on Dermal Absorption, 2017)	70 %
	Inhalation absorption (CAR, 2014)	100 %
	Body weight adult (HEAd hoc Recommendation No. 14)	60 kg

Calculations for Scenario BfR1

Systemic dermal exposure = Number of bottles handled x amount of a.s. from one bottle available for dermal contact x dermal absorption / body weight

Tier 1
Systemic dermal exposure adult = 2 x 10.44 mg x 70 % / 60 kg
= 2.4 x 10^{-1} mg/kg bw/d

Systemic inhalation exposure = saturated vapour concentration x inhalation rate x exposure duration x inhalation absorption / body weight

Tier 1
Systemic inhalation exposure adult = 0.137 mg/m^3 x 0.02083 m^3/min x 5 min x 100 % / 60 kg
= 2.38 x 10^{-4} mg/kg bw/d

Total systemic exposure = 2.438 x 10^{-1} mg/kg bw/d

Further information and considerations on Scenario BfR1

Reverse scenario for acute dermal exposure: $AEL_{acute\ dermal}$ x body weight / dermal absorption
= 1 mg/kg bw/d x 60 kg / 70 %
= 85.7 mg a.s./d

Given the a.s. concentration of the biocidal formulation (6.96 mg a.s./mL product, refer to table above), the calculated amount of biocidal product required for reaching the $AEL_{acute\ dermal}$ of 1 mg/kg bw would be 12.3 mL, which corresponds to 41 % of the total content of one refill bottle.

Table 44

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario BfR1 Adult	1/no PPE	2.38×10^{-4}	2.4×10^{-1}	n.a.	2.4×10^{-1}

- **Combined scenarios**

Not relevant.

3.6.3.1.3 Secondary exposure of the general public

Secondary inhalation and dermal exposure will concern persons staying in a room during operation of the LED. In addition, the active substance may end up on the floor and/or become attached to other surfaces and materials. Persons, who get in contact, in particular toddlers crawling and playing on the floor, might be exposed dermally and orally via hand-to-mouth contact.

- **Scenario BfR2**

Table 45

Description of Scenario BfR2
Secondary exposure - Inhalation exposure to transfluthrin during operation of the LED Exposure of adults and younger children during operation of the vaporiser unit is assessed by using the electrical evaporator model of ConsExpo (Pest Control Products – Electrical evaporators - Application). Exposure of infants and toddlers also represents a worst case for older children, considering the inhalation rates and body weights reported in HEAd hoc Recommendation No. 14 (2017). The model only assesses inhalation exposure. For estimation of dermal exposure during operation please refer to scenario BfR3. In line with the information provided by the applicant, the scenario is based on the application of the LED in a bedroom for 10 h per day for 4 months a year. As a worst case, the smallest bedroom from the ConsExpo General Fact Sheet (2014) with a volume of 16 m³ and a ventilation rate of 1/h is assumed. In accordance with HEAd hoc Recommendation No. 14 (2017), inhalation rates of 5.4 m³/day for an infant of 8 kg bw, 8 m³/day for a toddler of 10 kg bw and 16 m³/day for an adult of 60 kg bw are assumed for medium-term exposure. According to the applicant, the LED is intended to operate for 10 h during night time. Thus, the release (spray) duration is set to 600 min per day. Exposure duration is assumed to be 600 min per day as well, to account for the presence in a room not only for 8 h of sleeping, but during the whole time of the application as reasonable worst case.

Deviating from the default in the model, the mass generation rate for the LED is replaced by measured data for transfluthrin derived from an evaporation rate test with the biocidal product. According to the report submitted by the applicant, the average quantity of biocidal product released from the LED per day during 10 h of operation is 0.64 g. It has to be noted, that during the first days of operation, higher evaporation rates occur. The long-term evaporation rate measurement, covering up to 460 h of operation, shows that the average evaporation rate of the LED is around 0.157 g biocidal product/h on the first day, decreasing to 0.111 g biocidal product/h on the second day and reaching a steady-state level of 0.034 to 0.064 g biocidal product/h after approximately 60 h of operation (BioGenius GmbH (Germany), Report No BIO148a-17). Hence, for assessment of chronic exposure it is considered appropriate to use the upper limit of the determined evaporation rate of 0.064 g biocidal product/h as this is the actual evaporation on most days of operation and moreover representing the approximate mean value of all data over the “life-time” of the product. This equates a mass generation rate of 1.07 mg biocidal product/min.		
	Parameters	**Value**
Tier 1	Concentration a.s. in biocidal product (Applicant)	0.719 % (w/w)
	Amount in one bottle (Applicant)	30 mL
	Density of the b.p. (Applicant)	0.9679 g/cm³
	Amount a.s. in one bottle (= Conc. a.s. / density x amount in one bottle)	222.84 mg (= 7.428 mg a.s./mL)
	Frequency (Applicant)	120 days per year
	Spray duration (Applicant)	600 min
	Exposure duration (Expert judgement)	600 min
	Room volume (ConsExpo default)	16 m³
	Room height (ConsExpo default)	2.5 m
	Ventilation rate (ConsExpo default)	1/h
	Mass generation rate (Applicant)	1.07 mg biocidal product/min
	Airborne fraction (ConsExpo default)	1
	Density non-volatile (ConsExpo default)	1.5 g/cm³
	Include oral non-respirable material exposure	yes
	Inhalation absorption (CAR, 2014)	100 %
	Oral absorption (CAR, 2014)	100 %
	Inhalation rate, long-term (HEAd hoc Recommendation No. 14)	Adult: 16 m³/day Toddler: 8 m³/day Infant: 5.4 m³/day
	Body weight (HEAd hoc Recommendation No. 14)	Adult: 60 kg Toddler: 10 kg Infant: 8 kg
	For all other parameters refer to corresponding ConsExpo Web report in the Annex 4.	

Calculations for Scenario BfR2

Calculations are performed using ConsExpo Web. For corresponding reports refer to Annex 4.3.2.

Tier 1

Systemic inhalation exposure adult = 7.0×10^{-4} mg/kg bw/d

Systemic inhalation exposure toddler = 2.1×10^{-3} mg/kg bw/d

Systemic inhalation exposure infant = 1.8×10^{-3} mg/kg bw/d

Tier 1

Systemic oral exposure adult = 2.8×10^{-6} mg/kg bw/d

Systemic oral exposure toddler = 8.5×10^{-6} mg/kg bw/d

Systemic oral exposure infant = 7.2×10^{-6} mg/kg bw/d

Tier 1

Total systemic exposure adult = 7.0×10^{-4} mg/kg bw/d

Total systemic exposure toddler = 2.1×10^{-3} mg/kg bw/d

Total systemic exposure infant = 1.8×10^{-3} mg/kg bw/d

- **Scenario BfR3**

Table 46

Description of Scenario [BfR3]		
Secondary exposure - Dermal exposure to volatilised transfluthrin depositing on body surface during operation of the LED According to the applicant, the LED is intended to operate for 10 h per day throughout night time. Thus, application in bedrooms is expected. Therefore, persons sleeping in treated rooms may also be dermally exposed to volatilised transfluthrin condensing and depositing on horizontal body surfaces during application of the LED. Analogous to ConsExpo defaults used in scenario BfR2, a room volume of 16 m^3 and a room height of 2.5 m is assumed. Taking into account ESD No. 18 [1)], it is assumed that 10 % of the active substance released during the operating time is depositing evenly on horizontal surfaces. ENDURLED TFT is intended to be used during summer season. Thus, as a worst case, 50 % of the uncovered body surface are expected to be available for the deposition of the active substance. Accumulation of the active substance on the body surface is not considered relevant, assuming that remaining contaminations on the skin will be removed during daily personal hygiene measures.		
	Parameters	**Value**
Tier 1	Concentration a.s. in biocidal product (Applicant)	0.719 % (w/w)
	Amount of a.s. in one bottle (as calculated in scenario BfR1)	222.84 mg
	Operating time of LED (Applicant)	10 h per day
	b.p. release per day (Applicant)	0.64 g b.p.
	a.s. release per day (b.p. release per day x concentration a.s.)	4.6016 mg a.s.
	Amount of a.s. available for surface deposition (Applicant)	10 % [1)]
	Room volume (ConsExpo default)	16 m^3
	Room height (ConsExpo default)	2.5 m
	Floor area (= room volume / room height)	6.4 m^2 (= 64000 cm^2)
	Surface residue level of a.s. after operating time (a.s. release per day / floor area x amount of a.s. available for surface deposition)	0.00000719 mg/cm^2
	50 % of total body surface area (HEAd hoc Recommendation No. 14)	Adult: 8300 cm^2 Toddler: 2400 cm^2 Infant: 2050 cm^2
	Body weight (HEAd hoc Recommendation No. 14)	Adult: 60 kg Toddler: 10 kg Infant: 8 kg
	Dermal absorption (EFSA Guidance on Dermal Absorption, 2017)	70 %

[1)] Emission Scenario Document No. 18 for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses (2008)

Calculations for Scenario BfR3

Systemic dermal exposure = Surface residue level of a.s. x body surface area x dermal absorption / body weight

Tier 1

Systemic dermal exposure adult = 0.00000719 mg/cm^2 x 8300 cm^2 x 70 % / 60 kg
= **0.70 x 10^{-3} mg/kg bw/d**

Systemic dermal exposure toddler = 0.00000719 mg/cm^2 x 2400 cm^2 x 70 % / 10 kg
= **1.21 x 10^{-3} mg/kg bw/d**

Systemic dermal exposure infant = 0.00000719 mg/cm^2 x 2050 cm^2 x 70 % / 8 kg
= **1.29 x 10^{-3} mg/kg bw/d**

- **Scenario BfR4**

Table 47

Description of Scenario BfR4
Secondary exposure - Dermal and oral exposure to transfluthrin from contact to surface contaminations in treated rooms It is assumed that the active substance transfluthrin will deposit on the floor and become attached to other materials such as toys and bed linen. A toddler crawling over the floor can be exposed dermally and also orally by hand-to-mouth contact or mouthing of e.g. toys. Infants can be exposed dermally and orally to contaminations on bed linen and toys as well, for they may also be put to sleep during the day. It is assumed that calculating dermal exposure from contact to bed linen and from crawling on the floor will cover all possible exposure scenarios from contact to surface contaminations in treated rooms. Exposure to transfluthrin is assessed by using the „rubbing off" model of ConsExpo (Pest Control Products – Electrical evaporators – Post-application). The assessment for infants and toddlers is considered medium-term exposure and also represents a worst case for older children and adults. In line with the information provided by the applicant, the scenario is based on the application of the LED in a bedroom for 10 h per day for a maximum of 4 months a year. According to the evaporation data submitted by the applicant, the average quantity of biocidal product released from the LED per day during 10 h of operation is 0.64 g, which is equivalent to 0.0046 g of transfluthrin. About 10 % of the active substance released during the operating time is assumed to be depositing evenly on the floor (ESD No. 18)[1)]. As a worst case, the smallest bedroom of 7 m^2 (16 m^3 room volume) from the ConsExpo General Fact Sheet (2014) is assumed. Transfluthrin is a stable pyrethroid. In a study with another similar pyrethroid, accumulation of the active substance on surfaces after repeated or long-term use was observed (DOI: 10.1039/b200123n). Thus, as proposed by the applicant, an accumulation factor of 4 is considered acceptable to account for the accumulation of transfluthrin on the floor in-between cleaning intervals. The transfer coefficient for dislodgeable residues is set to 30 %. Thus, a dislodgeable amount of 0.07888 mg/m² is calculated. The rubbed surface is 7 m² and exposure time is set to 1 h/d, as proposed in the corresponding Fact Sheet. Taking into account the default transfer coefficient of 0.6 m^2/h results in a dislodgeable amount (dermal load) of 0.04734 mg/h. Considering that 10 % of dermal load will be available for hand-to-mouth transfer, an ingestion rate of 0.0000789 mg/min is calculated for Tier 1.

	Parameters	Value
Tier 1	Frequency (Applicant)	120 days per year
	Concentration a.s. in biocidal product (Applicant)	0.719 % (w/w)
	b.p. release per day (Applicant)	0.64 g b.p.
	a.s. release per day (b.p. release per day x concentration a.s.)	4.6016 mg a.s.
	Amount of a.s. available for surface deposition (Applicant)	10 % [1)]
	Floor area (ConsExpo General Fact Sheet, 2014)	7 m^2
	Accumulation factor (Applicant)	4
	Transfer coefficient for dislodgeable residues (Biocides Human Health Exposure Methodology, 2015)	30 %
	Dislodgeable amount (a.s. release per day x amount a.s. available for surface deposition x accumulation factor x transfer coefficient for dislodgeable residues / floor area)	0.07888 mg/m^2
	Exposed area (Body surface area of head, arms, hands, legs and feet; HEAd hoc Recommendation No. 14)	Toddler: 2822 cm^2 Infant: 2410 cm^2
	Transfer coefficient (ConsExpo default)	0.6 m^2/h
	Contact time (ConsExpo default)	60 min
	Contacted surface (ConsExpo default)	7 m^2
	Dermal absorption (EFSA Guidance on Dermal Absorption, 2017)	70 %
	Ingestion rate (Dislodgeable amount x Transfer coefficient x 10 %)	0.004734 mg/h = 0.0000789 mg/min
	Exposure duration (ConsExpo default)	60 min
	Oral absorption (CAR, 2014)	100 %
	Body weight (HEAd hoc Recommendation No. 14)	Toddler: 10 kg Infant: 8 kg
	For all other parameters refer to corresponding ConsExpo Web report in the Annex 4.	

