ADDENDUM TO PRODUCT ASSESSMENT REPORT

Product name:

Entfloher NL-0015509-0000

28 February 2023

Addendum to biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

Content

1. BACKGROUND

Major change application

With this major change application the Authorisation holder requested the authorisation of the use #2 – non professional use against crawling insects (incl. cockroaches and ants) as well further claims on the already authorised use #1 (ticks and fleas (adults)) by submitting further required efficacy testing with those target organisms to the authorised product, Entfloher (Non-Professional Use), NL-0015509-0000, for which NL acted as the refMS.
The above mentioned use had already been evaluated at first authorisation of the product and could have been authorised if the now submitted efficacy data would have been available.

A grouped application was submitted with NL as rMS and with the following MSs as cMS:

- DE
- BE

2. ASSESSMENT REPORT

2.1. SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1. Authorised use(s)

Use description

Table 1. Use # 1 – insecticide / acaricide -general public-indoor – pet areas

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide / acaricide
Target organism (including development stage)	*Ctenocephalides*- Fleas- eggs, larvae & adults Ticks: adults
Field of use	Indoors; in small areas where pets, mainly remain, including pet bedding (not for cats), carpets, or cushions
Application method(s)	spraying
Application rate(s) and frequency	3.13mL is sufficient for the treatment of one m2. This amount corresponds to a spraying time of 2 seconds per m2. Apply spraying from 30 cm distance onto preferred places of the fleas until the surface is slightly moistened. Maximum two applications per year. Residual efficacy up to 24 weeks (fleas: eggs & larvae) Residual efficacy up to 10 weeks (fleas: adults) Residual efficacy up to 11 weeks (ticks)
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	250 mL and 400 mL pressurized metal can (aluminium or tin plate) with a Bag-on-Valve System using compressed air as propellant

Use-specific risk mitigation measures

Do not apply on wet washable surfaces or materials.

Table 2. Use # 2 – insecticide-general public-indoor – cracks and crevices

Product Type(s)	PT 18 - Insecticides, acaricides & products to control arthropods
Where relevant, an exact description of the authorised use	The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for

	spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails of crawling insects.
Target organism (including development stage)	Crawling insects (incl. ants and cockroaches) - adults
Field of use	Indoors on cracks and crevices, non-porous surfaces
Application method(s)	spraying
Application rate(s) and frequency	0.8 mL per meter. This amount corresponds to a spraying time of 1 second per 2 meters. Apply spraying from 30 cm distance for some seconds to cracks and crevices in the close vicinity of hiding places, nests or trails of crawling insects Kills within 24 hours. Residual efficacy up to 10 weeks Maximum two applications per year.
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	Can 250 mL and 400 mL Metal (outer) Bag of aluminium (inner) valve with a bag welded on to it and positioned in the can

2.1.2. General directions for use

Instructions for use

Apply the product as soon as the first infestation is identified.

One can is sufficient to treat XX linear meters, or XX square meters.

Clean area before using the product.

Apply spraying from 30 cm distance onto relevant areas until the surface is slightly moistened.

After application leave the room immediately.

After application ensure adequate ventilation.

. Optimal efficacy is seen within 24 hours.

Humans and domestic animals may not enter the room at least for an hour after the application.

Where possible, combine the treatment with non-chemical measures.

The infestation should be monitored to see whether the treatment is sufficient.

Products should always be used in accordance with label recommendations.If the problem persists, contact a professional pest control operator.

2.1.3. Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can	250, 400 mL	Aluminium or tin plate can (outer) Bag of aluminium (inner) Propellant of the bag-on-valve system consist of compressed air.	Aerosol valve with a bag welded on to it and positioned in the can	General public (non-professional)	Yes

2.1.4. Efficacy against target organisms

Function and field of use

The product is authorised as insecticide / acaricide for indoor use by the general public (non-professional users). The product can be applied as a residual spray for the following use:

- Use #1: in areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions. Residual efficacy for 10 weeks (fleas: adults), residual efficacy for 11 weeks (ticks: adults), residual efficacy 24 weeks (fleas: eggs & larvae)

Additionally is intended to be used:

- Use #2: for spot application (aerosol) on cracks and crevices (non-porous surfaces) in the close vicinity of nests or trails. Residual efficacy for 10 weeks

Per use the following claims are intended:

- Use #1:
  The product is an insecticide / acaricide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) : in areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions.

