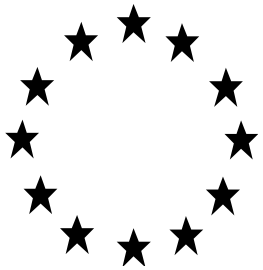
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT APPLICATIONS



Product identifier in R4BP	**Fliegenköder**
Product type(s):	18 (Insecticide)
Active ingredient(s):	Imidacloprid
Case No. in R4BP	BC-NF049891-33
Asset No. in R4BP	DE-0008943-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00005 710-05-18-00005-01-00-00-0000
Date	26.07.2023

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Overview of applications

Table 1 - Overview regarding all relevant applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment)
NA-APP	DE	BC-NX010480-23	30.09.2015	First authorisation including changes according to the comments from France (NA-MRS) The changes are included in the PAR First authorisation.
NA-AAT	DE	BC-EV020080-42	12.10.2015	Amendment by CA (correction of the name of the authorisation holder and the location of manufacturing sites) The changes are included in the SPC
NA-MIC	DE	BC-SL030853-27	30.11.2017	Minor change (change of the shelf life)

1 Conclusion

The ready-to-use biocidal product “Fliegenköder” formulated by Aeroxon with the active substance imidacloprid, is authorised for use as an insecticide (product-type 18) for the control of house flies (***Musca domestica***) in households.

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, “Fliegenköder” with the active substance imidacloprid (4.3 % w/w) is used as an insecticide (product-type 18) for the control of house flies (***Musca domestica***) in households.
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(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance imidacloprid including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.
2. The specific provisions from Inclusion Directive for the active substance imidacloprid (Commission Directive 2011/69/EU).

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

- Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

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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, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

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.

- Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children. For details see chapter 2.7.3.2 of this PAR.

- For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

Composition and formulation

The ready-to-use “Fliegenköder” contains the active substance imidacloprid.

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

No substance of concern has been identified.

Please refer to chapter 2.2 (Composition and formulation) and the confidential Annex 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 hazards 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 been shown to be efficacious for the uses 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 substance of concern has been identified the human health risk assessment for this product is based on the active substance.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3).

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).

Based on the risk assessment it is unlikely that the intended use(s) cause 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 uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

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

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and 4.9.5.6).

A risk assessment for the environment has been carried out for non-professional user and indoor use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

The biocidal product contains Imidacloprid which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.

However, a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR (CA-June22-Doc.4.2[3]).

Therefore, a comparative assessment of the biocidal product is not required.

[3] The document is available in CIRCABC at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/aa098b99-9f78-4606-b9e0-9275764168d2/details.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Fliegenköder

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Aeroxon s.r.o
Address of manufacturer	Dr. Sedlaka 827 CZ-3390 1 Klaotvy Czech Republic
Location of manufacturing sites	Dr. Sedlaka 827 CZ-3390 1 Klaotvy Czech Republic

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

Active substance	Imidacloprid
Name of manufacturer	Bayer CropScience AG
Address of manufacturer	Alfred-Nobel-Straße 50 40789 Monheim am Rhein Germany
Location of manufacturing sites	41538 Dormagen Germany

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Imidacloprid	((2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine)	Active substance	138261-41-3	428-040-8	4.3 (caloric bait formulation)

- The product (caloric bait formulation) contains a bittering agent.

  - Information on the full composition (including the carrier) is provided in the confidential[4] annex.

- 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 ☐ (The technical equivalence of the active substance from the new source was established by ECHA)

2.2.3 Information on endocrine disrupting properties

The biocidal product contains the active substance Imidacloprid, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.
Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

2.2.4 Information on the substance(s) of concern

No substance of concern was identified.

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

2.2.5 Candidate(s) for substitution

The following candidate for substitution was identified:

- Imidacloprid

Imidacloprid does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

Imidacloprid does meet the following criteria for substitution:

- Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT.

2.2.6 Type of formulation

AL (printed on a thin layer of self-adhesive stripes or motives)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[5]

Besides the active substance imidacloprid the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance imidacloprid is based on Commission Regulation (EU) No. 2021/849 (17th ATP):

The substance is classified as Acute Tox. 3 (H301).

The harmonised classification for Imidacloprid is aquatic acute 1 (H400) with M-factor 100 and aquatic chronic 1 (H410) with M-factor 1000.

The following classification and labelling is thus required for the product Fliegenköder:

Table 3

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Aquatic acute 1	H 400: Very toxic to aquatic life.
Aquatic chronic 1	H 410: Very toxic to aquatic life with long lasting effects

5 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.

Labelling	Code	Pictogram / Wording
	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
	P501	Dispose contents/container of to hazardous or special waste collection point
Note	-	

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.4.2 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 – Fly Bait transparent

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	The product Fly Bait consists of two inert ready-to-use paper/plastic strips (32.4 cm² per two strips) loaded with an insecticidal caloric bait formulation to be fixed to window frames or sills outside the reach of children. Fly Baits are available as transparent fly bait strips ready-for use.
Target organism(s) (including development stage)	Muscidae: House fly (*Musca domestica*) Adults

Field(s) of use	Indoor Indoor use in domestic areas
Application method(s)	Indoor Indoor use in domestic areas
Application rate(s) and frequency	Cream, Caloric bait formulation (printed in a thin layer onto transparent fly bait stripes ready for use) The product Fly Bait consists of two inert ready-to-use paper/plastic strips (32.4 cm² per two strips) loaded with an insecticidal caloric bait formulation to be fixed to window frames or sills outside the reach of children. Fly Baits are available as transparent fly bait strips ready-for use.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	2 - 12 transparent strips per cardboard box

2.4.1.1 Use-specific instructions for use

See chapter 2.5.1 1)

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5.2

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

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

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

2.4.2 Use 2 appropriate for authorisation – Fly Bait motif sticker

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	The product Fly Bait is an inert ready-to-use paper/plastic sticker (32.4 cm^2) loaded with an insecticidal caloric bait formulation to be fixed to windows glass outside the reach of children. Fly Baits are available as fly bait motif stickers ready-for use
Target organism(s) (including development stage)	Muscidae: House fly (*Musca domestica*) Adults
Field(s) of use	Indoor Indoor use in domestic areas
Application method(s)	Cream, Caloric bait formulation (printed in a thin layer onto motif sticker) The product Fly Bait is an inert ready-to-use paper/plastic sticker (32.4 cm^2) loaded with an insecticidal caloric bait formulation to be fixed to windows glass outside the reach of children. Fly Baits are available as fly bait motif stickers ready-for use
Application rate(s) and frequency	One Fly Baits sticker per 15 m^2 room. The sticker is active for 6 months.
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material	1 - 10 motif stickers per cardboard box

2.4.2.1 Use-specific instructions for use

See chapter 2.5.1

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5.2

2.4.2.3 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

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

See chapter 2.5.4

2.4.2.5 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

2.5 General directions for use

2.5.1 Instructions for use

1) Comply with the instructions for use.