[1)] Emission Scenario Document No. 18 for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses (2008)

Calculations for Scenario BfR4

Calculations are performed using ConsExpo Web. For corresponding reports refer to Annex 4.3.2.

Tier 1
Systemic dermal exposure toddler = 3.3 x 10^{-3} mg/kg bw/d
Systemic oral exposure toddler = 4.7 x 10^{-4} mg/kg bw/d
Tier 1
Systemic dermal exposure infant = 4.1 x 10^{-3} mg/kg bw/d
Systemic oral exposure infant = 5.9 x 10^{-4} mg/kg bw/d
Tier 1
Total systemic exposure toddler = 3.8 x 10^{-3} mg/kg bw/d
Total systemic exposure infant = 4.7 x 10^{-3} mg/kg bw/d

- **Scenario BfR5**

Table 48

Description of Scenario BfR5
Secondary exposure - Inhalation exposure to transfluthrin re-volatilised from surface contaminations after operation of the LED Due to its low vapour pressure of 9 x 10^{-4} Pa at 20°C (CAR, 2014), transfluthrin can be considered a non-volatile substance and inhalation exposure to transfluthrin re-volatilised from surface contaminations after application is expected to be insignificant. When applying the Tier-1 screening tool provided in HEEG Opinion 13 (2013), results conclude that exposure to inhaled vapour of the active substance volatilised from treated surfaces needs to be estimated and included into the risk assessment: 0.328 x (*mv* x *vp*/ $AEL_{long\text{-}term}$) = 0.328 x (371.2 g/mol x 0.0009 Pa/ 0.01 mg/kg bw/d) = 10.957 > 1 However, it is considered that inhalation exposures to transfluthrin re-volatilised from contaminated surfaces would not be greater than inhalation exposure during operation of the LED. Thus, exposure estimates from scenario BfR2 are taken as very worst case to address potential post-application inhalation of transfluthrin re-volatilised from surface contaminations.

Calculations for Scenario BfR5

Please refer to calculations of scenario BfR2.

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario BfR2 Adult	1/no PPE	7.0×10^{-4}	n.a.	2.8×10^{-6}	**7.0×10^{-4}**
Scenario BfR2 Toddler	1/no PPE	2.1×10^{-3}	n.a.	8.5×10^{-6}	**2.1×10^{-3}**
Scenario BfR2 Infant	1/no PPE	1.8×10^{-3}	n.a.	7.2×10^{-6}	**1.8×10^{-3}**
Scenario BfR3 Adult	1/no PPE	n.a.	0.7×10^{-3}	n.a.	**0.7×10^{-3}**
Scenario BfR3 Toddler	1/no PPE	n.a.	1.2×10^{-3}	n.a.	**1.2×10^{-3}**
Scenario BfR3 Infant	1/no PPE	n.a.	1.3×10^{-3}	n.a.	**1.3×10^{-3}**
Scenario BfR4 Toddler	1/no PPE	n.a.	3.3×10^{-3}	4.7×10^{-4}	**3.8×10^{-3}**
Scenario BfR4 Infant	1/no PPE	n.a.	4.1×10^{-3}	5.9×10^{-4}	**4.7×10^{-3}**
Scenario BfR5 Adult	1/no PPE	7.0×10^{-4}	n.a.	2.8×10^{-6}	**7.0×10^{-4}**
Scenario BfR5 Toddler	1/no PPE	2.1×10^{-3}	n.a.	8.5×10^{-6}	**2.1×10^{-3}**
Scenario BfR5 Infant	1/no PPE	1.8×10^{-3}	n.a.	7.2×10^{-6}	**1.8×10^{-3}**

- **Combined scenarios**

Table 50

Summary table: combined systemic exposure of the general public				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios BfR1 + BfR2 + BfR3 + BfR5 Adult	2.38×10^{-4} (acute) 1.4×10^{-3} (chronic)	2.4×10^{-1} (acute) 0.7×10^{-3} (chronic)	n.a. (acute) 5.6×10^{-6} (chronic)	2.4×10^{-1} (acute) 2.1×10^{-3} (chronic)
Scenarios BfR2 + BfR3 + BfR4 + BfR5 Toddler	4.2×10^{-3}	4.5×10^{-3}	4.9×10^{-4}	9.2×10^{-3}
Scenarios BfR2 + BfR3 + BfR4 + BfR5 Infant	3.6×10^{-3}	5.4×10^{-3}	6.0×10^{-4}	9.6×10^{-3}

3.6.3.2 Dietary exposure

Table 51

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Transfluthrin
Type of formulation	RTU liquid that is used in a vaporizing device. A refill bottle is inserted into the suitable heater, which is plugged into a power socket.
Substance(s) of concern	none
Field(s) of use	Indoor use in private homes
Target organism(s)	House mosquitoes, *Culex quinquefasciatus* (adults); Asian tiger mosquitoes, *Aedes albopictus* (adults)
Application rate(s) and frequency	Product contains 0.708 % w/w pure transfluthrin (1R-trans isomer) Application max. 10 h per day (0.64 g released product /d, equals 4.53 mg a.s. /d) One unit lasts 45 days (with 10 h vaporisation/day)

Intended use(s) (critical application with regard to dietary exposure)	
	In areas of hot climate (like Italy, Spain, Greece and southern France): The biocidal product can be used from beginning of June until mid-September on a daily basis.
Category(ies) of users	General public (non-professional)
Waiting periods after treatment	/
Further information	/

Conclusion

The intended use description of the transfluthrin-containing biocidal product ENDURLED TFT for which authorisation is sought indicates that contact with food, feed or livestock is not expected.
The product is to be used for the control of mosquitoes in private houses by non-professionals.

Contact with food or feed is avoided by applying appropriate risk mitigation measures:

- To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.
- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets (ECHA sentence N-127).

3.6.3.3 Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not relevant.

3.6.3.5 Summary of exposure assessment

Table 52

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
BfR1	Non-professionals	1/no PPE	Adult: 2.4×10^{-1}
BfR2	General public	1/no PPE	Adult: 7.0×10^{-4} Toddler: 2.1×10^{-3} Infant: 1.8×10^{-3}
BfR3	General public	1/no PPE	Adult: 0.7×10^{-3} Toddler: 1.2×10^{-3} Infant: 1.3×10^{-3}
BfR4	General public	1/no PPE	Toddler: 3.8×10^{-3} Infant: 4.7×10^{-3}
BfR5	General public	1/no PPE	Adult: 7.0×10^{-4} Toddler: 2.1×10^{-3} Infant: 1.8×10^{-3}

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) see Chapter 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

No MRLs are necessary.

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Endocrine disrupting properties

In the active substance evaluation (2014), transfluthrin has not been assessed for potential endocrine disrupting properties regarding human health. However, based on the available information and according to the SVHC-candidate list and the ED-list, there are no indications for endocrine disrupting properties of the active substance.
For further details on ED assessment please refer to sections 5.2 in the Confid. Annex.

3.6.4.5 Risk for industrial users

Not relevant.

3.6.4.6 Risk for professional users

Not relevant.

3.6.4.7 Risk for non-professional users

Table 53: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading Scenario BfR1 Adult	1	17	0.17 (acute inhalation)	2.38×10^{-4}	0.14	yes
	1	100	1 (acute dermal)	2.4×10^{-1}	24	yes

- **Local effects**

No local exposure assessment is performed, since the biocidal product ENDURLED TFT is not classified for local effects. However, the non-professional user has to be informed about the potential of pyrethroids like transfluthrin to provoke paresthesia (burning and prickling of the skin without irritation) in susceptible persons. Thus, the following advice has to be included on the label:

- Transfluthrin may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Conclusion

Primary exposure of the non-professional user to the biocidal product ENDURLED TFT, containing 0.719 % (w/w) transfluthrin, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed. No risk has been identified for non-professional users loading and starting the vaporising unit. According to the applicant, refill bottles are closed with a snap-fit wick mechanism, which prevents the bottle to be opened and ensures the release of the product only by evaporation through the wick. Thus, dermal contact to more than one third of the liquid content of a refill bottle is considered unlikely and therefore a potential risk considered acceptable, if the use-specific instructions for use are followed.

3.6.4.8 Risk for the general public

Table 54: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application Scenario BfR2 - Exposure during operation	1	1	0.01	Adult: 7.0×10^{-4} Toddler: 2.1×10^{-3} Infant: 1.8×10^{-3}	Adult: 7.0 Toddler: 21 Infant: 18	yes
Application Scenario BfR3 - Exposure during operation	1	1	0.01	Adult: 0.7×10^{-3} Toddler: 1.2×10^{-3} Infant: 1.3×10^{-3}	Adult: 7.0 Toddler: 12 Infant:13	yes
Post-application Scenario BfR4 - Exposure after operation	1	1	0.01	Toddler: 3.8×10^{-3} Infant: 4.7×10^{-3}	Toddler: 38 Infant: 47	yes
Post-application Scenario BfR5 - Exposure after operation	1	1	0.01	Adult: 7.0×10^{-4} Toddler: 2.1×10^{-3} Infant: 1.8×10^{-3}	Adult: 7.0 Toddler: 21 Infant: 18	yes

Table 55: Combined scenarios[5]

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)
Scenarios BfR1 + BfR2 + BfR3 + BfR5 Adult	1	17 100 1	0.17 (acute inhalation) 1 (acute dermal) 0.01 (chronic)	2.38×10^{-4} (acute inhalation) 2.4×10^{-1} (acute dermal) 2.1×10^{-3} (chronic)	0.14 24 21 Total: 45	yes
Scenarios BfR2 + BfR3 + BfR4 + BfR5 Toddler	1	1	0.01	9.2×10^{-3}	92	yes
Scenarios BfR2 + BfR3 + BfR4 + BfR5 Infant	1	1	0.01	9.6×10^{-3}	96	yes

- **Local effects**

No local exposure assessment is performed, since the biocidal product ENDURLED TFT is not classified for local effects. However, the general public has to be informed about the potential of pyrethroids like transfluthrin to provoke paresthesia (burning and prickling of the skin without irritation) in susceptible persons. Thus, the following advice has to be included on the label:

- Transfluthrin may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Conclusion

Secondary exposure of the general public to the biocidal product ENDURLED TFT, containing 0.719 % (w/w) transfluthrin, is considered acceptable, if the biocidal product is used as intended. No risk has been identified for the general public, resulting from inhalation and dermal exposure during operation of the vaporising unit, as well as from dermal and oral exposure towards active substance surface contaminations.

According to the applicant, refill bottles are closed with a snap-fit wick mechanism, which prevents the bottle to be opened and ensures the release of the product only by evaporation through the wick. Thus,

oral exposure of toddlers to the liquid biocidal formulation has not been assessed. However, when calculating a reverse scenario for acute oral exposure of a toddler, the ingestion of only 0.2 ml, which represents less than 1 % of the total content of one refill bottle, would already be sufficient to reach the $AEL_{acute\ oral}$ of 0.15 mg/kg bw.

Reverse scenario for acute oral exposure: $AEL_{acute\ oral}$ x body weight / oral absorption
= 0.15 mg/kg bw/d x 10 kg / 100 %
= 1.5 mg a.s./d / 7.428 mg a.s./mL
= 0.2 mL biocidal product/d

Hence, potential health risk for small children from oral exposure to the liquid content of the vaporiser has to be minimised by appropriate risk mitigation measures.

In conclusion, no health risk for the general public is expected, if the biocidal product is used as intended and the following points are included as risk mitigation measures or directions for use in the SPC and on the label:

- Place vaporiser unit out of the reach of children.

3.6.4.9 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance transfluthrin and no SoC for human health.

3.6.4.11 Summary of risk characterisation

3.6.4.11.1 Summary of risk characterisation for industrial user

Not relevant.

3.6.4.11.2 Summary of risk characterisation for professional user

Not relevant.

3.6.4.11.3 Summary of risk characterisation for non-professional user

Table 56

Scenario, Tier	Relevant reference value (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario BfR1 Adult, Tier 1	0.17 (acute inhalation)	2.38 x 10^{-4}	0.14	yes
	1 (acute dermal)	2.4 x 10^{-1}	24	yes

3.6.4.11.4 Summary of risk characterisation for indirect exposure

Table 57

Scenario, Tier	Relevant reference value (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario BfR2 Tier 1	0.01	Adult: 7.0 x 10^{-4} Toddler: 2.1 x 10^{-3} Infant: 1.8 x 10^{-3}	Adult: 7.0 Toddler: 21 Infant: 18	yes
Scenario BfR3 Tier 1	0.01	Adult: 0.7 x 10^{-3} Toddler: 1.2 x 10^{-3} Infant: 1.3 x 10^{-3}	Adult: 7.0 Toddler: 12 Infant:13	yes
Scenario BfR4 Tier 1	0.01	Toddler: 3.8 x 10^{-3} Infant: 4.7 x 10^{-3}	Toddler: 38 Infant: 47	yes
Scenario BfR5 Tier 1	0.01	Adult: 7.0 x 10^{-4} Toddler: 2.1 x 10^{-3} Infant: 1.8 x 10^{-3}	Adult: 7.0 Toddler: 21 Infant: 18	yes

3.7 Risk assessment for animal health

The biocidal product ENDURLED TFT is designed for usage in a plug-in electrically operated liquid vaporiser, intended for the daily indoor application in private housings for 10 h per day during summer season (max. 4 months). Hence, exposure of pets of the respective domestic premises to the biocidal product cannot be excluded. In general, as a worst case, the exposure and risk assessment for the general public (toddler) can be adopted for animals. However, due to a slower metabolism of pyrethroids, some pet species, especially cats or poikilothermic animals, like fish, reptiles and amphibians, are particularly susceptible towards the toxicity of the active substance transfluthrin. Thus, a potential health risk for these pets is not covered by the human secondary exposure and risk assessment.