  -Fleas: eggs, larvae, adults
  -Ticks: adults

- Use #2:
  The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) on cracks and crevices (non-porous surfaces) in the close vicinity of hiding places, nests or trails.

  Crawling insects (including ants and cockroaches)

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

The following organisms are to be controlled by the product:

- Use #1: Fleas (*Ctenocephalides*) – eggs, larvae and adults
  Ticks: adults

- Use #2: Crawling insects (including ants and cockroaches) - adults

2.1.5. Efficacy data

At an earlier stage authorisation was also sought against some additional target species. For this reason, efficacy data against these target species can be found in some of the efficacy study reports. These data are not relevant for authorisation of this product and are therefore not included in the efficacy table below.

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**
Insecticide & Acaricide	Insecticide; Control of crawling insects by indoor cracks & crevices treatment	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	Adults (mixed sex) of *Ctenocephalides felis* (cat flea), 10 per replicate, 5 treated replicates and 5 untreated replicates	Laboratory test (no choice test)	Treatments were applied by manual spraying onto carpet tiles (6.6 mm height, 2900 knobs/dm^2). The dose applied was 2.8 g/m^2 (3.13 mL/m^2), which is 0.063 g per tile (15 * 15 cm = 225 cm^2). The test organisms were exposed for 1 h to the surfaces 1 day (fresh) and 4, 8 and 10 weeks after treatment. Mortality was determined 24, 48 and 72 h after the exposure. Environmental conditions: Temp: 25-27 °C Hum: 56-64%	100% mortality after 24 h was achieved when cat fleas were exposed for 1 h to the surfaces 1 day, 4, 8 and 10 weeks after treatment. 0% mortality was observed after 24 and 48 h in the untreated control at any of the tested time points.	[redacted] (2021g) BIO048-21

Insecticide & Acaricide	Insecticide; Control of crawling insects	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	Adults of: *Ctenocephalides felis* (cat flea), 10 per replicate *Blattella germanica* (German cockroach), 10 per replicate *Blatta orientalis* (Oriental cockroach), 10 per replicate *Lasius niger* (black garden ant), 10 per replicate 5 replicates per test organism	Laboratory test	Treatments were applied by manual spraying onto non-porous glazed tiles, porous unglazed tiles and carpet. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The arthropods were exposed to the surfaces 1 day (fresh) and 2 weeks after treatment for 1 hour. The evaluations for knockdown and mortality were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.	For details on results see the following row.	[redacted] (2016a)

Details on results:

Blattella germanica:

	Knockdown or Mortality after 24 hours (1h exposure,1 day after treatment)		Knockdown or Mortality after 24 hours (1h exposure, 2 weeks after treatment)		Knockdown or Mortality after 24 hours (1h exposure, 4 weeks after treatment)		Knockdown or Mortality after 48 hours (1h exposure, 8 weeks after treatment)	
	knockdown	mortality	knockdown	mortality	knockdown	mortality	knockdown	mortality
Glazed tiles	100%	100%	100%	98%	100%	100%	86%	82%
Unglazed tiles	100%	100%	100%	100%	4%	4%	Not tested	Not tested

Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	Not tested	Not tested

Blatta orientalis:

	Knockdown or mortality after 24 hours (1h exposure, 1 day after treatment)		Knockdown or mortality after 24 hours (1h exposure, 2 weeks after treatment)		Knockdown or mortality after 24 hours (1h exposure, 4 weeks after treatment)		Knockdown or mortality after 24 hours (1h exposure, 8 weeks after treatment)	
	knockdown	mortality	knockdown	mortality	knockdown	mortality	knockdown	mortality
Glazed tiles	48%	76%	24%	20%	Not tested	Not tested	Not tested	Not tested
Unglazed tiles	6 %	4%	0 %	0%	Not tested	Not tested	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	0%	Not tested	Not tested	Not tested	Not tested
Untreated unglazed tiles	0%	0%	0%	0%	Not tested	Not tested	Not tested	Not tested

Lasius niger:

	Knockdown or mortality (1h exposure, 1 day after treatment)		Knockdown or mortality (1h exposure, 2 weeks after treatment)		Knockdown or mortality (1h exposure, 4 weeks after treatment)		Knockdown or mortality (1h exposure, 8 weeks after treatment)	
	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	98%	100 %	88%	98%	92%	34%	19%
Unglazed tiles	100 %	96%	16 %	20%	16%	30%	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	Not tested	Not tested