2) Remove protective paper.
3) Pull off the desired motif/window strip.
4) Place the protective paper on the remaining fly baits and store in the original packaging in a dry and frost-free place
5) During fixing touch the bait in the unprinted outer rim only.
6) Fix bait in the upper part of the window pane, inaccessible for children and pets.
7) Avoid any unnecessary contact to the preparation. Misuse may cause health damage.
8) Keep fly bait/stickers dry after application, protected from moisture and condensed water. No wet cleaning of fly bait/stickers. If this occurs accidentally, do not rinse out the cleaning cloth in sinks but immediately dispose it to domestic waste.

For the protection of the environment the instruction for use on label, leaflet and safety data sheet must be followed.

2.5.2 Risk mitigation measures

1) Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

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

1) IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
2) 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.
3) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
4) IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
5) If medical advice is needed, have product container or label at hand.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Dispose of contents to domestic waste.
2) Non-contaminated packages may be recycled.

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

1) Do not store near food, drink and animal feeding stuff.
2) Keep out of reach of children and non-target animals/pets.
3) Shelf-life: 45 months

2.5.6 Other information

1) The product contains a bittering agent.

Resistance management:

- Where an extended period of control is required, treatments should be alternated with products containing active substances with different modes of action.
- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- Avoid continuous use of the product.
- Products should always be used in accordance with label recommendations.

2.6 Packaging

Table 2

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**
Box	2-12 transparent strips per cardboard box	Paper	n/a	Non-professional	Yes
Box	1-10 motif stickers per cardboard box	Paper	n/a	Non-professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – Fly Bait transparent

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	The product Fly Bait consists of two inert ready-to-use paper/plastic strips (32.4 cm² per two strips) loaded with an insecticidal caloric bait formulation to be fixed to window frames or panes outside the reach of children. Fly Baits are available as transparent fly bait strips ready-for use.
Target organism(s) (including development stage)	Muscidae: House fly Adults
Field(s) of use	Indoor Indoor use in domestic areas
Application method(s)	Cream, Caloric bait formulation (printed in a thin layer onto self-adhesive stripes / motif sticker) The product Fly Bait consists of two inert ready-to-use paper/plastic strips (32.4 cm² per two strips) loaded with an insecticidal caloric bait formulation to be fixed to window frames or sills outside the reach of children. Fly Baits are available as transparent fly bait strips ready-for use
Application rate(s) and frequency	Two Fly Baits strips per 15 m^2 room. The strip is active for 6 months.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	2 - 12 transparent strips per cardboard box

3.1.1 Intended use 2 – Fly Bait motif sticker

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)

Where relevant, an exact description of the use	The product Fly Bait is an inert ready-to-use paper/plastic sticker (32.4 cm^2) loaded with an insecticidal paste to be fixed to windows glass outside the reach of children. Fly Baits are available as fly bait motif stickers ready-for use
Target organism(s) (including development stage)	Muscidae: House fly Adults
Field(s) of use	Indoor Indoor use in domestic areas
Application method(s)	Cream, Caloric bait formulation (printed in a thin layer onto self-adhesive stripes / motif sticker) The product Fly Bait is an inert ready-to-use paper/plastic sticker (32.4 cm^2) loaded with an insecticidal caloric bait formulation to be fixed to windows glass outside the reach of children. Fly Baits are available as fly bait motif stickers ready-for use
Application rate(s) and frequency	One Fly Baits sticker per 15 m^2 room. The sticker is active for 6 months.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	1 - 10 motif stickers per cardboard box

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	Visual inspection	Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	Fly Bait is a self-adhesive sticker. Each single unit sheet of sticker consists of protective paper and adhesive stickers	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04213
		Fly bait Imidacloprid, Caloric bait formulation (product; nominal a.s. content: 4.3%)	paste	Aeroxon Insect Control GmbH (**2013**); Statement
	ISO 2137 (2007); Penetrometer test ADR (2015)	Fliegenköder Imidacloprid Caloric bait formulation Batch No. B075, a.s. content: 4.4%	liquid (Due to the penetration of > 15 mm after 5 s in three tests the test item has to be assessed as liquid.)	consilab Gesellschaft für Anlagensicherheit mbH (**2021**) Study no.: CSL-21-0382.01
Colour at 20 °C and 101.3 kPa	Visual inspection	Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	The stickers are coloured red and yellow.	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04213
		Fly bait Imidacloprid, Caloric bait formulation (product; nominal a.s. content: 4.3%)	beige	Aeroxon Insect Control GmbH (**2013**); Statement
Odour at 20 °C and 101.3 kPa	Olfactory inspection	Fliegenköder including carrier:	odourless	Eurofins Agroscience Services EcoChem GmbH (**2013**),

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).		Study no.: S12-04213
		Fly bait Imidacloprid, Caloric bait formulation (product)	odourless	Aeroxon Insect Control GmbH (**2013**); Statement
Acidity / alkalinity	CIPAC MT 75.3	Fly bait Imidacloprid (Caloric bait formulation) Batch/Lot number: P-128 Content of a.s. (analysed): 4.3%	The mean pH value of a 1% (w/v) solution of Fly bait (plain paste) in water was determined to be 7.11 (20.0ºC). The acidity respectively alkalinity was not determined since the pH value of the formulation was > 4 and < 10.	Eurofins Agroscience Services EcoChem GmbH (**2013**); Study No. : S13-04117
Relative density / bulk density	EU Method A.3 / OECD 109 (oscillating densitometer)	Fliegenköder Cypermethrin (Caloric bait formulation); Batch No.: C010; Content a.i. (Cypermethrin): 7% w/w (bridging; for composition of the tested product, please refer to the conf. Annex)	D_4^{20} = 1.176	consilab Gesellschaft für Anlagensicherheit mbH (**2022a**)Study no.: CSL-22-0094.01
Storage stability test – **accelerated storage**	CIPAC MT 46; GIFAP Monograph 17	Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	<u>Storage for 2 weeks at 54°C:</u> **Stability of the commercial packaging material (visual):** start: cardboard package containing two sheets of sticker each with two coloured adhesive motive sticker; tightly sealed prior to opening	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04213

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			after storge: no visible damage or deterioration of the outer packaging **Weight change:** after storage: change in weight of ≤ 2.6% **appearance, colour, odour:** start: Each sheet of sticker consists of protective paper, two adhesive window motive stickers (coloured red and yellow) and backing sheet. The stickers are odourless. after storage: colour and odour: no change; sticker sheets: slightly waved; protective paper: partly peeled from the sticker **a.s. content:** start: 7.8 mg Imidacloprid per unit after storage: 7.6 mg Imidacloprid per unit **Applicability and Product Integrity of the sticker*:**	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			start: suitable after storage: suitable ** The applicability and product integrity of the sticker were tested by removal of the adhesive window foil from the sticker and application of the adhesive window foil onto a glass surface. The test was performed with an adequate number of stored and un-stored stickers and assessed by visual inspection.* **Conclusion:** Based on the given results, the test item is stable for two weeks at 54°C.	
Storage stability test – **long term storage at ambient temperature**		Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	<u>4-year-storage test at 20°C:</u> **Stability of the commercial packaging material (visual):** start: cardboard package containing two sheets of sticker each with two coloured adhesive motive sticker; tightly sealed prior to opening after 6 months: no visible damage after 12 months: no visible damage after 24 months: no visible damage after 48 months:	Eurofins Agroscience Services EcoChem GmbH (**2016**), Study no.: S12-04214