In the absence of corresponding information, such as species-specific AELs, no quantitative or qualitative exposure and risk assessment for cats and poikilothermic animals can be conducted. Hence, potential health risk for pyrethroid-sensitive pets has to be minimised by appropriate risk mitigation measures.

In conclusion, no health risk for pets is expected, if the biocidal product is used as intended and the following points are included as risk mitigation measures or directions for use in the SPC and on the label:

- Contains transfluthrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
- Keep cats away from treated areas. Due to their particular sensitivity to transfluthrin, the product can cause severe adverse reactions in cats.
- Do not apply in rooms where fish tanks and/or terrariums are present.
- For use only in areas that are inaccessible to pets and non-target animals.

3.8 Risk assessment for the environment

3.8.1 General information

Environmental risk assessment for the b.p. ENDURLED TFT is based on data for the active substance transfluthrin and a further substance of concern.
The biocidal product is sold within a set consisting of an electric diffuser and a refill (bottle containing the a.s. in the concentration of 0.719%).

The biocidal product consists of a liquid insecticide formulation in a refill bottle designed to fit into a suitable heater unit (with or without button to switch on and off the power). The refill bottle is inserted into the suitable heater, which is plugged into a power socket. The application can be stopped by switching of the heater and/or by disconnecting the heater from the power supply.

In addition to the active substance, the b.p. contains 2,6-Di-tert-butyl-p-cresol (BHT) as antioxidant. This substance has no legal classification but, according to the SDS a proposed classification as H400 and H410. This proposal is also confirmed by the information from the ECHA C&L inventory and the available REACH-Dossier. There, also M factors 1 (acute and chronic) are given. Based on the content of BHT in the b.p., the substance has to be considered as a substance of concern (SoC) as it would lead to a classification of the b.p.

The applicant has a letter of access to the data from the active substance dossier (c.f. Assessment Report Transfluthrin, eCA NL, March 2014). After active substance approval, new data were provided for transfluthrin that are also covered by the LoA. These data were discussed and new PNECs for water, sediment and soil for transfluthrin and a new $PNEC_{water}$ for the metabolite TFB-COOH were agreed on WG meeting IV-2017 as presented below. Following the WG meeting, an ad-hoc follow up was launched in order to agree on endpoints derived from a new submitted aerobic soil degradation study according to OECD 307.

3.8.2 Effects assessment

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

Exposure due to the use of the b.p. is possible for the environmental compartments air, sewage treatment plant, surface water, sediment, soil and groundwater.
Please refer to the details on environmental fate and behaviour and exposure assessment for the product given in sections 3.8.3 and 3.8.4.

- **Screening Step 2:**

The b.p. Endurled contains transfluthrin as the only active substance and BHT, which is a substance of concern as indicated in section 2.2.4 “Information on the substance of concern”. Hence, two relevant substances were identified and mixture toxicity assessment is required.

- **Screening Step 3: Screen on synergistic interactions**

There are no indications for synergistic interactions between the active substance transfluthrin and the SoC.

Table 58

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

The relevant substances as identified in Screening step 2 are characterized in the following sections concerning their environmental effects, fate, behaviour and exposure. Mixture toxicity assessment is provided below in section 3.8.5.8.

3.8.2.2 Aquatic compartment (including sediment and STP)

3.8.2.2.1 Active substance transfluthrin

- **Acute aquatic toxicity**

Table 59 summarises the available studies (evaluated during active substance approval in the CAR 2013 and AR 2014) and the respective acute effect values for the fresh water compartment.

Table 59

Summary table for acute aquatic toxicity							
Guideline/ Test method/ GLP status/ reliability	**Species**	**End point**	**Exposure**		**Results**	**Remarks**	**Reference**
			Design	**Duration**			
Fish							
OECD 203/ GLP/ reliability 1	*Oncorhynchus mykiss*	mortality	Flow-through	96 h	LC_{50} = 0.7µg/L	Nominal; actual concentrations >80%	CAR Transfluthrin
OECD 203/ GLP/ reliability 1	*Oncorhynchus mykiss*	mortality	Flow-through	96 h	LC_{50} > 100 mg/L	TFB-COOH	CAR Transfluthrin
Invertebrates							
OECD 202/ GLP/ reliability 2	*Daphnia magna*	immobilisation	static	48 h	EC_{50} = 1.2 µg/L	Mean measured conc.	CAR Transfluthrin
OECD 202/ GLP/ reliability 1	*Daphnia magna*	immobilisation	static	48 h	EC_{50} > 100 mg/L	TFB-COOH	CAR Transfluthrin
Algae (growth inhibition)							
OECD 201/ GLP/ reliability 2	*Scenedesmus subspicatus*	growth inhibition	static	96 h	E_rC_{50} > 100 µg/L NOE_rC = 50 µg/L	nominal	CAR Transfluthrin

- **<u>Chronic aquatic toxicity</u>**

After substance approval, new studies were provided for *Daphnia magna* chronic toxicity, early life stage toxicity with fish, *Chironomus riparius* chronic toxicity and *Lumbriculus variegatus* chronic toxicity for the active substance transfluthrin, as well as algae toxicity for the metabolite TFB-COOH. All available studies with their respective long-term effect values are summarised in Table 60.

Table 60

Summary table for chronic aquatic toxicity							
Guideline/ Test method	**Species**	**Endpoint**	**Exposure**		**Results**	**Remarks**	**Reference**
			Design	**Duration**			
Fish							
OCSPP 850.1400 OECD 210	*Pimephales promelas*	mortality, hatching, growth	flow-through	36 d	NOEC > 399 ng a.i./L	Mean measured	[redacted]

							Report No M-522816-01-1
Invertebrates							
OCSPP 850.1300, OECD 211 (2012)	*Daphnia magna*	reproduction, growth	flow-through	21 d	NOEC = 17.5 ng a.i./L	Mean measured	SynTech Research Laboratory (USA), Report No M-522462-01-1
Algae							
OCPPS 850.4500 (2012); *OECD 201 (2006)*	*Pseudokirchneriella subcapitata*	growth inhibition	static	96 h	E_rC_{50} > 100 mg/L, NOEC = 3.05 mg/L	TFB-COOH Nominal, measured > 90%	SynTech Research Laboratory (USA), Report No M-528046-01-1
Sediment organisms							
OECD 218	*Chironomus riparius*	emergence, development rate	static, spiked sediment	28 d	NOEC = 0.164 mg/kg dw sed	initially measured conc.	Bayer CropScience (Germany), Report No M-508598-01-1
OECD 225	*Lumbriculus variegatus*	mortality, reproduction and dry biomass	static, spiked sediment,	28 d	NOEC = 2.21 mg/kg dw sed	initially measured conc.	ECT Oekotoxikologie GmbH (Germany), Report No M-529774-01-1

The new chronic studies provided for transfluthrin and the algae study for TFB-COOH were considered as acceptable and the following new PNECs were agreed at the WG IV/2017:

The NOEC from *Daphnia magna* prolonged toxicity test (1.75×10^{-5} mg/L) is the lowest effect value for the active substance transfluthrin in surface water. As data for three trophic levels are available, an AF of 10 is used to calculate **$PNEC_{water}$ = 1.75×10^{-6} mg/L**.

For the metabolite **TFB-COOH** acute toxicity tests are available for fish, daphnia and algae. In all species, EC_{50} values are higher than 100 mg/L. An AF of 1000 is applied for PNEC derivation, giving a **$PNEC_{water,TFB\text{-}COOH}$ of > 0.1 mg/L** for TFB-COOH. It was proposed in the CAR, that another major metabolite of transfluthrin, TFB-OH, exhibits a similar toxicity like TFB-COOH, although no experimental data were submitted. Hence, **$PNEC_{water,TFB\text{-}OH}$ > 0.1 mg/L.**

For the third major metabolite **DCVA**, the "harmonised list of endpoints for pyrethroid metabolites" (BPC-35, 09/09/2020) reports a 48h-EC_{50} for *Daphnia magna* of 25 mg/L and a 96h-LC_{50} for *Oncorhynchus mykiss* of > 14.7 mg/L. In the AR from 2019 a $PNEC_{water,DCVA}$ of 0.0064 mg/L was derived based on QSAR (LC_{50} of 6.42 mg/L for Daphnia and an assessment factor of 1000). It should be noted that the baseline QSAR might not be representative for this type of molecule, but it was agreed in the AR to accept it for now.

- **Toxicity to sediment organisms**

For the sediment compartment, long-term tests with spiked sediment with *Chironomus riparius* and *Lumbriculus variegatus* were provided. The lowest NOEC of 0.164 mg/kg dw was found for *Chironomus riparius*. As two long-term studies are available, an AF of 50 would normally be applied. However, in the *Chironomus* test, the organisms were fed with fresh fish food 3 times per week, thus limiting exposure via sediment ingestion. Therefore, it was agreed at WG IV-2017 to use an AF of 100 for the derivation of the $PNEC_{sed}$. Thus, $PNEC_{sed}$ = 0.164 × 10^{-3} mg/kg dw sed. Converted to ww, the **$PNEC_{sed}$ is 3.57 × 10^{-4} mg/kg ww**.
For the metabolites no additional experimental data was available. As shown for the surface water, it can be assumed that the **metabolites are equally or less toxic than the parent compound also for sediment. Thus, the $PNEC_{sed}$ for the active substance covers also the possible effects of the metabolites**.

- **Toxicity to micro-organisms (STP)**

In the CAR and assessment report transfluthrin showed 0% respiration inhibition in an activated sludge respiration inhibition test (in most parts identical with OECD Guideline 209) at a concentration of 10000 mg/l which is far above its water solubility of 0.057 mg/l. As a worst-case estimate the NOEC for respiration of activated sludge was set equal to the water solubility resulting in a $PNEC_{STP}$ of 0.057 mg/L after application of an assessment factor of 1 to this value.
However, according to the Guidance on the BPR, Volume IV, Part B, Infobox Nr. 7, p. 127 (ECHA, April 2015) if no inhibition is observed for active substances tested at concentrations exceeding their water solubility, the NOEC is now set equal to the water solubility which is subsequently used to derive the $PNEC_{STP}$ by application of an assessment factor of 10. In case of transfluthrin this results in a **$PNEC_{STP}$ of 0.0057 mg/l.**
Deviating from the CAR, this $PNEC_{STP}$ was used in the risk assessment, since it was proposed by the applicant and no unacceptable risk was identified.

3.8.2.2.2 Substance of Concern: BHT

BHT was identified as substance of concern for the environment.

Aquatic effect data are available from the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975) that were used for the further effects assessment of BHT. A $PNEC_{water}$ of 0.199 µg/L is reported in the REACH-Dossier based on a short-term LC_{50} for fish (0.199 mg/L) determined by QSAR and an assessment factor of 1000. However, the following experimental short-term and long-term data are also reported in the REACH-Dossier (only valid studies with reliabilities 1 or 2 considered):

Table 61

Summary table for aquatic toxicity				
Guideline/ Test method	**Species**	**End point/ Type of test**	**Exposure**	**Results**
OECD 203	*Oryzias latipes*	mortality	96 h	LC_{50} = 1.1 mg/L
OECD 210	*Oryzias latipes*	not specified	30 d	NOEC = 0.053 mg/L
OECD 202	*Daphnia magna*	immobilisation	48 h	EC_{50} = 0.48 mg/L
OECD 211	*Daphnia magna*	reproduction	21 d	NOEC = 0.069 mg/L
OECD 201	*Pseudokirchneriella subcapitata*	growth rate	72 h	E_rC_{50} > 0.24 mg/L NOEC = 0.24 mg/L

The lowest effect value was the NOEC of 0.053 mg/L found for *Oryzias latipes* in a fish early-life stage toxicity test. For the derivation of the $PNEC_{water}$ an assessment factor of 10 is proposed as both short-term and long-term toxicity data for three trophic levels are available. Therefore:

$PNEC_{water;BHT}$ = 0.053 mg/L / 10 = 0.0053 mg/L = 5.3 µg/L

- **Toxicity to sediment organisms**

No studies with sediment organisms are available for BHT. Therefore, the $PNEC_{sed}$ is derived using the equilibrium partitioning method: Using a K_{susp_water} of 288 and the above derived $PNEC_{water}$ of 5.3 µg/L a $PNEC_{sed}$ of 1.3 mg/kg ww is calculated.

As the log Kow given in the REACH-Dossier is > 5, an additional factor of 10 has to be applied resulting in a **$PNEC_{sed}$ of 0.13 mg/kg ww**.