Ctenocephalides felis:

	Knockdown or mortality s (1h exposure, 1 day after treatment)		Knockdown or mortality (1 hour exposure, 2 weeks after treatment)		Knockdown or mortality (1 hour exposure, 4 weeks after treatment)	
	Knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7

Carpet	96%	100%	46 %	96%	24 %	42%		
Untreated carpet	0%	2%	0%	16 %	0%	0%		
Insecticide & Acaricide	Insecticide; Control of crawling insects by indoor cracks & crevices treatment	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	American cockroach (*Periplaneta americana*), 10 adults (mixed sex) per replicate, 5 treated replicates and 5 untreated replicates	Laboratory test (no choice test)	Treatments were applied by manual spraying onto non-porous glazed tiles. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The cockroaches were exposed for 1 h to the surfaces 1 day (fresh) and 4, 8 and 10 weeks after treatment. Mortality assessment was performed 1 and 2 days after exposure of individuals. Environmental conditions: Temp: 25-26 °C Hum: 56-64%	100% mortality after 24 h was achieved when cockroaches were exposed for 1 h to the surfaces 1 day, 4, 8 and 10 weeks after treatment. 0% mortality was observed after 24 and 48 h in the untreated control at any of the tested time points.	[redacted] (2021e) BIO046-21
Insecticide & Acaricide	Acaricide; Control of ticks and mites	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	*Ixodes ricinus* (tick); adults, 10 per replicate tested with populations of mixed age	Laboratory test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of knockdown and / or mortality. Treatments were	The results demonstrate that the applied product Convet Entfloher fulfills the requirements for the product intended for use as general surface treatment for consumers	[redacted] (2016a)	

			5 replicates per test organism		applied by manual spraying onto non-porous glazed tiles and porous unglazed tiles for European sheep tick, and onto non-porous glazed tiles, porous unglazed tiles and plywood for Red poultry and House dust mites. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The arthropods were exposed to the surfaces 1 day (fresh) and 2 weeks after treatment for 1 hour (Red poultry mites and House dust mites stayed continuously on the treated surface). The evaluations for mortality were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.	(according to the requirements of the relevant "Technical Notes for Guidance [TNsG]) against *Ixodes ricinus* (based on the requirements for cockroaches), fresh (1 day after treatment) and 2 weeks after treatment. **For details on results see the following row.**	
Details on results:							

Ixodes ricinus:

	Knockdown or Mortality (I hour exposure, 1 day after treatment)		Knockdown or Mortality (1 hour exposure, 2 weeks after treatment)		Knockdown or Mortality (1 hour exposure, 4 weeks after treatment)		Knockdown or Mortality (1 hour exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%	100%	100%
Unglazed tiles	100%	100 %	100%	100 %	100%	100 %	100%	100 %
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	0%	0%

Insecticide & Acaricide	Acaricide; Control of cat flea eggs and larvae	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	*Ctenocephalides felis* (cat flea eggs and larvae), 20 per replicate, 5 replicates	Laboratory test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of inhibition of development. Treatments were applied by manual spraying onto carpet discs. Carpet discs were placed next to each other to almost cover up 1 m^2. By spraying out of a distance of 30 cm for a defined time (lead to an amount of approx. 2.8 g), an area of 1 m^2 is treated. Within 24 hours after	The results demonstrate that the applied product Convet Entfloher fulfills after 1 day, 2 weeks, 4 weeks, 12 weeks, and 24 weeks aging the requirements for an ovicidal and larvicidal product intended for use as general surface treatment (according to the requirements of the relevant "Technical Notes for Guidance [TNsG] for PT 18 and PT 19: CA-DEC 12-Doc.6.2.a – Final") against Cat flea, Ctenocephalides felis (larvae and eggs): ≥80% inhibition	[redacted] (2016b)

					treatment insects are placed on the surfaces. The procedure was repeated 2 weeks, 4 weeks, 12 weeks, and 24 weeks after treatment.The evaluation for all the test units was made after development of the larvae or the eggs, respectively, into adult fleas in the untreated controls, which could be observed approx. 5 weeks after treatment or approx. 10 weeks after treatment for the last test point (24 weeks). For the evaluation the number of adult fleas was counted.	should occur of the development of produced eggs/larvae into adult fleas during the claimed ovicidal/larvicidal duration of action of the product. **For details on results see the following row.**	