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			no visible damage **Weight change:** after 6 months: change in weight of ≤ 1.01% after 12 months: change in weight of ≤ 0.44% after 24 months: change in weight of ≤ 0.63% after 48 months: change in weight of ≤ 0.19% **appearance, colour, odour:** start: Each sheet of sticker consists of protective paper, two adhesive window motive stickers (coloured red and yellow) and backing sheet. The stickers are odourless. after 6 months: no change after 12 months: no change after 24 months: no change after 48 months: no change **a.s. content:** start: 7.7 mg Imidacloprid per unit	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			after 6 months: 7.9 mg Imidacloprid per unit after 12 months: 7.6 mg Imidacloprid per unit after 24 months: 7.7 mg Imidacloprid per unit after 48 months: 7.5 mg Imidacloprid per unit **Applicability and Product Integrity of the sticker*:** start: suitable after storage: suitable ** The applicability and product integrity of the sticker were tested by removal of the adhesive window foil from the sticker and application of the adhesive window foil onto a glass surface. The test was performed with an adequate number of stored and un-stored stickers and assessed by visual inspection.* **Conclusion:** Based on the given results, the test item is stable for 48 months at 20°C.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Fliegenköder Cypermethrin (Caloric bait formulation); Batch No.: C010;	The appearance of the product remains unchanged after storage at 0±2°C for 7 days; no phase separation was observed.	consilab Gesellschaft für Anlagensicherheit mbH (**2022b**),

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Content a.i. (Cypermethrin): 7% w/w (bridging; for composition of the tested product, please refer to the conf. Annex)		Study no.: CSL-22-0094.04
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	method: Three stickers were applied onto the outer side of a Duran glass bottle and stored (72 h, temperature of 20 - 25°C and under a constant radiation of 5000 to 8000 lux of daylight.	Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	The application of the adhesive window foil onto the glass surface was without any difficulties. After the above described storage procedure the used sticker were found to be easily and residue-free removable from the glass surface. With regard to the sealed stickers, Fly Bait is stored and transported in cardboard boxes, thus is not exposed to direct UV-Vis light and is deemed to be stable during its storage and transportation. The product is stored and transported in cardboard boxes, thus it is not exposed to direct UV-Vis light.	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04213
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46; GIFAP Monograph 17	Fliegenköder including carrier: Fly Bait Imidacloprid; Batch No. N088/N093 / Stated amount of Imidacloprid (per unit): 7.7 mg. Nominal content 7.5 mg (per unit).	Please refer to the results of the accelerated storage test: The product was found to be stable at 54°C for two weeks. No humidity was measured. Taking into account that the product is intended to be used indoor attached to the window, no extreme humidity values are expected.	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04213

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**			The information about the packaging material is sufficient.	Dangerous Goods Database http://www.dgg.bam.de/en/
Wettability	-	-	Not required. Fly Bait is a ready-to-use product without any wetting or solution step before usage.	Waiving
Suspensibility, spontaneity and dispersion stability	-	-	Not required. Fly Bait is a ready-to-use product without any wetting or solution step before usage.	Waiving
Wet sieve analysis and dry sieve test	-	-	Not required. Fly Bait is a ready-to-use product without any wetting or solution step before usage.	Waiving
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not required since Fly Bait is not an emulsion.	Waiving
Disintegration time	-	-	Not required since Fly Bait is not a tablet.	Waiving
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not required since Fly Bait is not a tablet or granular formulation.	Waiving
Persistent foaming	-	-	Not required since Fly Bait is a solid ready-to-use product without any water contact during usage.	Waiving
Flowability/Pourability/Dustability	-	-	Not required since Fly Bait is neither a granular preparation nor a suspension.	Waiving
Burning rate — smoke generators	-	-	Not required. Fly Bait is not a smoke generator.	Waiving

<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>Burning completeness — smoke generators</td><td>-</td><td>-</td><td>Not required. Fly Bait is not a smoke generator.</td><td>Waiving</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td>-</td><td>-</td><td>Not required. Fly Bait is not a smoke generator.</td><td>Waiving</td></tr>
<tr><td>Spraying pattern — aerosols</td><td>-</td><td>-</td><td>Not required since Fly Bait is not an aerosol.</td><td>Waiving</td></tr>
<tr><td>Physical compatibility</td><td>-</td><td>-</td><td>Not required since Fly Bait is a ready-to-use product and not intended to be used with other products.</td><td>Waiving</td></tr>
<tr><td>Chemical compatibility</td><td>-</td><td>-</td><td>Not required since Fly Bait is a ready-to-use product and not intended to be used with other products.</td><td>Waiving</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>-</td><td>-</td><td>Not required since Fly Bait is a ready-to-use product and is not intended to be diluted/disolved.</td><td>Waiving</td></tr>
<tr><td>Surface tension</td><td>EU Method A.5 / OECD 115</td><td>Fliegenköder Cypermethrin (Caloric bait formulation);
Batch No.: C010;
Content a.i. (Cypermethrin): 7% w/w
(bridging; for composition of the tested product, please refer to the conf. Annex)</td><td>Surface tension (at 20°C, concentration: 1 g/L): 49.8 mN/m (surface-active material)</td><td>consilab Gesellschaft für Anlagensicherheit mbH (2022c),
Study no.: CSL-22-0094.02</td></tr>
<tr><td>Viscosity</td><td>OECD 114
(rotational rheometer)</td><td>Fliegenköder Cypermethrin (Caloric bait formulation);
Batch No.: C010;
Content a.i. (Cypermethrin): 7% w/w</td><td>Viscosity at 20°C:<table><tr><th>Shear rate [s^{-1}]</th><th>Mean η [mPa·s]</th></tr><tr><td>20.0</td><td>1172</td></tr><tr><td>22.6</td><td>1121</td></tr></table></td><td>consilab Gesellschaft für Anlagensicherheit mbH (2022d),
Study no.: CSL-22-0094.03</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>(bridging; for composition of the tested product, please refer to the conf. Annex)</td><td>
<table>
<tr><td>25.6</td><td>1083</td></tr>
<tr><td>29.0</td><td>1049</td></tr>
<tr><td>32.8</td><td>1014</td></tr>
<tr><td>37.1</td><td>980</td></tr>
<tr><td>42.0</td><td>948</td></tr>
<tr><td>47.6</td><td>915</td></tr>
<tr><td>53.8</td><td>884</td></tr>
<tr><td>60.9</td><td>853</td></tr>
<tr><td>69.0</td><td>823</td></tr>
<tr><td>78.1</td><td>794</td></tr>
<tr><td>88.4</td><td>766</td></tr>
<tr><td>100.0</td><td>739</td></tr>
</table>

Viscosity at 40°C:
<table>
<tr><th>Shear rate [s^{-1}]</th><th>Mean η [mPa·s]</th></tr>
<tr><td>20.0</td><td>543</td></tr>
<tr><td>22.6</td><td>517</td></tr>
<tr><td>25.6</td><td>498</td></tr>
<tr><td>29.0</td><td>482</td></tr>
<tr><td>32.8</td><td>466</td></tr>
<tr><td>37.1</td><td>452</td></tr>
<tr><td>42.0</td><td>437</td></tr>
<tr><td>47.6</td><td>423</td></tr>
<tr><td>53.8</td><td>410</td></tr>
<tr><td>60.9</td><td>297</td></tr>
<tr><td>69.0</td><td>385</td></tr>
</table>
</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			78.1 373 88.4 362 100.0 351 Overall, the same decrease of viscosity dependent on the shear rate was observed at 20 °C and at 40 °C. In conclusion, the test item can be described as a non-Newtonian fluid with shear-thinning properties.	