- **Toxicity to micro-organisms (STP)**

A study investigating the toxicity of BHT to the aquatic protozoa *Tetrahymena pyriformis* provides an EC_{50} (24h) of 1.7 mg/L based on growth inhibition. Additional data are available from two further tests performed on *Photobacterium phosphoreum* (15min-EC_{50} = 8.6 mg/L) and *Pseudomona fluorescens* (36h-NOEC =

50 mg/L), respectively. According to the Guidance on BPR (Vol IV, Part B, 2017) only the test using *Tetrahymena pyriformis* can be considered relevant for the risk assessment for STPs. The PNEC is thereby derived by applying an assessment factor of 10 on the EC_{50} (24h) of 1.7 mg/L, resulting in a **$PNEC_{STP}$ of 0.17 mg/L.**

The REACH-Dossier contains a further test according to OECD 209, which has been reported in 2000. In this test (static, 3 hrs), the respiration rate of activated sludge (0.32 g/L suspended solids) was measured at 0, 100, 1000, and 10000 mg/L. The sludge was taken from a wastewater treatment plant treating predominantly domestic sewage (Wupper area water authority). BHT was added to about 130 mL deionized water and stirred overnight before testing (equilibration phase). No effect was observed at the highest test concentration. BHT is almost water insoluble, so the NOEC has to be set equal to the limit of water solubility according to Infobox 7, on page 138 of the Guidance on BPR (Vol IV Environment Parts B+C, Version 2.0, October 2017) and divided by an AF of 10. As a water solubility of 1.5 mg/L is stated in the REACH-Dossier, the resulting **$PNEC_{STP}$ is 0.15 mg/L.**

3.8.2.3 Terrestrial compartment (including groundwater)

3.8.2.3.1 Active substance transfluthrin

In the CAR and AR for a.s. approval, only short-term effect data for earthworms are available for transfluthrin.

After a.s. approval, further toxicity studies for the active substance transfluthrin were provided. In the following Table 62 all available terrestrial effect data are summarised:

Table 62

Summary table for terrestrial toxicity						
Guideline/ Test method	**Species**	**Endpoint/ Type of test**	**Duration**	**Results**	**Remarks**	**Reference**
OECD 207	*Eisenia fetida*	mortality	14 d	LC_{50} = 184 mg/kg dw	already available in CAR	Bayer AG, Report No MO-03-009355
OECD 222 GLP	*Eisenia fetida*	mortality, reproduction, growth	56 d	NOEC = 10 mg/kg dw	new study	BioChem agrar GmbH (Germany), Report No M-503247-01-1
OECD 232	*Folsomia candida*	reproduction	28 d	NOEC = 18 mg/kg dw	new study	BioChem agrar GmbH

						(Germany), Report No M-504775-01-1
OECD 216	*Nitrogen transformation*		28 d	NOEC = 3.9 mg/kg dw NOEC = 5.24 mg/kg dw (normalised to standard soil)	new study	BioChem agrar GmbH (Germany), Report No M-500036-01-1
OECD 208	Terrestrial plants (5 species) most sensitive *Lycopersicon esculentum*	seedling emergence, growth	21 d	EC_{50} = 75.73 mg/kg soil dw = 210.4 mg/kg soil dw (normalised to standard soil) NOEC = 18 mg/kg dw = 50 mg/kg dw (normalised to standard soil)	new study	Bayer CropScience (Germany), Report No M-535993-01-1

All effect values are based on nominal concentrations, as no analytical monitoring was performed. The studies were considered as acceptable at the WG IV/2017 and it was agreed to derive a new $PNEC_{soil}$ based on the NOEC from the soil microorganism study and an assessment factor of 50. Therefore, **$PNEC_{soil}$** = 5.24 mg/kg dw / 50 = 0.1 mg/kg dw = **0.09 mg/kg ww**

Studies on non-target arthropods and bees were demanded for the product authorisation stage in the active substance assessment report. However, since the application of the products is intended for indoor use only, these studies are not required for this product.

No experimental data was provided for the major metabolites. In the AR from 2019 a $PNEC_{soil,DCVA}$ of 0.0128 mg/kg ww and a $PNEC_{soil,TFB\text{-}COOH}$ of 0.012 mg/kg ww were derived based on QSAR.

3.8.2.3.2 Substance of Concern: BHT

Terrestrial effect data are available from the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975).
The following experimental short-term and long-term data are reported in the REACH-Dossier (only valid studies with reliabilities 1 or 2 considered):

Table 63

Guideline/ Test method	Species	End point/ Type of test	Duration	Results
OECD 208	terrestrial plants (6 species) most sensitive: *Allium cepa*	seedling emergence, growth, survival	16 d	EC_{50} = 20.9 mg/kg soil dw = 61.5 mg/kg soil dw (normalised* to standard soil*) NOEC = 4.74 mg/kg dw (shoot fresh weight) = 14 mg/kg soil dw (normalised to standard soil*)
OECD 222 GLP/ reliability	*Eisenia fetida*	mortality, reproduction, growth	56 d	NOEC = 25 mg/kg dw (reproduction) NOEC > 100 mg/kg dw (mortality, growth)

* organic carbon content of the natural soil used in the plant study is given as 0.68 %

Only two reliable studies are available, a short-term study with plants and an earthworm reproduction study. From the earthworm reproduction study, it seems that earthworms are less sensitive to BHT than sensitive plants, as no effects were found on the survival of earthworms up to 100 mg/kg dw which is the relevant endpoint from short-term study with earthworms. Thus, the EC_{50} from the short-term plant study of 20.9 mg/kg dw = 61.5 mg/kg dw (normalised to a standard organic carbon content of 2 %, as plants are only exposed via the porewater) is used as basic effect value for the $PNEC_{soil}$.
As neither a long-term study for plants nor a reliable study for soil microorganisms is available, an assessment factor of 1000 is applied. This results in a **$PNEC_{soil}$** of 61.5 µg/kg dw. = **54.4 µg/kg ww**.

3.8.2.4 Non-compartment specific effects

3.8.2.4.1 Active substance transfluthrin

As transfluthrin has a high log Kow (> 5), a bioaccumulation potential of the substance is indicated and thus assessment of secondary poisoning is required.
Based on the estimated log Kow of 1.54 and 1.85 respectively, the metabolites TFB-OH and TFB-COOH are not expected to bioaccumulate: Epiwin calculates for DCVA a log Kow of 3.38. Although this log Kow > 3 indicates a potential for bioaccumulation, no assessment for secondary poisoning was performed in the CAR for transfluthrin. Consequently, the assessment of secondary poisoning is solely performed for the active substance.

- **Effects on fish-eating and worm-eating birds**

As no dietary tests are available for birds, a $PNEC_{oral,birds}$ cannot be calculated.

- **Effects on mammals**

Based on a 2-generation study with rats, a chronic NOEC of 200 mg/kg feed is reported in the CAR. Using an assessment factor of 30 results in a **$PNEC_{oral,mammal}$** of **6.7 mg/kg food**.

3.8.2.4.2 Substance of concern: BHT

In the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975) a **$PNEC_{oral,mammal}$ of 16.67 mg/kg food** is reported, derived with an assessment factor of 30. No further information is given. Looking at the repeated dose toxicity studies with rats, a NOAEL of 25 mg/kgbw/day is reported. In addition, from a reproduction toxicity study with rats also a NOAEL of 25 mg/kg bw/day was derived. (c.f. REACH-Dossier BHT). Lower NOAELs from mammalian studies relevant for a derivation of a $PNEC_{oral}$ were not found in the REACH-Dossier. With a conversion factor of 20, a NOEC of 500 mg/kg food can be derived according to the BPG Guidance, Vol IV part B+C. With an assessment factor of 30, the $PNEC_{oral,mammal}$ is 16.67 mg/kg food. Therefore, the $PNEC_{oral,mammal}$ reported in the REACH-Dossier is used for the further risk characterisation of BHT.

3.8.2.5 Summary of effects assessment

All derived PNEC values are indicated in Table 64 for transfluthrin, Table 65 for the major metabolites TFB-COOH and TFB-OH, Table 66 for the major metabolite DCVA and Table 67 for the SoC BHT.

Table 64

Summary table on calculated PNEC values for a.s. transfluthrin	
Compartment	**PNEC**
Surface water	1.75×10^{-6} mg/L
Sediment	3.57×10^{-4} mg/kg ww sed
STP	5.7×10^{-3} mg/L
Soil	9×10^{-2} mg/kg ww soil
$PNEC_{oral,mammal}$	6.7 mg/kg food

Table 65

Summary table on calculated PNEC values for major metabolites TFB-COOH and TFB-OH		
Compartment	**PNEC - TFB-COOH**	**PNEC - TFB-OH**
Surface water	> 0.1 mg/L	> 0.1 mg/L
Sediment	n.a.	n.a.
STP	5.7×10^{-3} mg/L	5.7×10^{-3} mg/L
Soil	0.012 mg/kg ww	n.a.

Table 66

Summary table on calculated PNEC values for major metabolite DCVA	
Compartment	**PNEC**
Surface water	0.0064 mg/L
Sediment	n.a.
STP	5.7×10^{-3} mg/L
Soil	0.0128 mg/kg ww

Table 67

Summary table on calculated PNEC values for BHT (substance of concern)	
Compartment	**PNEC**
Surface water	5.3×10^{-3} mg/L
Sediment	1.3×10^{-1} mg/kg ww
STP	1.5×10^{-1} mg/L
Soil	5.4×10^{-2} mg/kg ww
$PNEC_{oral,mammal}$	16.67 mg/kg food

3.8.3 Fate and behaviour

3.8.3.1 Active substance transfluthrin

The fate and behaviour assessment is predominantly based upon data given in the AR (2014) and CAR (2013) of transfluthrin. The main parameters are summarised briefly in the subsequent paragraph. For detailed information, refer to the above mentioned assessment reports.

Apart from this, the applicant provided LoAs for a new aerobic soil metabolism/degradation study performed with transfluthrin according to OECD 307 (Bayer CropScience (Germany), Report No, M-534584-01-1) and two degradation studies with transfluthrin in activated sludge according to OECD 314B (for results see confidential Annex for Member States only). The re-calculated half-lives and formation fractions derived from the OECD 307 study have been discussed during an ad-hoc follow up following WGIV-2017 and were agreed by the 24th BPC (2018).

Ready biodegradability

Transfluthrin is not readily biodegradable. No study on inherent biodegradability is available.
Consequently, a degradation rate constant of 0 h^{-1} should actually be used to calculate the elimination in sewage treatment plants.

Biodegradation in STP

For exposure refinement two degradation studies with transfluthrin in activated sludge according to OECD 314B have been submitted (for details see Confidential Annex for Member States only). The studies support a degradation rate in STP for transfluthrin of 0.05 h^{-1} for use in exposure calculations. Consideration of primary degradation of the active ingredient requires consideration of all major metabolites, if any. In the present case, biodegradation of transfluthrin in activated sludge resulted in the formation of DCVA at relevant amounts for which a degradation rate of 0.002 h^{-1} at 20°C is used in exposure calculations, together with a formation fraction of 1. According to the degradation scheme, the formation of DCVA is consequently associated with the formation of TFB-OH as the second major metabolite. Since the studies do not provide information regarding the degradation of this metabolite, a default degradation rate in STP of k = 2.8881E-08 h^{-1} ($1x10^6$ d) is used in the exposure calculations together with a formation fraction of 1.

Biodegradation and dissipation in soil

A summary of the half lives in soil for transfluthrin and its relevant metabolites is given in Table 68 and Table 69. The available studies do not provide any information about the degradation of the known metabolite DCVA (3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid) results from the cleavage of the ester bond and is expected to be formed at the same amount as TFB-COOH. From this reason, it should be considered as major metabolite in the groundwater assessment as well. Based on the lack of data a default half-life of $1x10^6$ days and a formation fraction of 1 was used in PEC calculations.

Table 68

Summary table on half lives in soil					
Process	DT_{50} measured in test	DT_{50} at 12°C	Rate constant at 12°C/ formation fraction	Remarks	Reference
aerobic biodegradation	Transfluthrin: 2.76d	Transfluthrin: 5.17d	Transfluthrin: 0.134 d^{-1}	Transfluthrin: Geomean (n=4, 3 x FOMC, 1 x DFOP)	Bayer CropScience (Germany), Report No M-534156-01-1: IUC5-b0b2b680-602a-4de3-aa05-97494b69343f Bayer CropScience (Germany), Report No, M-534584-01-1: ba85727a-ea63-3d49-8146-270db1ccc1a4 WGIV-2017
	TFB-COOH: 1.71d	TFB-COOH: 3.23d	TFB-COOH: 0.215 d^{-1} f.f. 0.6190	TFB-COOH: Geomean (n=4, SFO) Arithmetic mean (n=4)	
	DCVA: 1x10^{6}d	DCVA: 1x10^{6}d	f.f. 1	Default	

Table 69

Summary table of identified relevant metabolites and transformation- or reaction products in soil				
Process	Metabolite/ transformation- or reaction product	[%] of active substance	Remarks	Reference
aerobic biodegradation	TFB-COOH	Max. 36.5% (2 DAT)	Decrease to 3.8% (7 DAT)	Bayer CropScience (Germany), Report No M-534156-01-1: IUC5-b0b2b680-602a-4de3-aa05-97494b69343f
	DCVA (not determined in the study due to label position)	see TFB-COOH	n.d.	

Biodegradation and dissipation in water

Transfluthrin is not readily biodegradable in laboratory tests. In aquatic environments transfluthrin will rapidly partition into the sediment reaching levels of max. 42-47% of AR on the first day after application. In two aerobic water/sediment systems (OECD 308), the degradation T50 was estimated to be 13.8 and 28.1 days when normalised to 12°C for use in risk assessment. Due to rapid sorption the dissipation T50 in sediment was 19.9 and 33.6 days whereas dissipation T50 from water was estimated to be < 13.3 days, all values after normalisation to 12°C.

Non-extractable residues after 100 days (20°C) reached 4.4 and 7.9% AR, mineralization after 100 days was 3 and 12.6% of AR respectively.