Details on results:
Cat fleas, *Ctenocephalides felis* (larvae)

	Observed adult fleas within 39 days after continuous exposure , starting 1 day after treatment	Observed adult fleas within 39 days after continuous exposure , starting 2 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 4 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 12 weeks after treatment	Observed adult fleas within 67 days after continuous exposure , starting 24 weeks after treatment

Larvae on treated carpet	0%	0%	0 %	0%	0%
Larvae on untreated controls	75%	66%	75%	85%	62%

Cat fleas, *Ctenocephalides felis* (eggs)

	Observed adult fleas within 39 days after continuous exposure , starting 1 day after treatment	Observed adult fleas within 39 days after continuous exposure , starting 2 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 4 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 12 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 24 weeks after treatment
Eggs on treated carpet	0%	0 %	0 %	0%	0%
Eggs on untreated controls	82%	77%	75%	71%	55%

Insecticide & Acaricide	Acaricide; Control of ticks and mites in pet areas	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	Cat fleas (*Ctenocephalides felis*), 20 adults (mixed sex) per replicate, 5 treated replicates and 5 control replicates.	Simulated-use test (choice test) Residual efficacy on carpet	Treatments were applied by manual spraying onto carpet in a test box leaving half of the carpet area untreated as choice option. The dose applied was 2.8 g/m². The fleas were exposed directly after treatment to the carpet on day 0 (fresh) and 2, 4, 8 and 10 weeks after treatment. Mortality was	100% mortality after 24 h exposure on freshly treated carpet and until 10 weeks after treatment. 0% mortality in untreated control after 24 h.	(2021c) BIO021a-21

					assessed after 24 and 48 h exposure of the individuals. Environmental conditions: Temp: 24-25 °C Hum: 45-65%		
Insecticide & Acaricide	Insecticide; Control of crawling insects by indoor cracks & crevices treatment	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	Black garden ants (*Lasius niger*), 20 workers per replicate, 5 replicates (+ 5 control)	Laboratory test (no choice test)	Treatments were applied by manual spraying onto non-porous glazed tiles. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The ants were exposed for 1 h to the surfaces 1 day (fresh) and 4, 8 and 10 weeks after treatment. The evaluations for mortality were made 1 and 2 days after exposure of individuals. Environmental conditions: Temp: 25-27 °C Hum: 56-64%	100% mortality after 24 h was achieved when ants were exposed for 1 h to the surfaces 1 day and 4, 8 and 10 weeks after treatment. Observed mortality in the untreated control after 24 h was ≤ 1% for all tested time points and ≤ 4% after 48 h for all tested time points.	[redacted] (2021f) Biology 047-21
Insecticide & Acaricide	Insecticide; Control of crawling	Convet Entfloher; permethrin	Black garden ants (*Lasius niger*),	Simulated–use test	Treatments were applied by manual spraying onto	99 – 100% mortality after 24 h exposure on freshly	[redacted] (2021b)

	insects by indoor cracks & crevices treatment	0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	50 workers per replicate, 3 replicates (+ 3 control)	(choice test) Residual efficacy in cracks & crevices	non-porous glazed tiles in a test box with areas left untreated as choice. The dose applied was 2.8 g/m² and applied in a way representing crack and crevice treatment. The ants were exposed to the surfaces 0 d after treatment (fresh) and 2, 4, 9 and 12 weeks after treatment. Mortality was assessed after 24 and 48 h exposure of the individuals.	treated surface and until 9 weeks after treatment; 90% mortality after 24 h exposure 12 weeks after treatment. Mortality in untreated control after 24 h ≤ 3%.	BIO020a-21
Insecticide & Acaricide	Acaricide; Control of crawling insects	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	Adults of: *Blattella germanica* (German cockroach), 10 per replicate, 3 replicates *Blatta orientalis* (Oriental cockroach), 10 per replicate, 3 replicates *Lasius niger*	Simulated use (choice) test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of mortality. Treatments were applied by manual spraying onto glazed tiles and plywood. One half of the tiles is covered with aluminium foil to prevent contact	The results demonstrate that the applied product Convet Entfloher fulfills the requirements for a product intended for use as general surface treatment or aerosol for consumers (according to the Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and	[redacted] (2017)