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. Fliegenköder/Fly Bait is a beige, odourless (pasty) liquid formulation. (The caloric bait formulation is applied to self-adhesive stickers (the stickers are red and yellow)). The mean pH value of a 1% (w/v) solution of Fly bait (caloric bait formulation) in water is 7.11 (20.0ºC). Based on the results of the storage tests, the product (in the original packaging) is stable for 2 weeks at 54°C and for 48 months at 20°C. At renewal-stage read-across data on a similar product had been submitted. Based on these results the relative density of the product is about 1.176 at 20°C. The product did not separate after 7 days at 0°C. Surface tension of the product (1 g/L) was 49.8 mN/m at 20°C, so that the material can be regarded as surface-active. Since the viscosity of the test item decreased with increasing shear rates at 20°C and 40°C, the test item can be described as a non-Newtonian fluid with shear-thinning properties. (For composition of the tested product „Fliegenköder Cypermethrin", please refer to the conf. Annex.)

3.3 Physical hazards and respective characteristics

Table 3: 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 Manual of Tests and Criteria, Rev. 7 (2019), Class 1 and Appendix 6, DSC-measurements in gold-plated stainless-steel crucibles under air are performed	Fliegenköder Imidacloprid (Caloric bait formulation); Batch No.: B103, 4.1 % Imidacloprid	Exothermic decomposition energy: In the temperature range of 110 - 290°C an exothermic effect could be observed with an average energy release of -330 J/g.	In accordance with the CLP criteria of section 2.1.4.3. the acceptance procedure for the hazard class 'explosives' need not be applied if the exothermic decomposition energy is less than 500 J/g.	consilab Gesellschaft für Anlagensicherheit mbH (**2021a**); Study No.: CSL-21-0804.02
Flammable gases	study scientifically unjustified	-	-	Not relevant as Fly Bait is not a gaseous product.	Waiving
Flammable aerosols	study scientifically unjustified	-	-	Not relevant as Fly Bait is not an aerosol dispenser.	Waiving
Oxidising gases	study scientifically unjustified	-	-	Not relevant as Fly Bait is not a gaseous product.	Waiving
Gases under pressure	study scientifically unjustified	-	-	Not relevant as Fly Bait is not a gaseous product.	Waiving
Flammable liquids	DIN EN ISO 3679 (Rapid Tester NPV 310)	Fliegenköder Imidacloprid (Caloric bait formulation); Batch No.: B103, 4.1 % Imidacloprid	Flash point 287.0 °C	With a flash point of 287.0 °C (> 60 °C), the product does not have to be classified as Flammable Liquid.	consilab Gesellschaft für Anlagensicherheit mbH (**2021c**); Study No.: CSL-21-0804.01

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable solids	study scientifically unjustified	-	-	Not relevant, as Fly Bait is not a solid.	Waiving
Self-reactive substances and mixtures	UN Test H.2 in Part II, Section 28.4.2 of the UN-MTC (2019); ST/SG/AC.10/11/Rev. 7 (2020/2021)	Fliegenköder Imidacloprid; Batch No.: C241; 4.3% Imidacloprid	SADT >75°C for a 50 kg package (liquid formulation)	Since the exothermic decomposition energy determined by DSC-measurements is greater than 300 J/g and since the exothermic decomposition starts at 110 °C (onset temperature), the self-accelerating decomposition temperature (SADT) for a 50 kg package was determined. Since the SADT was determined to be >75°C for a 50 kg package, self-reactive properties can be excluded (classification criteria according to Section 2.8.2.1. of Annex I, Part 2, of the CLP Regulation).	consilab Gesellschaft für Anlagensicherheit mbH (2022); CSL-22-1650
Pyrophoric liquids	UN Test N.3, in Part III, Section 33 of the UN-MTC (2019)	Fliegenköder Imidacloprid (Caloric bait formulation); Batch No.: B103, 4.1 % Imidacloprid		No ignition was observed during the two parts of the test concerning the pyrophoric properties of liquids. Therefore, the product has no pyrophoric properties.	consilab Gesellschaft für Anlagensicherheit mbH (**2021e**); Study No.: CSL-21-0804.05
Pyrophoric solids	study scientifically unjustified	-	-	The product does not contain any pyrophoric compounds. No pyrophoric properties are expected.	Waiving

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-heating substances and mixtures	study scientifically not necessary	-	-	The study does not need to be conducted, because the product undergoes exothermic decomposition at a temperature below or equal to 140°C.	Waiving
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary	-	-	The study does not need to be conducted, because the product is known to be soluble in water to form a stable mixture.	Waiving
Oxidising liquids	UN Test O.2 in Part III, Section 34 of the UN-MTC (2019)	Fliegenköder Imidacloprid, Batch No.: B103, 4.1 % Imidacloprid	The mean pressure rise time for the product (36.38 s) taken from four tests is greater than the mean pressure rise time for the reference item nitric acid 65 % (2.49 s).	The product does not have to be classified as oxidizing liquid.	consilab Gesellschaft für Anlagensicherheit mbH (**2021b**); Study No.: CSL-21-0804.04
Oxidising solids	study scientifically unjustified	-	-	Not relevant, as Fly Bait is not a solid.	Waiving
Organic peroxides	study scientifically not necessary	-	-	Based on the product composition. No organic peroxides were incorporated. No further consideration required.	Waiving

<table>
<tr><th>Hazard class / characteristics</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Parameter</th><th>Results</th><th>Reference</th></tr>
<tr><td>Corrosive to metals</td><td>UN Test C.1. in Part III, Section 37.4 of the UN-MTC (2019)</td><td>Fliegenköder Imidacloprid (Caloric bait formulation); Batch No.: B103, 4.1 % Imidacloprid</td><td></td><td>The product has no corrosive properties to metals.</td><td>consilab Gesellschaft für Anlagensicherheit mbH (2021d); Study No.: CSL-21-0804.06</td></tr>
<tr><td colspan="3"></td><td colspan="2"><table>
<tr><td>Type of material</td><td>Aluminium (7075-T6)</td><td>Steel (S235JR+CR)</td></tr>
<tr><td>Exposure time (days)</td><td>14</td><td>14</td></tr>
<tr><td>Temperature during exposure</td><td>55.0 °C</td><td>55.0 °C</td></tr>
<tr><td>Mass loss of the most corroded sample (%)</td><td>< 0.1</td><td>0.7</td></tr>
<tr><td>Max. intrusion depth (µm)</td><td>No intrusion depths could be found microscopically</td><td>44.3</td></tr>
</table>The test is considered positive if for any specimen the mass loss on the metal specimen is more than 26.5 % after 14 days or if the deepest intrusion exceeds 240 µm.</td><td></td></tr>
<tr><td>Auto-ignition temperature (liquids and gases)</td><td>Regulation (EC) No 440/2008, Method A.15, DIN 51794, DIN EN 14522</td><td>Fliegenköder Imidacloprid (Caloric bait formulation); Batch No.: B103, 4.1 % Imidacloprid</td><td></td><td>Auto-ignition Temperature: 440 °C</td><td>consilab Gesellschaft für Anlagensicherheit mbH (2021f); Study No.: CSL-21-0804.03</td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td>study scientifically unjustified</td><td>-</td><td>-</td><td>Not relevant, as Fly Bait is not a solid.</td><td>Waiving</td></tr>
<tr><td>Dust explosion hazard</td><td>study scientifically unjustified</td><td>-</td><td>-</td><td>Not relevant, as Fly Bait is not a solid.</td><td>Waiving</td></tr>
</table>