Two metabolites, NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH), were detected in amounts > 10 % of AR in the water phase, maximum levels were 38 and 59% of AR, respectively. The same metabolites were found in sediment with maximum levels of 2.9% of AR for TFB-OH and 26% of AR for TFB-COOH. As mentioned above, it can be assumed that DCVA was formed at same amounts as TFB-COOH but it was not detected due to label position.

The DT50 of metabolite TFB-OH was estimated to be < 26.6 days when normalized to 12°C, a reliable estimate of the DT50 of metabolite TFB-COOH could not be obtained.

Abiotic degradation

Transfluthrin is hydrolytically stable at 25 °C, pH 5 and 7. The $DT_{50,hydrolysis}$ at pH 9, 25 °C is 14 days. Reliable information on aqueous or soil photolysis are not available. However, this is not considered necessary for risk assessment according to the AR (2014) of transfluthrin.

Distribution in soil

According to the AR (2014) the sorption to soil could not be determined in a batch equilibrium experiment due to the low water solubility and high log K_{ow} of transfluthrin. A log K_{oc} of 4.7 was obtained at pH 6 using the HPLC-method according to OECD 121 and is used in the environmental risk assessment.

3.8.3.2 Substance of concern: BHT

Ready biodegradability

For BHT information is available from the REACH Dossier. BHT was degraded to 4.7% (radiochem. meas.) within 28 days of a modified MITI test (OECD 301C) and has to be considered therefore as not readily biodegradable. Further information on biodegradation in water, water/sediment or soil is not available.

Distribution in soil

Based on the estimated data using PCKOCWIN v 1.66, an adsorption coefficient of 23030 (K_{OC}) and 4.362 (log K_{OC}) is reported in the REACH Dossier. This value has been updated by RefMS with EPIWEB 4.1. K_{OC} values of 14750 (MCI method) und 8183 (K_{OW} method) have been determined, leading to a mean K_{OC} of 11467 and a log K_{OC} of 4.06. This value has been used for environmental risk assessment of BHT.

Bioconcentration

As described in the CAR for the active substance transfluthrin, bioconcentration factors (BCF) were available for fish (*Lepomis macrochirus*, BCF = 1783 L/kg, average normalised to 5% lipid content) and earthworm (estimated as 10452 L/kg from log K_{OW}).

For BHT experimentally derived BCF values are reported in the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975). The following information is given there:

“A bioconcentration study with *Cyprinus carpio* was conducted by MITI in 1992 to measure a bioconcentration factor (BCF) of 2,6 -di-tert-butyl-p-cresol (BHT) in the aquatic environment. This test was performed in accordance with "Bioaccumulation test of chemical substance in fish and shellfish" stipulated in the Japanese Order Prescribing the Items of the Test relating to the new chemical substance (1974). This guideline corresponds to OECD guideline 305C. The test water was analysed twice a week, the total exposure time was 56 days. Three concentration levels were tested (5, 50 and 500 µg/L, nominal). In the highest test concentration, the exposure was terminated after 6 weeks of exposure as the fish showed curved backbones due to toxic effects of the compound in this high concentration. After 8 weeks the BCFs in the three replicates of the remaining levels were 760 – 1500 (5 µg/L) with an average of 1120 and 230 – 2500 (50 µg/L) with an average of 1277.”

For the further assessment, the BCF of 1277 L/kg is used.

3.8.4 Exposure assessment

3.8.4.1 General information

The environmental exposure is assessed applying the Guidance on the BPR (2017) and the OECD Emission Scenario Document (ESD) for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses (No. 18, 2008) amended by the Technical Agreements for Biocides (TAB, European Chemicals Agency – ECHA, 2017) where relevant.

Releases into the environment can take place from processes at any stage of the life cycle of a substance. In accordance with regulation (EU) No 528/2012 of the European parliament and with the Guidance on the BPR: Volume IV part B+C (Version 2.0 October 2017), in the further course of the

report designated as `Guidance on the BPR (2017) `, the potential for environmental exposure is considered for the following stages of the product life cycle for ENDURLED TFT.

Production stage

In accordance with the risk assessment framework presented in the Guidance on the BPR (2017) it is not necessary to specifically quantify the potential for environmental exposure associated with this stage of the product life cycle.

Formulation stage

According to the Guidance on BPR (2017) those emissions are considered as negligible compared to the emissions which arise from the use step.

Private/non-professional use

ENDURLED TFT is an insecticide formulation for use in a refillable plug-in electrical vaporizer to control adult house mosquitoes (*Culex quinquefasciatus*) and Asian Tiger mosquitoes (*Aedes albopictus*). The product is intended to be used by non-professional users indoors in domestic places. 28.9 g of the liquid insecticide formulation is inserted into a suitable heater. The refill formulation contains 0.719% (w/w) transfluthrin, as manufactured, typically equivalent to 0.708 % w/w (pure, 1R-trans isomer). For calculation purposes, the value of 0.71% is assumed. Beside transfluthrin, BHT is contained at 1.0% (w/w). The b.p. is then activated by plugging the dispenser into an electrical socket in any room of an accommodation unit. The active substance is vaporized and knocks down and kills the target organisms. The product shall be used for up to 10 hours per day. A brief summary of the intended use is given in Table 71.

Table 70

Summary of the intended use	
Product Type(s)	18
Where relevant, an exact description of the authorised use	Liquid vaporizer
Target organism (including development stage)	House mosquitoes, *Culex quinquefasciatus* (adults) Asian tiger mosquitoes, *Aedes albopictus* (adults)
Field of use	Indoor
Application method(s)	Diffuser (electric vaporizer)
Application rate(s) and frequency	The b.p. can be used up to 10h per day. Based on a claimed maximum duration of use of 45 days, a release rate of 0.456 mg transfluthrin per hour can be assumed.
Category(ies) of user(s)	General public

Service life

ENDURLED TFT is intended to be applied as a target insecticide with no envisaged residual activity. Therefore, a specific service life of the product is not considered.

Waste disposal

According to Guidance on the BPR (2017), it is not foreseen to quantify the potential for environmental exposure associated with this stage of the product life cycle.

Table 71 gives an overview of the overall approach of the environmental exposure assessment for ENDURLED TFT.

Table 71

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Control of mosquitoes in private houses by non-professionals
ESD(s) used	ESD for insecticides, acaricides and products to control other arthropods for household and professional uses. OECD Environment, Health and Safety Publications. Series on Emission Scenario. No. 18, July 2008.
Approach	Scenario 1: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C). Version 2.0. October 2017. Technical Agreements for Biocides Environment (ENV) Version 2.0, August 2018
Groundwater simulation	No. As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken.
Confidential Annexes	No tonnage based scenarios provided.
Life cycle steps assessed	Scenario 1 Production/Formulation/Service life: No. Use: Yes
Remarks	From the ESD the emission models for indoor treatments for diffusers were applied.

3.8.4.2 Fate and distribution in exposed environmental compartments

ENDURLED TFT consists of a liquid insecticide formulation in a bottle designed to fit a suitable heater unit. The refill bottle is inserted into the suitable heater, which is plugged into a power socket.

Estimation of emissions following the indoor use of a diffuser is calculated by determining the amount of active substance (and SoC) that reaches the floor per day and subsequently the sewage treatment plant (STP) via wet cleaning events. Then, the active substance (and the SoC) may be released to the surface water via effluent from the STP and consecutively aquatic sediments may be exposed. Soil can be exposed indirectly from application of residue-containing sewage sludge or directly from deposition of a.s. or the SoC after venting the treated room. Groundwater might be exposed through leaching events from soil. Furthermore, a release to the outdoor air compartment after venting of the treated rooms is possible, but emissions are not considered to be of relevance because of instant dilution as stated in the Emission Scenario Document No. 18 (OECD, 2008) and confirmed in the Assessment Report on Transfluthrin (CA The Netherlands, March 2014).

Table 72

Identification of relevant receiving compartments based on the exposure pathway[6]					
	Freshwater	**Freshwater sediment**	**STP**	**Soil**	**Groundwater**
Scenario 1: Control of mosquitoes in private houses by non-professionals	Yes, via STP	Yes, via STP	Yes	Yes, via STP	Yes, via STP

Three relevant metabolites of transfluthrin have been identified in degradation studies. DCVA, TFB-OH, and TFB-COOH were detected in the water/sediment simulation study, whereas TFB-COOH and DCVA were found in the soil degradation study, too. In the following, TFB-COOH but not TFB-OH is taken into account in the risk assessment, as TFB-COOH has been detected as a relevant metabolite in all compartments and results from the oxidation of TFB-OH. Thus TFB-OH is an intermediate metabolite and covered by the assessment of TFB-COOH.

All relevant input parameters of both active substances and its metabolites used for calculating the fate and distribution in the environment are summarised in Table 73. Short descriptions of the relevant studies as well as further fate and behaviour results are given in section 3.8.3.

Table 73

Input parameters for calculation of the fate and distribution in the environment						
Input	**Value**				**Unit**	**Remarks**
	Transfluthrin	**TFB-COOH**	**DCVA**	**BHT**		
Molecular weight	371.2	194.1	209.1	220.4	g/mol	
Melting point	32	-	-	-	°C	

Boiling point	242	-	-	-	°C	
Vapour pressure (at 12°C)	5.06E-04	*1.73E-01	0.103	*9.4E-02	Pa	
Water solubility (at 12°C)	0.051	*5.07E-03	105.9	*8.61	mg/L	
Log Octanol/water partition coefficient	5.94	*1.58	3.38	*5.1	Log 10	
Organic carbon/water partition coefficient (log Koc)	4.7	*1.81	1.92	*4.06	L/kg	
Henry's Law Constant (at 12°C)	*3.68	*6.62E-03	0.203	*2.41	$Pa/m^3/mol$	
Biodegradability	Not readily biodegradable	-	-	Not readily biodegra-dable		
DT_{50} for biodegradation in STP (20°C)	0.59	1×10^6	12.9		d	Degradation rate of transfluthrin is used in SimpleTreat Method 2 according to TAB ENV 213 (February 2021)
DT_{50} for biodegradation in surface water (at 12ºC)	<13.3	-	-	-	d	Not considered in exposure assessment
DT_{50} for hydrolysis in surface water (at 12ºC /pH)	>1000	-	-	-	d	Hydrolytically stable; Not considered in exposure assessment
DT_{50} for degradation in soil (at 12ºC)	5.17	3.23	174.80	1.0E+06 (default)	d	
Formation fraction		0.619	1			

*calculated via EPIWEB 4.1

3.8.4.3 Emission estimation

Scenario 1 - Control of mosquitoes in private houses by non-professionals

According to the instructions for use, the device is used over a period of 45 days with a daily operating time of 10 hours. In line with ENV 148, TAB v. 2.1 (2019) two diffusers per house are considered in the emission estimation. As ENDURLED TFT is a ready-to-use product, emissions during mixing/loading do not need to be taken into account.

Emission to air and floor during application

Emissions to air and to floor during application are calculated based on formula (31) and (32) of the ESD PT18 (OECD, 2008).

Per default it is assumed that 90% of the product is released to air and 10% to the floor.

The input values for determining releases to the environment in the course of indoor use of a diffuser as well as the calculated emission rates are summarised in **Table 74**.

Table 74

Local emissions to air and floor			
Input	**Value**	**Unit**	**Remarks**
Quantity of commercial product contained in the device/diffuser, Q_{prod}	28.9	g	(S)
Maximal duration of use of the device/diffuser (autonomy), T_{Max}	450	h	(S) 45 days, max. 10h per day
Duration of use per day, T_{Day}	10	h/d	(D)
Fraction emitted to air, $F_{application,\ air}$	0.9	-	(D)
Fraction emitted to floor, $F_{application,\ floor}$	0.1	-	(D)
Number of rooms (per house), N_{appl}	2	1/house	ENV 148 (TAB v. 2.1)
Transfluthrin			
Fraction of transfluthrin in the commercial product, F_{AI}	0.0071	-	(S)
BHT			
Fraction of BHT in the commercial product, F_{AI}	0.01	-	(S)
Output			
Transfluthrin			
Local emission to air, $E_{application,\ air} = Q_{prod}\ x\ F_{AI}\ x\ \frac{T_{Day}}{T_{MAX}}\ x\ F_{application,air} \times N_{appl}$	8.21E-03	g x d^{-1}	(O)

Local emission to floor, $E_{application,\ floor} = Q_{prod}\ x\ F_{AI}\ x\ \frac{T_{Day}}{T_{MAX}}\ x\ F_{application,floor} \times N_{appl}$	9.12E-04	g x d^{-1}	(O)
BHT			
Local emission to air, $E_{application,\ air} = Q_{prod}\ x\ F_{AI}\ x\ \frac{T_{Day}}{T_{MAX}}\ x\ F_{application,air} \times N_{appl}$	1.16E-02	g x d^{-1}	(O)
Local emission to floor, $E_{application,\ floor} = Q_{prod}\ x\ F_{AI}\ x\ \frac{T_{Day}}{T_{MAX}}\ x\ F_{application,floor} \times N_{appl}$	1.28E-03	g x d^{-1}	(O)

Release estimation of the b.p. during cleaning step

ESD PT 18 (OECD, 2008) considers both, dry and wet cleaning methods, resulting in releases either to solid wastes or to waste water. In Table 75, only the calculations for local emissions caused by wet cleaning are presented, as it is the only relevant pathway that leads to emissions into the sewer system. According to TAB. Vers. 2.1, 2019, ENV 148 only about 30% of the surface area in a house is considered to be wet cleaned. Thus, a F_{clean} of 0.296 (i.e. 38.5 m² from general 130 m²) was taken up in equation (36) of ESD PT18 (OECD, 2008). The default value of 1 is used as the fraction emitted to wastewater during the cleaning step, assuming 100% cleaning efficiency according to Table 3.3.-8 in the ESD.