			(black garden ant), 20 per replicate, 3 replicates		with the product. Thereto, after spraying only one half of the tile is treated with the product. The spray jet hits the tiles sloping at an angle of 45° at a distance of 30 cm. The dosage is 2.8 g/m2 (approx. 0.071 g per test unit). The cockroaches are anaesthetized (with CO2) and placed inside a shelter (cardboard cup lying) which is placed on the untreated side. The cockroaches are then kept in the shelter, due to a plastic beaker pulled over the shelter, for 24 hours. Afterwards, the plastic beaker is removed and the cockroaches are able to move free inside the test unit. No acclimatization of ants is done before testing. Ants are placed	Evaluation (Parts B&C), ECHA 2017) against Blattella germanica (glaced tiles, plywood) and partly against Blatta orientalis and Lasius niger (glaced tiles only). No residual efficacy was demonstrated in this study. **For details on results see the following row.**	

					directly on the top of their shelter (cardboard cup, two openings), so that they have to move downwards a certain way and get some time to explore their environment without getting into contact to the treated area. The crawling insects are kept inside the arena for 24 hours (free running). After 24 hours evaluation of mortality is done		

Details on results:

Blattella germanica (German cockroach), *Blatta orientalis* (Oriental cockroach), *Lasius niger* (black garden ant)

	Surface	% mortality after 24 hours	% mortality after 48 hours
Blattella germanica	Glazed tiles	100%	100%
Blatta orientalis	Glazed tiles	93%	100%
Lasius niger	Glazed tiles	100%	100%
Blattella germanica	Plywood	93%	Not tested
Blatta orientalis	Plywood	0%	Not tested
Lasius niger	Plywood	70%	Not tested

Insecticide & Acaricide	Insecticide; Control of other arthropods	Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this	*Blattella germanica* (German cockroach)	Simulated – use test (choice test)	Treatments were applied by manual spraying onto non-porous glazed tiles in a	German cockroach: 100% mortality after 24 h on fresh and until 12 weeks after treatment.	[redacted] (2021a) BIO019a-21

		product is identical in composition to Entfloher	*Periplaneta americana* (American cockroach) 20 adults (mixed sex) and 20 nymphs (N3-4, mixed sex) per replicate, 3 replicates (and 3 control)	Residual efficacy in cracks & crevices	test arena with areas left untreated as choice. The dose applied was 2.8 g/m² and applied in a way representing crack and crevice treatment The cockroaches were exposed to the surfaces 0 d after treatment (fresh) and 2, 4, 9 and 12 weeks after treatment. Mortality was assessed after 24 and 48 h exposure of the individuals. Environmental conditions: Temp: 25-26 °C Hum: 54-64%	American cockroach: 100% mortality after 24 h on fresh and until 4 weeks after treatment, ≥90% after 24 h 9 and 12 weeks after treatment. No mortality in untreated control.	
Acaricide	Acaricide	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	*Rhipicephalus sanguineus* (dog tick); adults, 10 per replicate, 5 replicates	Laboratory test	Treatments were applied by manual spraying onto non-porous glazed tiles and porous unglazed tiles. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The ticks were	**For details on results see the following row.**	[redacted] 2018

					exposed to the surfaces 1 day (fresh), 1 month and 2 months after treatment for 1 hour. The evaluations for the control and for knockdown and mortality of treated individuals were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.		

Details on results:

Rhipicephalus sanguineus (Brown dog tick)

	Knockdown or (1 hour exposure, 1 day after treatment)		Knockdown or (1 hour exposure, 1 month after treatment)		Knockdown or Mortality (1 hour exposure, 2 months after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%
Unglazed tiles	100%	100%	100%	100%	100%	100%
Untreated glazed tiles	0%	2%	0%	6 %	0%	0%
Untreated unglazed tiles	0%	2%	0%	4%	0%	0%

Insecticide & Acaricide	Acaricide; Control of ticks and mites in pet areas	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is	Sheep ticks *(Ixodes ricinus)*, 5 adults (mixed sex) per replicate, 5 replicates	Simulated-use test Residual efficacy on carpet	Treatments were applied by manual spraying onto carpet in a test box. The dose applied was 2.8 g/m². The ticks	100% knockdown (unable to crawl upwards on arm in a 5 min period) after 1 h exposure, 100% mortality after 24 h on	(2021d) Bio022a-21

		identical in composition to Entfloher			were exposed directly after treatment to the carpet on day 0 (fresh) and 2, 4, 8 and 11 weeks after treatment. Ticks knockdown was evaluated after 1 hour contact time on the treated carpet. Following, the ticks were put on human arm to check if the ticks were able to crawl upwards within a 5 min period. After that the ticks were transferred in clean beakers. Mortality was assessed after 24 hours. Environmental conditions: Temp: 22-25 °C RH: 39-61%	freshly treated carpet and until 11 weeks after treatment. 0% knockdown after 1 h and 0% mortality after 24 h in untreated control for all tested time points.	