Table 8

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. All the studies were performed using the caloric paste that covers the foil sticker. Based on the results in can be concluded that Fly bait is not flammable, explosive, nor oxidising or capable of self-heating. It is neither pyrophoric, do not contain organic peroxides or is corrosive to metals. It has the auto-ignition temperature of 440°C. No classification in respect of physical hazards is warranted, no special labelling necessary.

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, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC/PDA	HPLC/PDA analysis of the blank formulation showed no significant interference (< 3%) with the signal of imidacloprid.	R^2 = 1.000 Range: 2.51 - 501.5 ng/injection	70 - 130% (n = 5)	98-101	99	1.1	5.0 mg/unit, equivalent to 0.07% (w/w)	Eurofins Agroscience Services EcoChem GmbH (**2013**), Study no.: S12-04212

Table 16

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance were acceptable
Methods for the detection of imidacloprid in soil, air and water were provided and deemed acceptable at EU level. During the next active substance renewal, the limit of 0.0048 µg/L based on PNECwater should be considered for the analytical methods for the determination of residues of Imidacloprid in surface water. Methods for body fluids and tissues seemed to be not necessary as Imidacloprid was not classified as toxic or very toxic. Since December 17th 2022, according to the 17th ATP of CLP-Regulation, Imidacloprid is classified as Acute tox. 3. During the next active substance renewal, the need for analytical methods for body fluids and tissues according to this classification should be considered.
The product is not intended to be used in contact with food/feed of plant and animal origin; therefore, analytical methods for the determination of active substances in food/feed of plant and animal origin are not required.
Analytical methods for the determination of residues of substances of concern are not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The product “Fliegenköder” (“Fly bait transparent” and “Fly bait motif sticker”) is an insecticide (PT18) and contains the active substance imidacloprid (7.5 mg a.i. per sticker corresponding to 4.3% a.i. in the formulation). One motif sticker (surface: 32.4 cm²) should be attached on the window glass, while the adhesive plastic strip (surface of two strips: 32.4 cm²) should be attached on window frames or sills. The product “Fliegenköder” (“Fly bait transparent” and “Fly bait motif sticker”) is intended for use as bait for the control of house flies (*Musca domestica*) in households by non-professionals.
The overall data package supports the label claim that the product “Fliegenköder” can be used for efficient housefly (*Musca domestica*) control in households with a residual efficacy of 6 months and a shelf life of 45 months.

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

The product “Fliegenköder” is intended to be used to control adult house flies (*Musca domestica*) indoors. Houseflies are a nuisance and a hygienic problem. They annoy people, lay their eggs on open food sources or contaminate food. The product is therefore used to protect health and food.

3.5.3 Effects on target organisms, including unacceptable suffering

The target organisms are attracted by the bait and feed on it. Due to its mode of action the active substance imidacloprid leads to knock down and mortality of adult houseflies.

3.5.4 Mode of action, including time delay

Imidacloprid acts as a contact insecticide as well as upon ingestion. Imidacloprid is a neonicotinoid, belonging to the 4A group of insecticides according of the IRAC classification scheme. These act as nicotinic acetylcholine receptor (nAChR) agonists. Neonicotinoids bind to nicotinic acetylcholine receptors of cells. Ultimately, this blockage causes paralysis and death of the insect within a time delay of some hours.

3.5.5 Efficacy data

The efficacy data package consisted of five simulated-use studies (for details see table 25).
In the simulated-use studies by anonymous (2012, 2013) knockdown and 24 h mortality were monitored over time and resulted in sufficient efficacy outcomes with the motif sticker product: 8 h knockdown values exceeded 80% (93% in the fresh bait study and 88% in the aged bait study, respectively) and 24 h mortality values exceeded 90% (i.e. 99% in both studies). Mortality in the untreated controls was 1%. Therefore, this studies sufficiently prove the efficacy of the fresh and 6-months aged motif sticker product under real use condition against adult houseflies (*Musca domestica*).
The study by Kinsey (2014) compared five different stickers, which varied in their colour composition to the originally tested sticker in the studies by anonymous (2012, 2013). The test was conducted with an artificial light source; therefore, the results for 8 h knockdown (19.5 – 35%) and 24 h mortality (39.8 – 52.5%) were not as high as in the studies by anonymous (2012, 2013). However, as the results were comparable for all six sticker designs, including the one originally tested, the German CA considers the data for the sticker varieties as sufficient and concludes that the design and colour did not influence the efficacy.
The simulated-use study by anonymous (2015) evaluated the efficacy of the 2-years aged sticker in packaging and 6-months aged under usage conditions (i.e. attached to a window). The knock-down was 88%, and mortality was 99 - 100% after 24 h. In the untreated controls a mortality of 3% was demonstrated. Furthermore, a simulated use study (anonymous 2016) was conducted with a bait that had been aged for 4 years and 3 months in packaging and under usage conditions (i.e. attached to a window). Knockdown was 89% after 10 h and 24 h mortality values exceeded 94%. In accordance with the TNsG for PT18 (2016) the German CA considers that the efficacy of the 4 years and 3 months aged product is proven. According to the use description, the product should be efficacious for 6 months after opening. A shelf life of 3 years and 9 months plus an in-use period of 6 months has been proven by the submitted study.

The German CA considers that the results are suitable for extrapolation to the transparent strips for the following reasons: The surface of two strips is equivalent to the surface of one sticker, and also the amount of active ingredient on two strips is equivalent to the amount on one sticker. These two transparent products induce no optical difference to the flies, and the flies therefore will equally land on them as on the motif stickers.

The overall data package supports the label claim that the product “Fliegenköder” can be used for efficient housefly (*Musca domestica*) control in households with a residual efficacy of 6 months and a shelf life of 45 months.