Table 75

Local emissions to wastewater, STP			
Input	**Value**	**Unit**	**Remarks**
Fraction emitted to waste water during the cleaning step, F_{ww}	1	-	(D)
Cleaning efficiency, F_{CE}	1	-	Table 3.3.-8, ESD PT18
Fraction of treated area subjected to cleaning, F_{clean}	0.296	-	ENV 148, TAB v. 2.1
Transfluthrin			
Emission to floor during application, $E_{application,\ floor}$	9.12E-04	g x d^{-1}	(O)
BHT			
Emission to floor during application, $E_{application,\ floor}$	1.28E-03	g x d^{-1}	(O)
Output			
Transfluthrin			
Emission to wastewater, treated surface, $E_{treated.ww} = E_{application.floor} \times F_{ww} \times F_{CE}\ F_{clean}$	2.7E-04	g x d^{-1}	(O)

Local emissions to wastewater, STP			
BHT			
Emission to wastewater, treated surface, $E_{treated.ww} = E_{application.floor} \times F_{ww} \times F_{CE}\, F_{clean}$	3.8E-04	g x d^{-1}	(O)

The distribution of transfluthrin and the SoC (BHT) in the sewage treatment plant is calculated using SimpleTreat 4.0. According to the CAR (2013) of transfluthrin, the a.s. is not biodegradable and for that reason the degradation rate constant in sewage treatment plant was originally set to k_{STP}= 0 h^{-1} (Guidance on the BPR (2017), chapter 2.3.6.4, table 4). However, the manufacturer of the a.s. provided two studies commissioned by BAYER AG Crop Science (OECD 314B), to refine the assessment. A deviating distribution in the STP for the a.s. is justified in these studies. The STP modelling results well as calculation of the PECs are presented in the confidential annex for Member States only to this PAR.

In absence for substance specific information, no biodegradation of BHT in the STP has been assumed. The calculated distribution in the STP is summarised in Table 87.

3.8.4.4 Aquatic compartment (including STP and sediment)

Release estimation to sewage treatment plant

The input values for determining releases to STP and the calculated emission rates are summarised in Table 76. According to ESD PT18 (OECD, 2008) 4000 public buildings are connected to one STP. Furthermore, a simultaneity factor (F_{sim}) was implemented which represents the simultaneity of treatments by the houses connected to the STP. For indoor applications, the ESD PT18 (OECD, 2008) presumes per default a daily application of the biocidal products, leading to a simultaneity factor of 5.5% (F_{sim} = 0.055). As the b.p. is intended to be used daily for a period of 10 h per day during the whole year, the default F_{sim} is considered appropriate and was not further refined.

Table 76

Local emissions to wastewater, STP			
Input	**Value**	**Unit**	**Remarks**
Number of private houses connected to STP, N_{houses}	4000	-	(D)
Simultaneity factor indoor, F_{sim}	0.055	-	(D)
Transfluthrin			
Emission to wastewater, treated surface, $E_{treated,ww}$	2.7E-04	g x d^{-1}	(O)
BHT			
Emission to wastewater, treated surface, $E_{treated,ww}$	3.8E-04	g x d^{-1}	(O)

Local emissions to wastewater, STP			
Output			
Transfluthrin			
Local emission to wastewater, STP $\boldsymbol{Elocal_{water}} = E_{treated,ww} \times N_{houses} \times F_{sim}$	5.94E-02	g x d^{-1}	(O)
Local emission to wastewater, STP $\boldsymbol{Elocal_{water}} = E_{treated,ww} \times N_{houses} \times F_{sim}$	5.94E-05	kg x d^{-1}	(O)
BHT			
Local emission to wastewater, STP $\boldsymbol{Elocal_{water}} = E_{treated,ww} \times N_{houses} \times F_{sim}$	8.36E-02	g x d^{-1}	(O)
Local emission to wastewater, STP $\boldsymbol{Elocal_{water}} = E_{treated,ww} \times N_{houses} \times F_{sim}$	8.36E-05	kg x d^{-1}	(O)

Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment)

According to the intended use of ENDURLED TFT, indirect emission to surface water and sediment via output of the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment were estimated according Guidance for BPR: Volume IV, Parts B+C, Vers. 2.0, 2017.

- **PEC_{STP}** (=$Clocal_{eff}$) and $Clocal_{inf}$ according to equation 35, 36 and 41, chapter 2.3.6.7 Guidance on the BPR (2017)

  $$Clocal_{inf} = \frac{Elocal_{water}}{EFFLUENT_{stp}}$$

  $$Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$$

  $$PEC_{stp} = Clocal_{eff}$$

- **$PEC_{local,water}$** according to equation 48 and 51, chapter 2.3.7.3.1, Guidance on the BPR (2017)

  $$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \times SUSP_{water}) \times DILUTION}$$

  $$PEClocal_{water} = Clocal_{water}$$

- **$PEC_{local,sed}$** according to equation 53, chapter 2.3.7.4, Guidance on the BPR (2017)

  $$PEClocal_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \times PEClocal_{water}$$

- **C_{sludge}** according to equation 39, chapter 2.3.6.7, Guidance on the BPR (2017)

$$C_{sludge} = \frac{Fstp_{sludge} \times Elocal_{water}}{SLUDGERATE}$$

All relevant input parameters are summarized in Table 77 and the corresponding results are displayed in Table 88.

Table 77

Input parameters for calculation of concentrations and PECs in aquatic compartment			
Input	**Value**	**Unit**	
EFFLUENTstp	2000	$m^3\ d^{-1}$	(D)
$Kp_{susp,transfluthrin}$	5.012E+03	$L\ kg^{-1}$	(S)
$K_{susp\text{-}water,transfluthrin}$	1.254E+03	-	(S)
$Kp_{susp,BHT}$	1.148E+03	$L\ kg^{-1}$	(S)
$K_{susp\text{-}water,BHT}$	287.938	-	(S)
$SUSP_{water}$	15	$mg\ L^{-1}$	(D)
DILUTION	10	-	(D)
RHO_{susp}	1150	$kg\ m^{-3}$	(D)
SLUDGERATE	790	$kg\ d^{-1}$	(D)

Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment) – Metabolites

Three relevant metabolites have been identified in water/sediment studies: TFB-OH, DCVA and TFB-COOH. In the risk assessment, TFB-COOH but not TFB-OH is taken into account, as TFB-COOH results from the oxidation of TFB-OH. Thus TFB-OH is an intermediate metabolite and is covered by the assessment of TFB-COOH. For the metabolites, a quantitative exposure and risk assessment has been conducted according to the decisions of AHEE 3 & 4 in 2019, which are also specified in TAB ENV 213 (February 2021) by using the results (DT_{50} and formation fraction) derived from the OECD 314B studies (see confidential Annex for Member States only for details). For the aquatic compartments, degradation is not taken into account. Hence, as a first tier approach for the aquatic environment, the environmental exposure is assessed by considering the maximum occurrence of each metabolite in the water/sediment studies and the molar mass ratio of metabolite and parent. Input parameters for the metabolites are summarised in Table 73. The results are summarised in Table 89 in the confidential annex for Member States only.

3.8.4.5 Terrestrial compartment (including groundwater)

Estimation of Predicted Environmental Concentrations for soil and groundwater – transfluthrin and BHT

The application of sludge from the STP onto agricultural and grassland soil leads to an indirect emission to soil. The leaching of transfluthrin and BHT through soil following sludge application causes indirect emission to groundwater.

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 69, chapter 2.3.7.5, Guidance on the BPR, Vol. IV, Part B+C (2017);
- $PEC_{local\_groundwater}$ according to equation 71, chapter 2.3.7.6, Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation.

All relevant input data for the calculations can be found in Table 73.The results for transfluthrin and BHT are summarized in Table 90 in the confidential annex for Member States only.

Estimation of Predicted Environmental Concentrations for soil and groundwater – Metabolites

The quantitative risk assessment of the relevant metabolites in soil and groundwater, which are indirectly exposed via sewage sludge application, was performed in line with the agreements laid down under ENV 10 in the TAB (v.2.1, 2019).

A degradation half-life and formation fraction, is available for TFB-COOH (Table 73). For the second primary metabolite DCVA a half-life of 174.8 days at 12°C and a formation fraction of 1 was considered according to the harmonized LoEP (latest version May 2020). In absence of substance specific data, solubility, organic carbon-water partitioning coefficient (K_{OC}) and vapour pressure were estimated by QSAR (EPISUITE – EPIWEB 4.1) and used to derive $K_{air\text{-}water}$ and $K_{soil\text{-}water}$ according to equation 24-27, chapter 2.3.5.2 and 2.3.5.3, Guidance on the BPR (2017). The estimation of the local PECs for the terrestrial compartment is then performed according to the above mentioned equations.

The resulting PECs in soil and groundwater for TFB-COOH and DCVA are shown in Table 91 in the confidential annex for Member States only.

3.8.4.6 Atmosphere

A release to the outdoor air compartment after venting of the treated rooms is possible, but emissions are considered as not relevant because of instant dilution as stated in the Emission Scenario Document PT 18 (OECD, 2008).

3.8.4.7 Non-compartment specific effects

- **Primary poisoning**

Primary poisoning is excluded due to the indoor use of the b.p. ENDURLED TFT.

- **Secondary poisoning**

The assessment of the potential impact of substances on top predators (secondary poisoning) is based on Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017. Possible effects are estimated on birds and mammals in the environment via uptake through the aquatic food-chain water → aquatic organisms → fish → fish-eating mammal or fish-eating bird and the terrestrial food-chain soil → earthworm → worm-eating birds or mammals. The scenario for secondary poisoning foresees that 50% of the diet comes from a local area and 50% of the diet comes from a regional area. Therefore, $PECloca l_{water}$, $PECloca l_{soil}$ and $PEC_{groundwater}$ values are reduced to 50% for the assessment of PEC_{biota}.

Default values for biomagnification in fish (BMF) were taken from table 23, Guidance on BPR (2017). The experimental BCF_{fish} for transfluthrin is estimated to be < 2000 L kg^{-1}, leading to a BMF of 1. For BHT, a BMF of 10 has been derived considering a log K_{OW} of 5.1. The concentration of transfluthrin in earthworms is calculated according to equation 100 of the Guidance on the BPR (2017). Using the estimated log K_{OW}-value of 5.94, the $BCF_{earthworm}$ is estimated to be 10452 L.kg^{-1}. The corresponding $PEC_{oral,worm}$ was estimated using the estimated concentration of transfluthrin in groundwater and soil due to the application of ENDURLED TFT.
For BHT, a $BCF_{earthworm}$ of 1903 L kg^{-1} is estimated based on a log K_{OW} of 5.1. The $PEC_{oral,worm}$ was derived following the same approach as for transfluthrin.

The resulting $PEC_{oral,fish}$ and $PEC_{oral,worm}$ are presented in Table 92 in the confidential annex for Member States only.

3.8.4.8 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

3.8.5 Risk characterisation

In the risk assessment of the b.p., the a.s., its relevant major metabolites DCVA and TFB-COOH and the identified substance of concern BHT are taken into account. TFB-OH is only an intermediate metabolite and covered by the assessment of the a.s. and TFB-COOH.

3.8.5.1 Aquatic compartment (sediment and STP)

Only the PEC/PNEC ratios are presented here, as the PECs are based on the confidential OECD 314B study. Although the PECs for the SoC BHT are not confidential, for better readability all PECs are presented in the confidential annex for Member States only.

Table 78

	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
transfluthrin	1.1 x 10^{-4}	3.37 x 10^{-2}	1.8 x10^{-1}
TFB-COOH	9.96 x 10^{-4}	5.68 x 10^{-6}	n.a.
DCVA	1.07 x 10^{-3}	0.09	n.a.
BHT	1.13 x 10^{-4}	3.1 x 10^{-4}	3.2 x 10^{-3}

For none of the metabolites a PNEC$_{sed}$ is available. As shown for surface water, it can be assumed that the metabolites are less toxic than the parent compound also for sediment organisms.
Thus, the risk characterisation for the active substance covers also the metabolites.

Conclusion

For the intended indoor use of the b.p. ENDURLED TFT no unacceptable risks were identified for the aquatic compartment, including STP and sediment.,

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

For transfluthrin the PEC$_{soil}$ was calculated without degradation according to the procedure for rapidly degrading substances. According to the new soil biodegradation study, the half-life of transfluthrin in soil is >2 days, which would usually require calculation of the PNEC value as time weighted average (TWA approach, see guidance on the BPR vol. IV part B+C (2017) section 3.10.2).
However, PNEC$_{soil}$ was agreed as initial value at the BPC ENV WG meeting IV-2017, before harmonisation of the soil DT$_{50}$ was undertaken during an ad-hoc follow up. In addition, the half-life at 20°C is only slightly above the trigger value of 2 days. Therefore, the PNEC$_{soil}$ based on nominal

concentrations is compared with the $PEC_{initial}$. $PNEC_{soil}$ transfluthrin was determined as 9×10^{-2} mg/kg ww from the nominal NOEC.

For **TFB-COOH**, the PEC_{soil} is 6.64 x 10^{-6} mg/kg ww and for **DCVA** 6.89 x 10^{-5} mg/kg ww .