Conclusion on the efficacy of the product
To demonstrate efficacy against the intended target species, laboratory and simulated-use studies were submitted for Entfloher (permethrin 0.6%, pyriproxyfen 0.1% with 3.125 mL/m^2). With the tests provided the following uses could be authorised: Indoor use against fleas (eggs, larvae and adults) and ticks (adults), including residual efficacy up to 10 weeks (fleas: adults), residual efficacy up to 11 weeks (ticks: adults) and residual efficacy up to 24 weeks (fleas: eggs & larvae): in areas where pets (dogs and cats) mainly remain, including pet bedding, carpets or cushions. Indoor use against crawling insects (adults) including cockroaches and ants including residual efficacy up to 10 weeks: spot application on cracks and crevices (non-porous surfaces) in the close vicinity of nests or trails. Fur a full evaluation of the label claims see section 2.2.1.8.

Evaluation of the label claims
Per use the following claims have been intended
Use 1:
The product is an insecticide / acaricide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) : in areas where pets (dogs and cats) mainly remain, including pet bedding, carpets, or cushions. Residual efficacy for 10 weeks (fleas: adults), residual efficacy for 11 weeks (ticks: adults), residual efficacy 24 weeks (fleas: eggs & larvae)

-Fleas: Eggs, larvs, adults
-Ticks: adults

Use 2:
The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) on cracks and crevices (non-porous surfaces) in the close vicinity of nests or trails. Residual efficacy for 10 weeks

Crawling insects (including ants and cockroaches)

The provided efficacy data for these target species are evaluated below.

Use 1:

Fleas:

Tests provided with Cat fleas (*Ctenocephalides felis*)

Laboratory test
Adults:up to 10 weeks (100% mortality after 24 hours)
Eggs: up to 24 weeks (0% observed adult fleas after 39 days)
Larvea: up to 24 weeks (0% observed adult fleas after 39 days and 67 days)

Simulated-use test
Adults: up to 10 weeks (100% mortality after 24 hours)

The criterion for a ovicidal or larvicidal product were met, a claim against eggs and larvae of *Ctenocephalides felis* can be authorized, including a residual efficacy up to 24 weeks.

For an adulticidal claim against fleas sufficient efficacy was demonstrated including residual efficacy up to 10 weeks.

Ticks:

-Tests provided with Sheep ticks (*Ixodes ricinus*) & Brown dog ticks (*Rhipicephalus sanguineus*)

Laboratory tests with both tick species:
Non-porous tiles: up to 8 weeks (100% mortality after 24 hours)
Porous tiles: up to 8 weeks (100% mortality after 24 hours)

Simulated-use test with Sheep ticks:
Carpet: up to 11 weeks (100% knockdown after 1 hour and 100% mortality after 24 hours). This test on carpet can be considered a simulated use test. The tested tick species are so-called ambush ticks with a passive strategy to find a host. If a tick has fallen down it will not crawl around. It will stay where it is and wait for a host. In a choice test a tick would be placed on the untreated area and not move (away or towards the treated area), which will give the same results as the laboratory test conducted.

Sufficient efficacy against *Ixodes ricinus* was demonstrated in laboratory tests and a simulated-use test; additionally, efficacy against *Rhipicephalus sanguineus* was shown in a laboratory test.

Use 2:

Crawling insects (including ants and cockroaches)

Cockroaches

-Tests provided with German cockroaches (*Blattella germanica*)

Laboratory test
Non-porous tiles: up to 4 weeks (>90% mortality)
Porous tiles: up to 2 weeks (>90% mortality)

Simulated-use test
Non-porous tiles: >100% mortality after 24 and 48 hours
Plywood (porous surface): >93% mortality after 24 hours
Cracks & crevices treatment on non-porous tiles: up to 12 weeks (100% mortality after 24 hours)

The laboratory test and the simulated-use test showed sufficient efficacy against German cockroaches. The newly provided simulated-use test mimicked the intended use of this product as spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails).