Table 17

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>PT18</td><td>Indoor</td><td>Window Sticker „Fly Bait Imidacloprid“; fresh;
transparent</td><td>Musca domestica (adult; age: 3-4 d; mixed sex)</td><td>simulated-use test:
test room: 30 m³ with 2 external windows;
light regime: daylight;
temperature: 24-25°C;
relative humidity: 49-60%;
one sticker per room; sticker application onto the glass of the window;
replicates: 4 (each with 100 flies);
control: without sticker</td><td>Evaluation: 1 h, 4 h, 8 h, 24 h after introduction of test insects into test chamber
Test criteria:
- knock down/mortality up to 10 hours – mortality after 24 hours</td><td>
<table>
<tr><td></td><td colspan="3">Window sticker “Fly Bait Imidacloprid”
Batch: N088/N093 Active: 7.5 mg Imidacloprid per sticker</td></tr>
<tr><td>test after:</td><td>% knock down / mortality totally per room</td><td>% knock down / mortality in 1.5 m area *</td><td>% knock down / mortality on sill</td></tr>
<tr><td>1 hour</td><td>5 (3 - 7)</td><td>3 (2 - 4)</td><td>1 (0 - 2)</td></tr>
<tr><td>4 hours</td><td>66 (54 - 76)</td><td>9 (33 - 49)</td><td>11 (6 - 15)</td></tr>
<tr><td>8 hours **</td><td>93 (91 - 94)</td><td>58 (55 - 65)</td><td>23 (21 - 28)</td></tr>
<tr><td colspan="4">% mortality of flies (collected flies showing efficacy after 8 hours, and flies remained in the test rooms) 24 hours after test start:
100
(99 - 100)</td></tr>
</table>
</td><td>anonymous</td></tr>
</table>

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**
						<table><tr><th></th><th colspan="3">Untreated Control</th></tr><tr><th>test after:</th><th>% knock down / mortality totally per room</th><th>% knock down / mortality in 1.5 m area *</th><th>% knock down / mortality on sill</th></tr><tr><td>1 hour</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td>4 hours</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td>8 hours **</td><td>0 (0 - 1)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td colspan="4">% mortality of flies (collected flies showing efficacy after 8 hours, and flies remained in the test rooms) 24 hours after test start: 1 (0 - 2)</td></tr></table> Note: all means rounded on integers * 1.5 m area: in a width of 1.5 metres in front of the windows ** The flies which have been showing efficacy after 8 hours were collected for additional evaluation of mortality for up to 24 hours after test start. Therefore the flies were transferred to insecticide-free transparent plastic beakers. The beakers were sealed with lids and provided with cellulose swabs soaked in 10 % sugar solution	

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	Window Sticker „Fly Bait Imidacloprid“; aged: 6 month (south side window); transparent	*Musca domestica* (adult; age: 3-4 d; mixed sex)	simulated-use test: test room: 30 m³ with 2 external windows; light regime: daylight; temperature: 24-26°C; relative humidity: 43-60%; one sticker per room; sticker application onto the glass of the window; replicates: 4 (each with 100 flies); control: without sticker	Evaluation: 1 h, 4 h, 8 h, 24 h after introduction of test insects into test chamber Test criteria: - knock down/mortality up to 10 hours – mortality after 24 hours	**Window sticker “Fly Bait Imidacloprid”** **6 months aged** (under use conditions) Batch: N088/N093 Active: 7.5 mg Imidacloprid per sticker test after: / % knock down / mortality totally per room / % knock down / mortality in 1.5 m area * / % knock down / mortality on sill 1 hour: 20 (11 - 29) / 10 (6 - 12) / 7 (5 - 10) 4 hours: 61 (36 - 72) / 53 (29 - 65) / 19 (11 - 27) 8 hours **: 88 (75 - 96) / 78 (64 - 84) / 25 (19 - 33) **% mortality of flies** (collected flies showing efficacy after 8 hours, and flies remained in the test rooms) **24 hours after test start:** **100** (99 - 100)	anonymous

<table>
<tr><th colspan="7">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>
<table>
<tr><th></th><th colspan="3">Untreated Control</th></tr>
<tr><th>test after:</th><th>% knock down / mortality totally per room</th><th>% knock down / mortality in 1.5 m area *</th><th>% knock down / mortality on sill</th></tr>
<tr><td>1 hour</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr>
<tr><td>4 hours</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr>
<tr><td>8 hours **</td><td>0 (0 - 1)</td><td>0 (-)</td><td>0 (-)</td></tr>
<tr><td colspan="4">% mortality of flies (collected flies showing efficacy after 8 hours, and flies remained in the test rooms) 24 hours after test start:
1
(0 - 3)</td></tr>
</table>
Note: all means rounded on integers
* 1.5 m area: in a width of 1.5 metres in front of the windows
** The flies which have been showing efficacy after 8 hours were collected for additional evaluation of mortality for up to 24 hours after test start. Therefore the flies were transferred to insecticide-free transparent plastic beakers. The beakers were sealed with lids and provided with cellulose swabs soaked in 10 % sugar solution
</td><td></td></tr>
<tr><td>PT18</td><td>Indoor</td><td>variants of the stickers (printed with different transparent colors): green, yellow, red, blue, neutral (without color) and butterfly motif design; untreated control</td><td>Musca domestica (adult; age: 3-5 d; mixed sex)</td><td>simulated-use test:
test chamber: 5.1 x 2.4 x 2.5 m, containing a simulated window (1 x 1 m) illuminated by an artificial light source; light:</td><td>Evaluation: 2 h, 4 h, 8 h, 24 h after introduction of test insects into test chamber
Test criteria: knock down and mortality</td><td>Percentage affected (knocked down and dead) houseflies following exposure to 6 window sticker product variants over a 24 hour experimental period (Means ± standard errors, n = 4)
<table>
<tr><th>Time post application</th><th>Green</th><th>Yellow</th><th>Red</th><th>Blue</th><th>Neutral</th><th>Butterfly Motif</th><th>Untreated control</th></tr>
<tr><td>2 hrs</td><td>9.3 (± 3.4)</td><td>6.8 (± 0.9)</td><td>5.0 (± 2.0)</td><td>10.0 (± 4.5)</td><td>3.0 (± 1.1)</td><td>9.8 (± 1.8)</td><td>2.8 (± 1.7)</td></tr>
<tr><td>4 hrs</td><td>16.3 (± 4.6)</td><td>12.3 (± 1.9)</td><td>10.0 (± 3.8)</td><td>16.5 (± 5.5)</td><td>9.8 (± 1.8)</td><td>19.0 (± 1.6)</td><td>3.5 (± 2.1)</td></tr>
<tr><td>8 hrs</td><td>26.0 (± 3.2)</td><td>19.5 (± 2.3)</td><td>21.5 (± 4.0)</td><td>35.0 (± 6.1)</td><td>24.3 (± 2.3)</td><td>30.0 (± 3.1)</td><td>4.8 (± 2.1)</td></tr>
<tr><td>24 hrs</td><td>52.5 (± 1.4)</td><td>45.0 (± 7.4)</td><td>39.8 (± 9.4)</td><td>50.8 (± 4.0)</td><td>50.8 (± 7.9)</td><td>44.3 (± 5.0)</td><td>10.0 (± 2.0)</td></tr>
</table>
</td><td>anonymous</td></tr>
</table>

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**
				dark 16:8; temperature: 20.0-23.7°C; relative humidity: 29.8-50.7%; Lux: 6.0-7.0 mWm^{-2}; one sticker per test chamber; sticker application onto the glass of the window; replicates: 4 for each treatment (total: 28 tests, each with 100 flies)			