PEC_{soil} for **BHT** is 8.76×10^{-4} mg/kg ww and $PNEC_{soil}$ was derived as 5.4 x 10^{-2} mg/kg ww .

For the major metabolites DCVA and TFB-COOH $PNEC_{soil}$ values of 0.0128 mg/kg ww and 0.012 mg/kg ww were derived based on QSAR.

According to the risk quotient indicated in Table 79, no unacceptable risks are expected for the soil compartment from active substance transfluthrin (covering its metabolites) and the SoC.

Table 79

Calculated PEC/PNEC values[7]	
	$PEC/PNEC_{soil}$
transfluthrin	1.83 x 10^{-4}
TFB-COOH	5.53 x 10^{-4}
DCVA	5.38 x 10^{-3}
BHT	1.6 x 10^{-2}

- **Groundwater**

For the a.s. **transfluthrin** a PEC of 3.24 x 10^{-6} µg/L was calculated for leaching into groundwater with degradation processes.
A PEC for groundwater was also calculated for the major metabolites **TFB-COOH** with 8.98 × 10^{-4} µg/L and **DCVA** with 3.13 × 10^{-2} µg/L.
For the SoC **BHT** a PEC of 4.32 x 10^{-3} µg/L was calculated.
The trigger value for groundwater concentration is 0.1 µ/L each for active substance, all metabolites and SoCs.
The PECs for groundwater for the active substance with degradation, the major metabolites TFB-COOH, DCVA and the SoC BHT without degradation are below the trigger value of 0.1 µg/L. Thus, for groundwater no unacceptable risk was identified, for both the active substance and its major metabolites TFB-COOH, DCVA as well as the SoC BHT.

Conclusion

No unacceptable risks were identified for the intended indoor use of the b.p. ENDURLED TFT for the terrestrial compartment, including groundwater.

3.8.5.3 Atmosphere

Transfluthrin

Transfluthrin has a DT_{50} in air of 2.4 days. This implies a potential concern for long-range transport (LRT) in the atmosphere. However, LRT is expected to be rather limited as already justified in the Assessment Report on transfluthrin (CA The Netherlands, March 2014). Additionally the atmospheric ozone depletion potential of transfluthrin has been characterized as negligible.

BHT

According to data of the U.S. Department of commerce, National Institute of Standards and Technology (NIST)[8], BHT shows some absorption peaks in the infrared range, mainly located between 7 and 9 µm wavelength, matching the atmospheric window. BHT can thus be considered as potential greenhouse gas. A DT_{50} in air of 7 d was found for BHT in a OECD SIDS report (2002)[9], indicating potential for transportation to the stratosphere, but it does not contain Br, Cl or F substituents. For this reason and because its atmospheric lifetime is less than one year, ozone depletion potential of BHT is considered negligible.

Despite these findings, risk to the atmosphere is considered to be acceptable. A release to the outdoor air compartment after venting of the treated rooms is possible, but emissions are considered as not relevant because of instant dilution as stated in the Emission Scenario Document PT 18 (OECD, 2008)

8 http://webbook.nist.gov/cgi/cbook.cgi?ID=C128370&Type=IR-SPEC&Index=2#IR-SPEC

9 https://hpvchemicals.oecd.org/ui/handler.axd?id=6D30349E-EF9F-496C-A2AF-6D497D4F1CCA

Conclusion

No unacceptable risks were identified for the intended indoor use of the b.p. ENDURLED TFT for the atmosphere.

3.8.5.4 Non-compartment specific

- **Primary poisoning**

Primary poisoning due to the indoor use of the b.p. ENDURLED TFT is assumed to be negligible, as exposure is not probable.

- **Secondary poisoning**

Active substance transfluthrin

The $PNEC_{oral,mammal}$ is 6.67 mg/kg food. For birds no $PNEC_{oral}$ could be derived. The results of the assessment for secondary poisoning are summarized in Table 80.

Table 80

Scenario	**$PEC_{oral\ predator}$**	**PEC/ $PNEC_{birds}$**	**PEC/ $PNEC_{mammals}$**
Fish	5.26×10^{-5} mg kg^{-1}	n.a.	7.85×10^{-6}
Worm	1.06×10^{-5} mg kg^{-1}	n.a.	1.58×10^{-6}

Substance of concern BHT

For BHT a $PNEC_{oral,mammal}$ of 16.67 mg/kg food was given in the REACH-Dossier (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15975).

The results of the assessment for secondary poisoning are summarized in **Table 81**.

Table 81

Scenario	**$PEC_{oral\ predator}$**	**PEC/ $PNEC_{birds}$**	**PEC/ $PNEC_{mammals}$**
Fish	1.48×10^{-2} mg kg^{-1}	**n.a.**	$.8.87 \times 10^{-4}$
Worm	2.98×10^{-3} mg kg^{-1}	**n.a.**	1.79×10^{-4}

Conclusion:

As PEC/PNEC is < 1 for the a.s. transfluthrin and the SoC BHT for both scenarios, the risk for secondary poisoning from the intended indoor use of the b.p. ENDURLED TFT is acceptable.

3.8.5.5 PBT assessment

PBT assessment was carried out during active substance evaluation. For detailed information please refer to the assessment report for transfluthrin (eCA NL, March 2014).

Conclusion

According to the assessment report for the a.s. transfluthrin and for the major metabolite TFB-COOH and DCVA two of the PBT criteria are not fulfilled.

The metabolite TFB-OH does not meet any of the PBT criteria. Thus the a.s. and its major metabolites are not considered as PBT substances.

3.8.5.6 Endocrine disrupting properties

According to the CAR for transfluthrin, there are some indications for potential endocrine disrupting properties of metabolites of the active substance on environmental non-target organisms. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the product as well as the ED-assesment for the co-formulants is summarised in the sections 5.1 and 5.2 of the confidential annex.

3.8.5.7 Summary of risk characterisation

As indicated in Table 82, for all environmental compartments which were assessed in this report, no unacceptable risks were identified for the intended use of b.p. ENDURLED TFT.

Table 82

Summary table on calculated PEC/PNEC values						
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**	**PEC/ $PNEC_{mammals}$ fish**	**PEC/ $PNEC_{mammals}$ worm**
transfluthrin	1.10×10^{-4}	3.37×10^{-2}	1.8×10^{-1}	1.83×10^{-4}	7.85×10^{-6}	1.58×10^{-6}
TFB-COOH	9.96×10^{-4}	5.68×10^{-6}	n.a.	n.a.	n.a.	n.a.
DCVA	1.07×10^{-3}	n.a.	n.a.	n.a	n.a.	n.a.
BHT	1.13×10^{-4}	3.1×10^{-4}	3.2×10^{-3}	1.6×10^{-2}	8.87×10^{-4}	1.79×10^{-4}

3.8.5.8 Mixture toxicity assessment

Tiered approach

According to the available data for the relevant substances identified in section 2.2.4, tier 1 of the mixture toxicity assessment has to be followed.

- **Tier 1 PEC/PNEC summation**

In Table 83 the results of PEC/PNEC summation of the a.s. transfluthrin and the SoC BHT are given for all assessed environmental compartments.

Table 83

Compartment	Sum of PEC/PNECs
Surface water	3.4×10^{-2}
Sediment	1.83×10^{-1}
STP	2.23×10^{-4}
Soil	1.61×10^{-2}
Groundwater	4.32×10^{-3}
Secondary poisoning Mammal aquatic Mammal terrestric	 8.95×10^{-4} 1.81×10^{-4}

According to tier 1 of mixture toxicity assessment, no unacceptable risks for the environment from the b.p. ENDURLED TFT are identified.

Conclusion of mixture toxicity

As indicated in Table 83, no unacceptable risks were identified for the environmental compartments.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Table 84

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Testing facility / study reference	Author	Year	Owner company
1	3.1 Appearance (at 20 °C and 101,3 kPa) 3.2 Acidity/ alkalinity 3.3 Relative density / bulk density 3.4.1 Storage stability tests 3.8 Surface tension	Determination of physical-chemical properties and storage stability tests for Transfluthrin-based LED ”LGECT05”: 2 weeks at 54 °C and 36 months at 20 °C. Study No Mo5978	BioGenius GmbH (Germany), Study No Mo5978	[redacted]	2021	Endura S.p.A.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Testing facility / study reference	Author	Year	Owner company
	3.9 Viscosity					
2	3.4.1 Storage stability tests	Low temperature stability of ENDURLED TFT Report No 1127	Endura S.p.A. (Italy), Report No 1127	[redacted]	2018	Endura S.p.A.
3	3.5 Technical characteristics of the biocidal product and 6.7 Efficacy data to support these claims (efficacy data)	Efficacy of a Liquid Emanator Device (LED) against House mosquitoes, Culex quinquefasciatus, and Asian tiger mosquitoes, Aedes albopictus. Annex to report BIO148a-17 (study Mo5950) Evaporation rate ot the LED refills of study Mo5950 Study No Mo5950 Report No BIO148a-17	BioGenius GmbH (Germany), Report No BIO148a-17	[redacted]	2017, 2020 (annex)	Endura S.p.A.
4	3.5 Technical characteristics of the biocidal product	Evaporation rate test of aged LED refills after 24 and 36 months of storage at 20 °C Study No Mo5950 Report No BIO081-21a	BioGenius GmbH (Germany), Report No BIO081-21a	[redacted]	2021	Endura S.p.A.
5	3.5 Technical characteristics of	Measurement of the plastic stopper and neck of the bottle temperature during use of the liquid emanator device ENDURLED TFT (LEGCT05)	Endura S.p.A. (Italy),	[redacted]	2023	Endura S.p.A.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Testing facility / study reference	Author	Year	Owner company
	the biocidal product	Report No 1309	Report No 1309			
6	3.8 Surface tension	CERTIFICATE OF ANALYSIS - Surface tension according to EC 440/2008 test A.5. Report No AAG40328 Study No STULV20AA0465-1	Eurofins Biolab Srl (Italy), Report No AAG40328		2020	Endura S.p.A.
7	4.1 Explosiveness	ENDURLED TFT - 21.539213.0001 UN Gap Test. Report No J4028007980R2/2021	DEKRA (UK), Report No J4028007980R2/2021	[redacted]	2021	Endura S.p.A.
8	4.1 Explosiveness	LGECT05 - ENDURLED TFT, Batch No.: E23/21, EXPLOSIVE PROPERTIES (UN MANUAL OF TESTS AND CRITERIA, KOENEN TEST 1(b)/2(b), TIME / PRESSURE TEST 1(c)/2(c)). Report No PS20210081-2	Siemens AG Prozess-Sicherheit (Germany), Report No PS20210081-2	[redacted]	2021	Endura S.p.A.
9	4.8 Self-reactive substances and mixtures	LGECT05 - ENDURLED TFT, Batch No.: E22/21, SCREENING EXPLOSIVE AND SELF-REACTIVE PROPERTIES (UN MANUAL OF TESTS AND CRITERIA, APPENDIX 6). Report No PS20210081-1	Siemens AG Prozess-Sicherheit (Germany), Report No	[redacted]	2021	Endura S.p.A.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Testing facility / study reference	Author	Year	Owner company
			PS20210081-1			
10	4.16 Corrosive to metals	Determination of the Metal Corrosive Properties and Flash Point for ENDURLED TFT. Study No Mo7065	BioGenius GmbH (Germany), Study No Mo7065	[redacted]	2021	Endura S.p.A.
11	4.17.1 Auto-ignition temperature (liquids and gases)	Auto-ignition temperature (liquids and gases) A.15. Report No PS20180095-1	Siemens AG Prozess-Sicherheit (Germany), Report No PS20180095-1	[redacted]	2018	Endura S.p.A.
12	4.17.1 Auto-ignition temperature (liquids and gases)	Measurement of the wick's temperature during use of the liquid emanator device ENDURLED TFT (LGECT05). Report No 1211	Endura S.p.A. (Italy), Report No 1211	[redacted]	2021	Endura S.p.A.
13	5 Methods of detection and identification (analytical methods)	MV179 EDA: HPLC - Determination of Transfluthrin in liquid formulation (LED) LGECT05 Study No MV179	Endura S.p.A. (Italy), Study No MV179	[redacted]	2018	Endura S.p.A.
14	5 Methods of detection	Validation of Method MV179: EDA: HPLC - Determination of Transfluthrin in liquid formulation	BioGenius GmbH	[redacted]	2018	Endura S.p.A.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Testing facility / study reference	Author	Year	Owner company
	and identification (analytical methods)	(LED) LGECT05 Study No Mo5977	(Germany), Study No Mo5977			
15	5 Methods of detection and identification (methods for the determination of residues)	Determination of 2,6-di-tert-butyl-hydroxytoluene and its transformation products in indoor dust and sediment by gas chromatography-mass spectrometry coupled with precolumn derivatization. doi 10.1016/j.scitotenv.2017.11.115	doi 10.1016/j.scitotenv.2017.11.115	[redacted]	2018	
16	5 Methods of detection and identification (methods for the determination of residues)	Analysis of the antioxidant butylated hydroxytoluene (BHT) in water by means of solid phase extraction combined with GC/MS. doi 10.1016/S0043-1354(01)00453-5	doi 10.1016/S0043-1354(01)00453-5	[redacted]	2002	

4.2 List of studies for the active substance(s)

4.2.1 Transfluthrin

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

- Addtionally, the applicant has access to new information on the active substance, which was not assessed during the active substance approval (see chapter 4.2.1.2 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval of the active substance transflutrhin for use in insecticides, acaricides and products to control other arthropods (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