-Tests provided with Oriental cockroaches (*Blatta orientalis*)
Laboratory test
Non-porous tiles: <90% mortality
Porous tiles: <90% mortality

Simulated-use test
Non-porous tiles: >90% mortality after 24 and 48 hours
Plywood (porous surface): 0% mortality after 24 hours
No cracks & crevices treatment simulated use test was provided with oriental cockroaches.

Although the mortality results of the laboratory test are less than 90%, the data of the simulated use test on non-porous tiles are sufficient and can be considered worst case. However, as the design of the provided simulated use test against oriental cockroaches is not representative of a crack and crevice treatment, the data for this cockroach species will not be used for assessment of efficacy of the product.

-Tests provided with American cockroaches (*Periplaneta americana*)
Laboratory test
Non-porous tiles: up to 10 weeks (100% mortality after 24 hours)

Simulated-use test
Cracks & crevices treatment on non-porous tiles: up to 12 weeks (≥90% mortality after 24 hours)

In addition to the earlier provided test against cockroaches, a laboratory test against American cockroaches and simulated-use tests against American and German cockroaches were submitted. The simulated-use tests represented the intended use of this product as spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails. Based on the available data against American and German cockroaches, sufficient efficacy for a general claim against cockroaches and therefore against crawling insects has been demonstrated.

As no data is provided about the time it takes for >90% knockdown, the claim in the authorised uses will state that the product: kills within 24 hours.

Ants

Tests provided with Black garden ants (*Lasius niger*)

Laboratory test
Non-porous tiles: up to 4 weeks (98% knockdown or mortality after 24 hours)
Porous tiles:1 day (100% mortality)
Non-porous tiles: up to 10 weeks (100% mortality after 24 hours)

Simulated-use test
Non-porous tiles: >100% mortality after 24 and 48 hours
Plywood (porous surface): <90% mortality after 24 hours
Cracks & crevices treatment on non-porous tiles: up to 12 weeks (≥90% mortality after 24 hours)

The laboratory tests and the simulated-use tests showed efficacy against *Lasius niger* on non-porous surfaces. The newly provided simulated-use test furthermore sufficiently represented the intended use of this product as spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails. Based on the submitted data against Black garden ants, sufficient efficacy for a general claim against ants has been demonstrated.

As no data is provided about the time it takes for >90% knockdown, the claim in the authorised uses will state that the product kills within 24 hours.

The efficacy studies with the product were are all conducted with an application rate of 3.13 mL product/m^2 (=250 mL/80m2). As use #2 is not a surface treatment, but a crack and crevices treatment, the application was converted to a linear dosage in the following way:
Spraying from 30 cm distance over one linear meter gives a line of 25 cm x 1 m. To be in line with the tested application rate of 250 mL product/80 m2, apply 250 ml per 320

meter. This amount corresponds to 0.8ml/m and a spraying time of 1 second per 2 meters.

Human health

Application of the product by surface treatment via spraying (use #1) is already authorized. Based on the risk assessment, which assumed a treament area of 5m2, no adverse health effects are expected for the non-professional user and the general public after exposure to permethrin by indoor spraying of small areas where pets (dogs and cats) mainly remain (use #1).

Application in cracks and crevices is also done by spraying (use #2) at the same dosing as for spraying small surfaces (i.e. 250 mL product/80m^2, equal to a spraying time of 2 seconds per m^2). However, the treated area for application of the product in cracks and crevices is expected to be much lower than the area treated during surface treatment. Therefore, exposure during the application of the product in cracks and crevices is covered by the risk assessment on surface treatment application that was already considered acceptable for human health.

In conclusion, no adverse health effects are expected for application of the product in cracks and crevices by spraying (use #2) for the non-professional user and the general public.

Environment

For application of the product for the non-professional control of pet fleas (eggs and larvae) by spraying (use #1), as already authorised, the environmental risk assessment demonstrated that calculated concentrations of the active substances in environmental compartments presented an acceptable risk for the STP, groundwater and primary and secondary poisoning of birds and mammals. However, by spraying a safe use could not be demonstrated as the PEC/PNECs for surface water and sediment were > 1. This risk was considered acceptable provided that the following risk mitigation measure was included in the label: "Do not apply on wet washable surfaces or materials". New claims on the already authorised use #1 (ticks and fleas (adults)) are covered by the claims for use #1 already assessed for the environmental aspect.

Application of the product in cracks and crevices for the non-professional control of crawling insects by spraying (use #2) was already considered acceptable for the environment.