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>PT18</td><td>Indoor</td><td>Window Sticker „Fly Bait Imidacloprid“; aged product: 31 month old sticker was aged for 6 month (south side window); transparent</td><td>Musca domestica (adult; age: 3-4 d; mixed sex)</td><td>simulated-use test:
test room: 30 m³ with 2 external windows;
light regime: daylight;
temperature: 24-26°C;
relative humidity: 41-60%;
one sticker per room; sticker application onto the glass of the window;
replicates: 4 (each with 100 flies);
control: without sticker</td><td>Evaluation: 1 h, 4 h, 8 h, 24 h after introduction of test insects into test chamber
Test criteria:
- knock down/mortality up to 10 hours – mortality after 24 hours</td><td>
<table>
<tr><th colspan="4">Window sticker “Fly Bait Imidacloprid”
2 years and 7 month old and
<u>6 months aged</u> (under use conditions)
Batch: N088/N093C Active: 7.5 mg Imidacloprid per sticker</th></tr>
<tr><th>test after:</th><th>% knock down / mortality total per room</th><th>% knock down / mortality in 1.5 m area *</th><th>% knock down / mortality on sill</th></tr>
<tr><td>1 hour</td><td>22 (17 - 27)</td><td>10 (7 - 12)</td><td>8 (3 - 11)</td></tr>
<tr><td>4 hours</td><td>54 (44 - 66)</td><td>29 (19 - 40)</td><td>16 (13 - 17)</td></tr>
<tr><td>8 hours</td><td>80 (71 - 91)</td><td>37 (30 - 48)</td><td>24 (22 - 34)</td></tr>
<tr><td>10 hours **</td><td>88 (84 - 95)</td><td>40 (35 - 48)</td><td>27 (25 - 36)</td></tr>
<tr><td colspan="4">% mortality of flies (collected flies showing efficacy after 10 hours, and flies remained in the test rooms) 24 hours after test start:
100
(99 - 100)</td></tr>
</table>
</td><td>anonymous</td></tr>
</table>

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**
						<table><tr><th></th><th colspan="3">Untreated Control</th></tr><tr><th>test after:</th><th>% knock down / mortality total per room</th><th>% knock down / mortality in 1.5 m area *</th><th>% knock down / mortality on sill</th></tr><tr><td>1 hour</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td>4 hours</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td>8 hours</td><td>0 (-)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td>10 hours **</td><td>0 (0 - 1)</td><td>0 (-)</td><td>0 (-)</td></tr><tr><td colspan="4">% mortality of flies (collected flies showing efficacy after 10 hours, and flies remained in the test rooms) 24 hours after test start: 3 (2 - 5)</td></tr></table> Note: all means rounded to integers * 1.5 m area: in a width of 1.5 metres in front of the windows ** The flies which have been showing efficacy after 10 hours were collected for additional evaluation of mortality for up to 24 hours after test start. These flies were transferred to insecticide-free transparent plastic beakers. The beakers were sealed with lids and provided with cellulose swabs soaked in 10 % sugar solution	

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	Window Sticker „Fly Bait Imidacloprid“; aged product: 43 month old sticker was aged for 8 months (north side window); transparent	*Musca domestica* (adult; age: 3-4 d; mixed sex)	Simulated-use test: test room: 30 m³ with 2 external windows; light regime: daylight; temperature: 23-25°C; relative humidity: 59-64%; one sticker per room; sticker application onto the glass of the window; replicates: 4 (each with 100 flies); control: without sticker	Evaluation: 1 h, 4 h, 8 h, 24 h after introduction of test insects into test chamber Test criteria: - knock down/mortality up to 10 hours – mortality after 24 hours	**Age of products: Stored 3 years, 7 months and aged 8 months under usage conditions** **Window sticker "Fly Bait Imidacloprid"** **3 years and 7 months old and** **8 months aged** (under use conditions) Batch: N088 / N093C Active: 7.5 mg Imidacloprid per sticker test after: / % knock down / mortality total per room / % knock down / mortality in 1.5 m area * / % knock down / mortality on sill 1 hour: 14 (10 - 16) / 7 (5 - 9) / 7 (3 - 9) 4 hours: 43 (27 - 49) / 26 (17 - 35) / 15 (8 - 23) 8 hours: 59 (53 - 65) / 32 (26 - 38) / 23 (18 - 31) 10 hours: 89 (86 - 91) / 52 (41 - 60) / 30 (23 - 42) **% mortality of flies 24 hours after test start:** **94** (91 - 97) Note: All means rounded to integers. * 1.5 m area: in a width of 1.5 metres in front of the windows. Untreated controls showed 0 % knock down / mortality after 10 hours and on average of 4 replicates 6 % mortality after 24 hours.	anonymous

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**
						rel. humidity: 39 – 6 **Untreated Control** test after: / % knock down / mortality total per room / % knock down / mortality in 1.5 m area * / % knock down / mortality on sill 1 hour: **0** (-) / 0 (-) / 0 (-) 4 hours: **0** (-) / 0 (-) / 0 (-) 8 hours: **0** (-) / 0 (-) / 0 (-) 10 hours: **0** (-) / 0 (-) / 0 (-) **% mortality of flies 24 hours after test start:** **6** (5 - 10) Note: All means rounded to integers. * 1.5 m area: in a width of 1.5 metres in front of the windows.	

3.5.6 Occurrence of resistance and resistance management

While neonicotinoids have shown to be comparably resistent to resistance development, resistance has in fact appeared in some insects (e.g *Musca domestica* (Abbas et al. 2014, Li et al. 2012)). Enhanced detoxification mediated by cytochrome-P450-dependent monooxygenases appears to be the major mechanism.

The current application as a window sticker does not seem to pose a problem in this regard.

Resistance management advices should be included on the label or associated leaflet for the products:

- Where an extended period of control is required, treatments should be alternated with products containing active substances with different modes of action.
- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- Avoid continuous use of the product.
- Products should always be used in accordance with label recommendations.

References:

Abbas, N., Khan, H., and Ali Shad, S. (2014). Cross-Resistance, stability, and fitness cost of resistance to imidacloprid in Musca domestica L., (Diptera: Muscidae). *Parasitology Research*

Li, J., Wang, Q., Zhang, L., Gao, X. (2012). Characterization of imidacloprid resistance in the housefly *Musca domestica* (Diptera: Muscidae). *Pesticide Biochemistry and Physiology, 102* 109-114

3.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the efficacy studies.

3.5.8 Evaluation of the label claims

The overall data package supports the label claim that the product “Fliegenköder” can be used for efficient housefly (*Musca domestica*) control in households with a residual efficacy of 6 months and a shelf life of 45 months.

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

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

3.5.10 Data waiving and conclusion

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 19

Conclusion on the efficacy
The overall data package supports the label claim that the product “Fliegenköder” can be used for efficient housefly (*Musca domestica*) control in households. Residual efficacy: 6 months shelf life: 45 months

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 20

Imidacloprid	Value	Study	Safety factor
AEL long-term	0.06 mg/kg bw/d	Rat, 2-yr - AR, 2011	100
AEL medium-term	0.2 mg/kg bw/d	Rat, 2-gen., supported by dog, 90-d and rabbit, developmental) - Assessment report (RMS DE, revised 2015)	100
AEL acute	0.4 mg/kg bw/d	Rat, acute neurotoxicity, supported by dog, 28-d (acute effects) - Assessment report (RMS DE, revised 2015)	100
ARfD	Not derived	Assessment report (RMS DE, revised 2015)	
ADI	Not derived	Assessment report (RMS DE, revised 2015)	

Table 21

Imidacloprid	Value	Reference
Inhalative absorption	100 %	Default, AR, 2011
Oral absorption	100 %	Default, AR, 2011
Dermal absorption	70 %	Default according to EFSA Guidance on Dermal Absorption (2017)

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)

Data waiving was acceptable for the following information requirements	
	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. Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the biocidal product 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 does not contain components classified for skin irritation. Based on the pH, classification is also not required.
Classification of the product according to CLP	Not classified.