4.2.1.2 New information on the active substance

Table 85

No	Data set according to Annex II Regulation (EU) No 528/2012	Title	Study reference / Testing facility	Author(s)	Year	Owner company
1	9.1.6.1 Long term toxicity testing on Fish	Early Life Stage Toxicity of Transfluthrin Technical to the Fathead minnow (Pimephales promelas) Under Flow-Through Conditions. Bayer CropScience Report No: M-522816-01-1	[redacted] Report No M-522816-01-1	[redacted]	2015	Bayer CropScíence
2	9.1.6.2 Long term toxicity testing on Invertebrates	Chronic Toxicity of Transfluthrin Technical to the Daphnia magna Under Flow-Through Conditions. Bayer CropScience Report No: M-522462-01-1	SynTech Research Laboratory	[redacted]	2015	Bayer CropScíence

No	Data set according to Annex II Regulation (EU) No 528/2012	Title	Study reference / Testing facility	Author(s)	Year	Owner company
			(USA), Report No M-522462-01-1			
3	9.1.3.1 Growth inhibition test on Algae	Toxicity of Transfluthrin-Tetrafluorobenzoic acid to the Green Algae Pseudokirchneriella subcapitata During a 96 Hour Exposure. SynTech Research Laboratory, USA. Bayer CropScience Report No: M-528046-01-1	SynTech Research Laboratory (USA), Report No M-528046-01-1	[redacted]	2015	Bayer CropScíence
4	9.1.9 Studies on sediment-dwelling organisms	Chironomus riparius 28-day chronic toxicity test with transfluthrin (tech.) in a water-sediment system using spiked sediment. Bayer CropScience Report No: M-508598-01-1	Bayer CropScience (Germany), Report No M-508598-01-1	[redacted]	2015	Bayer CropScíence
5	9.1.9 Studies on sediment-dwelling organisms	A study on the chronic toxicity to the sediment dweller Lumbriculus variegatus. ECT Oekotoxikologie GmbH, Flörsheim/Main Bayer CropScience Report No: M-529774-01-1	ECT Oekotoxikologie GmbH (Germany), Report No M-529774-01-1	[redacted]	2015	Bayer CropScíence
6	9.3.1 Reproduction study with earthworms	Transfluthrin a.s. (BCS-AW53131): Sublethal toxicity to the earthworm Eisenia fetida in artificial soil. BioChem agrar GmbH Bayer CropScience Report No: M-503247-01-1	BioChem agrar GmbH (Germany),	[redacted]	2014	Bayer CropScíence

No	Data set according to Annex II Regulation (EU) No 528/2012	Title	Study reference / Testing facility	Author(s)	Year	Owner company
			Report No M-503247-01-1			
7	9.3.1 Reproduction study with other soil-dwelling non-target invertebrate	Effects on the reproduction of the collembolan Folsomia candida. BioChem agrar GmbH Bayer CropScience Report No: M-504775-01-1	BioChem agrar GmbH (Germany), Report No M-504775-01-1	[redacted]	2014	Bayer CropScíence
8	9.2.1 Tests with soil micro-organismen	Transfluthrin a.s. (BCS-AW53131): Effects on the activity of soil microflora (Nitrogen transformation test). BioChem agrar GmbH Bayer CropScience Report No: M-500036-01-1	BioChem agrar GmbH (Germany), Report No M-500036-01-1	[redacted]	2014	Bayer CropScíence
9	9.2.3 Toxicity to plants	Transfluthrin a.s.: Effects on the seedling emergence and growth of five species of non-target terrestrial plants (Tier 2) Bayer CropScience Report No: M-535993-01-1	Bayer CropScienc e (Germany), Report No M-535993-01-1	[redacted]	2015	Bayer CropScíence
10	10.2 Fate and behaviour in soil / 10.2.1	[methylene-14C]transfluthrin: Aerobic Degradation / Metabolism in Four Soils. Bayer CropScience Report No: M-534156-01-1	Bayer CropScienc e (Germany), Report No	[redacted]	2015	Bayer CropScíence

No	Data set according to Annex II Regulation (EU) No 528/2012	Title	Study reference / Testing facility	Author(s)	Year	Owner company
			M-534156-01-1			
11	10.2 Fate and behaviour in soil / 10.2.1	Kinetic Evaluation of the Degradation of Transfluthrin and its Metabolite NAK4723 under Aerobic Laboratory Soil Conditions. Bayer CropScience AG, Monheim, Germany. Study No. EnSa-15-0752. Bayer CropScience Report No: M-534584-01-1.	Bayer CropScienc e (Germany), Report No, M-534584-01-1	[redacted]	2015	Bayer CropScíence
12	10.2 Further studies on fate & behaviour in the environment	Amendment No. 1 to final report: Transfluthrin: Degradation in activated sludge. Study ID: Ml5404998-0. Bayer AG Report No EnSa-17-0107. Date of amendment 2018-09-14 Bayer Report No M-589221-01-1	Bayer AG (Germany), Report No M-589221-01-1	[redacted]	2017	Bayer CropScience
13	10.2 Further studies on fate & behaviour in the environment	Degradation of Transfluthrin in Activated Sludge. Bayer Study no. BAY-047/5-12 Bayer Report No M-767751-01-1	Bayer AG (Germany), Report No M-767751-01-1	[redacted]	2021	Bayer S.A.S., Environmental Science

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

Not relevant.

4.3.2 Safety for the general public

Scenario BfR2 - Inhalation during operation of the LED - Adult
(Pest Control Products – Electrical evaporators - Application)

Substance		
Name	Transfluthrin	
CASNumber	118712-89-3	
Molecular weight	371	g/mol
KOW	6.1	10Log
Product		
Name	ENDURLED TFT	
Weight fraction substance	0.719	%
Population		
Name	Adult	
Body weight	60	kg
Scenario 2 (Application – adult)		
Frequency	120	days per year
Inhalation		
Exposure model	Exposure to spray - Spraying	
Spray duration	600	minute
Exposure duration	600	minute
Weight fraction substance	0.719	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	16	m^3/day
Spraying towards person	no	
Mass generation rate	1.07	mg/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	Log-normal	
Median diameter	8	µm
Arithmetic coefficient of variation	0.3	
Maximum diameter	50	µm

Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	Non-respirable spray model	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario 2 (Application – adult)		
Inhalation		
Mean event concentration	6.3×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	6.5×10^{-3}	mg/m³
Internal dose on day of exposure	**7.0×10^{-4}**	**mg/kg bw/day**
Dermal		
Internal dose on day of exposure	n.a.	**mg/kg bw/day**
Oral		
Internal dose on day of exposure	**2.8×10^{-6}**	**mg/kg bw/day**
Integrated		
Internal dose on day of exposure	**7.0×10^{-4}**	**mg/kg bw/day**

Scenario BfR2 - Inhalation during operation of the LED - Toddler
(Pest Control Products – Electrical evaporators - Application)

Substance		
Name	Transfluthrin	
CASNumber	118712-89-3	
Molecular weight	371	g/mol
KOW	6.1	10Log
Product		
Name	ENDURLED TFT	
Weight fraction substance	0.719	%
Population		
Name	Toddler	
Body weight	10	kg
Scenario 2 (Application – toddler)		
Frequency	120	days per year
Inhalation		
Exposure model	Exposure to spray - Spraying	
Spray duration	600	minute
Exposure duration	600	minute
Weight fraction substance	0.719	%
Room volume	16	m³

Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	8	m³/day
Spraying towards person	no	
Mass generation rate	1.07	mg/min
Airborne fraction	1	
Density non-volatile	1.5	g/cm³
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	Log-normal	
Median diameter	8	µm
Arithmetic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	Non-respirable spray model	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario 2 (Application – toddler)		
Inhalation		
Mean event concentration	6.3×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	6.5×10^{-3}	mg/m³
Internal dose on day of exposure	**2.1×10^{-3}**	**mg/kg bw/day**
Dermal		
Internal dose on day of exposure	n.a.	**mg/kg bw/day**
Oral		
Internal dose on day of exposure	**8.5×10^{-6}**	**mg/kg bw/day**
Integrated		
Internal dose on day of exposure	**2.1×10^{-3}**	**mg/kg bw/day**

Scenario BfR2 - Inhalation during operation of the LED - Infant
(Pest Control Products – Electrical evaporators - Application)

Substance		
Name	Transfluthrin	
CASNumber	118712-89-3	
Molecular weight	371	g/mol
KOW	6.1	10Log
Product		
Name	ENDURLED TFT	

Weight fraction substance	0.719	%
Population		
Name	Infant	
Body weight	8	kg
Scenario 2 (Application – infant)		
Frequency	120	days per year
Inhalation		
Exposure model	Exposure to spray - Spraying	
Spray duration	600	minute
Exposure duration	600	minute
Weight fraction substance	0.719	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	5.4	m^3/day
Spraying towards person	no	
Mass generation rate	1.07	mg/min
Airborne fraction	1	
Density non-volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	Log-normal	
Median diameter	8	µm
Arithmetic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	Non-respirable spray model	
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario 2 (Application – infant)		
Inhalation		
Mean event concentration	6.3×10^{-3}	mg/m^3
Peak concentration (TWA 15 min)	6.5×10^{-3}	mg/m^3
Internal dose on day of exposure	**1.8×10^{-3}**	**mg/kg bw/day**
Dermal		
Internal dose on day of exposure	n.a.	**mg/kg bw/day**
Oral		
Internal dose on day of exposure	**7.2×10^{-6}**	**mg/kg bw/day**

Integrated		
Internal dose on day of exposure	**1.8×10^{-3}**	**mg/kg bw/day**

Scenario BfR4 - Dermal and oral exposure to transfluthrin from contact to surface contaminations in treated rooms - Toddler
(Pest Control Products – Electrical evaporators – Post-application)

Substance		
Name	Transfluthrin	
CASNumber	118712-89-3	
Molecular weight	371	g/mol
KOW	6.1	10Log
Product		
Name	ENDURLED TFT	
Weight fraction substance	0.719	%
Population		
Name	Toddler	
Body weight	10	kg
Scenario 4 (Post-application – toddler)		
Frequency	120	days per year
Inhalation		
Exposure model	n.a.	
Absorption model	n.a.	
Dermal		
Exposure model	Direct product contact	
Exposed area	2822	cm^2
Loading	Rubbing off	
Weight fraction substance	100	%
Transfer coefficient	0.6	m^2/hr
Dislodgeable amount	0.0789	mg/m^2
Contact time	60	min
Contacted surface	7	m^2
Absorption model	Fixed fraction	
Absorption fraction	0.7	
Oral		
Exposure model	Direct product contact	
Loading	Constant rate	
Weight fraction substance	100	%
Ingestion rate	7.89E-05	mg/min
Exposure duration	60	min
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario 4 (Post-application – toddler)		
Inhalation		

Mean event concentration	n.a.	mg/m³
Peak concentration (TWA 15 min)	n.a.	mg/m³
Internal dose on day of exposure	n.a.	**mg/kg bw/day**
Dermal		
Dermal load	1.7×10^{-5}	mg/cm²
External event dose	4.7×10^{-3}	mg/kg bw
External dose on day of exposure	4.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	**3.3×10^{-3}**	**mg/kg bw/day**
Oral		
Internal dose on day of exposure	**4.7×10^{-4}**	**mg/kg bw/day**
Integrated		
Internal dose on day of exposure	**3.8×10^{-3}**	**mg/kg bw/day**

Scenario BfR4 - Dermal and oral exposure to transfluthrin from contact to surface contaminations in treated rooms - Infant
(Pest Control Products – Electrical evaporators – Post-application)

Substance		
Name	Transfluthrin	
CASNumber	118712-89-3	
Molecular weight	371	g/mol
KOW	6.1	10Log
Product		
Name	ENDURLED TFT	
Weight fraction substance	0.719	%
Population		
Name	Infant	
Body weight	8	kg
Scenario 4 (Post-application – infant)		
Frequency	120	days per year
Inhalation		
Exposure model	n.a.	
Absorption model	n.a.	
Dermal		
Exposure model	Direct product contact	
Exposed area	2410	cm²
Loading	Rubbing off	
Weight fraction substance	100	%
Transfer coefficient	0.6	m²/hr
Dislodgeable amount	0.0789	mg/m²
Contact time	60	min
Contacted surface	7	m²
Absorption model	Fixed fraction	
Absorption fraction	0.7	

Oral		
Exposure model	Direct product contact	
Loading	Constant rate	
Weight fraction substance	100	%
Ingestion rate	7.89E-05	mg/min
Exposure duration	60	min
Absorption model	Fixed fraction	
Absorption fraction	1	
Results for scenario 4 (Post-application – infant)		
Inhalation		
Mean event concentration	n.a.	mg/m³
Peak concentration (TWA 15 min)	n.a.	mg/m³
Internal dose on day of exposure	n.a.	**mg/kg bw/day**
Dermal		
Dermal load	2.0×10^{-5}	mg/cm²
External event dose	5.9×10^{-3}	mg/kg bw
External dose on day of exposure	5.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	**4.1×10^{-3}**	**mg/kg bw/day**
Oral		
Internal dose on day of exposure	**5.9×10^{-4}**	**mg/kg bw/day**
Integrated		
Internal dose on day of exposure	**4.7×10^{-3}**	**mg/kg bw/day**

5 Confidential annex (Access level: “Restricted” to applicant and authority)

See confidential document.

6 Confidential annex – MS only (Access level: “Restricted - Authority”)

See separate document.