3. DECISION

Sufficient information has been provided to demonstrate efficacy of Entfloher against crawling insects (incl. cockroaches and ants) as well as further claims on the already authorised use #1 (adult fleas and ticks).

4. ANNEXES

4.1. LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Protection claimed
3.4.1 Storage stability accelerated	[redacted]	2016	Determination of physico-chemical Properties and Storage Stability Tests for ConVet Umgebungsspray: 8 weeks at 40 °C and up to 36 months at 20 °C Amendement No. 1 to 8 weeks interim report (25 August 2016)	BioGenius GmbH, Bergisch Gladbach, Germany	Mo5437	ConVet GmbH & Co. KG	yes
3.4.1 Storage stability, long term at ambient temperature	[redacted]	2019	Determination of physico-chemical Properties and Storage Stability Tests for ConVet Umgebungsspray: 8 weeks at 40 °C and up to 36 months at 20 °C	BioGenius GmbH, Bergisch-Gladbach, Germany	Mo5437	ConVet GmbH & Co. KG	yes
4.2 Flammability	[redacted]	2016	Flash Point A.9. of Convet Umgebungsspray	BioGenius GmbH, Bergisch-Gladbach, Germany	Mo5489	ConVet GmbH & Co. KG, Monheim, Germany	yes
4.17.1 Auto-ignition temperature (liquids and gases)	[redacted]	2016b	ConVet Umgebungsspray: Auto-Ignition Temperature (Liquids and Gases) A.15	Siemens AG, Frankfurt/Main, Germany	Mo5462	ConVet GmbH & Co. KG, Monheim, Germany	yes
4.17.3 (Cf. 4.2) Dust explosion hazard	[redacted]	2016a	ConVet Umgebungsspray: Pyrophoric Properties (Liquids) A.13	Siemens AG, Frankfurt/Main, Germany	Mo5462	ConVet GmbH & Co. KG, Monheim, Germany	yes
5 Methods of detection and identification	[redacted]	2016	Validation of Method: MV137-CVT: GC-Determination Permetrin and Pyriproxyfen in Umgebungsspray	BioGenius GmbH, Bergisch-Gladbach, Germany	Mo5436	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2016a	Residual efficacy of an aerosol product on treated surfaces against crawling arthropod species	BioGenius GmbH, Germany	Mo5387	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2016b	Residual efficacy of an aerosol product on carpet against Flea eggs and larvae	BioGenius GmbH, Germany	Mo5387	ConVet GmbH & Co. KG	yes

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Protection claimed
6.7 Efficacy data		2017	Simulated use test (choice-test) to determine the residual efficacy of an aerosol product on treated surfaces against crawling arthropod species	BioGenius GmbH, Germany	Mo5116	ConVet GmbH & Co. KG	yes
6.7 Efficacy data		2018	Residual efficacy of an aerosol product on treated surfaces against Brown dog tick	BioGenius GmbH, Germany	Mo6162	ConVet GmbH & Co. KG	yes
6.7		2021a	Efficacy of the aerosol product "Entfloher" tested in a simulated-use test for Cracks and Crevices application against 2 different cockroaches species	BioGenius GmbH, Bergisch Gladbach, Germany	BIO019a-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021b	Efficacy of the aerosol product "Entfloher" tested in a simulated-use test for Cracks & Crevices applications against black garden ants	BioGenius GmbH, Bergisch Gladbach, Germany	BIO020a-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021c	Efficacy of the aerosol product "Entfloher" tested in a simulated-use test against cat fleas	BioGenius GmbH, Bergisch Gladbach, Germany	BIO021a-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021d	Efficacy of the aerosol product "Entfloher" tested in a simulated-use test against sheep ticks	BioGenius GmbH, Bergisch Gladbach, Germany	BIO022a-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021e	Residual efficacy of the aerosol product “Entfloher” tested in a lab test against American cockroaches	BioGenius GmbH, Bergisch Gladbach, Germany	BIO046-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021f	Residual efficacy of the aerosol product "Entfloher" tested in a lab test against Black ants	BioGenius GmbH, Bergisch Gladbach, Germany	BIO047-21 (report number)	ConVet GmbH & Co. KG	yes
6.7		2021g	Residual efficacy of the aerosol product "Entfloher" tested in a lab test against Cat fleas	BioGenius GmbH, Bergisch Gladbach, Germany	BIO048-21 (report number)	ConVet GmbH & Co. KG	yes