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) No 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. 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 biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products 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 irritation in relevant concentrations. Based on the pH, classification is also not required.
Classification of the product according to CLP	Not classified

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 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 respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory irritation.
Classification of the product according to CLP	Not classified

3.6.2.4 Skin sensitization

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 not required. According to Annex III of the BPR (Regulation (EU) No 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. Based on safety data sheets and other information for each of the individual components in the biocidal product, 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 biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products 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 any components that are known to have skin-sensitising properties. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified.

3.6.2.5 Respiratory sensitization (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 the 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 respiratory tract sensitising properties. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified.

3.6.2.6 Acute toxicity

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) No 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. 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 biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral): 3046 mg/kg bw
Justification for the selected value	Only the active substance imidacloprid is classified for acute oral toxicity. According to the 17th ATP to Regulation (EC) No 1272/2008, the LD_{50} (oral) of imidacloprid is 131 mg/kg bw. All other components are not classified for acute oral toxicity. Hence, the LD_{50} (oral) of these components are assumed to be above 2000 mg/kg bw. The LD_{50} (oral) of the biocidal product is estimated according to the equation provided in Annex II, point 3.1.3.6.1 of Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

3.6.2.6.1 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) No 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)

Data waiving was acceptable for the following information requirements	
	No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. 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 biocidal product 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
Justification for the selected value	The LC_{50} (inhalation) of all components is estimated to be above 5 mg/L. None of the components is classified for acute inhalation toxicity.
Classification of the product according to CLP	Not classified.

3.6.2.6.2 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. Based on safety data sheets and other information for each of the individual components in the biocidal products, 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 biocidal product was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal) > 2000 mg/kg bw
Justification for the selected value	The LD_{50} (dermal) of all components is estimated to be above 2000 mg/kg bw. None of the components is classified for acute dermal toxicity.
Classification of the product according to CLP	Not classified.

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	In the absence of reliable dermal absorption data, default values according to EFSA Guidance on Dermal Absorption (2012 or 2017) can be applied.

Table 39

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s)	Imidacloprid All scenarios
Value(s)	70 %
Justification for the selected value(s)	Default according to EFSA Guidance on Dermal Absorption (2017)

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

Not relevant.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

In the active substance evaluation (2011), imidacloprid has not been assessed for potential endocrine disrupting properties. 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. No co-formulant of the biocidal product Fliegenköder was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. There is no data indicating that any co-formulant of the biocidal product may have endocrine disrupting properties based on the existing knowledge and

the available scientific information from ECHA databases. Therefore, the co-formulants are not considered to have endocrine disrupting properties. For details refer to the Confidential Annex.

3.6.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on the available information for the single components: Not classified.
Eye irritation	Based on the available information for the single components: Not classified.
Respiratory tract irritation	Based on the available information for the single components: Not classified.
Skin sensitisation	Based on the available information for the single components: Not classified.
Respiratory sensitization (ADS)	Based on the available information for the single components: Not classified.
Acute toxicity by oral route	Based on the available information for the single components: Not classified.
Acute toxicity by inhalation	Based on the available information for the single components: Not classified.
Acute toxicity by dermal route	Based on the available information for the single components: Not classified.
Information on dermal absorption	70 % (EFSA Guidance on Dermal Absorption, 2017)
Available toxicological data relating to non-active substance(s)	Not relevant.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not relevant.

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			No			No	n.a.
Dermal			Yes			Yes	n.a.
Oral			No			Yes	n.a.

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)**
1	Application	Unwrapping and fixing of the bait foil (covers also disposal)	Non-professional user
2	Secondary exposure	Dermal and oral contact of infants to bait foil (inhalation not relevant, represents also worst case for children and adults)	General public

3.6.3.1.1 Professional exposure

Not relevant.

3.6.3.1.2 Non-professional exposure

Except for dermal absorption, no new guidance on exposure assessment with relevant changes for this scenario is available. Hence, the corresponding exposure scenario was directly adopted from the first PAR. Only the dermal absorption value has been adapted.

- **Scenario [1]**

Table 43

Description of Scenario [1]		
Unwrapping and fixing of the bait foil (covers also disposal) The biocidal product is an inert ready-to-use paper/plastic sticker (32.4 cm^2) loaded with an insecticidal caloric bait formulation to be fixed to windows. It is intended to be placed out of the reach of children. The protective paper cover is removed; the sticker peeled off the backing sheet and placed on the window pane. A sufficient non-treated rim surrounds the insecticidal area on the sticker in order to prevent dermal contact with the insecticidal bait caloric bait formulation during the fixing of the sticker to the window. Incidental dermal exposure to imidacloprid is expected to be limited to the finger tips and may arise from accidentally touching the surface containing the active substance while unwrapping and placing the sticker on the window. Normally, and according to the instructions for use, the sticker should be held only by the outer rim that is free of imidacloprid. It is assumed that the primary exposure assessment also covers the removal and disposal of used baits. The stickers are used the whole summer season and are fixed occasionally during this time period. Thus, exposure is considered as medium-term exposure. Inhalation exposure is considered not relevant for the following reasons: Release of any particles or vapours during use is not expected. No contamination of surfaces or air will occur. In view of the low vapour pressure of 4×10^{-10} Pa (at 20°C, CAR, imidacloprid) inhalation exposure by vapour during the placing of the sticker is considered to be low compared to dermal exposure. This vapour pressure results in a saturated vapour concentration of 4.13×10^{-8} mg/m^3. Taking into account an exposure duration of 1 h for installing the stickers, an inhalation rate of 1.25 m^3/h and an inhalation absorption of 100 % a systemic inhalation exposure of 8.6×10^{-10} mg/kg bw/d or 5.9×10^{-6} % of total (dermal) systemic exposure is estimated. Hence, the impact of inhalation exposure is considered to be insignificant.		
	Parameters	Value
Tier 1	Dermal absorption (EFSA Guidance on Dermal Absorption, 2017)	70 %
	Body weight adult (HEADhoc Recommendation No 14, 2017)	60 kg
	Imidacloprid content on one foil (applicant)	7.5 mg/32.4 cm^2 or 0.23 mg/cm^2
	Surface of finger tips for dermal contact (proposal of the applicant)	5 cm^2
	Transfer coefficient foil to skin (Biocides Human Health Exposure Methodology, 2015)	20 %
	Number of baits used in an average house (Proposal of the applicant)	5

Calculations for Scenario [1]

Systemic dermal exposure = imidacloprid content (per cm² foil) x surface fingertips x transfer coefficient x number of baits x dermal absorption / body weight

= 0.0134 mg/kg bw/d

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 [1]	1	-	0.0134	-	0.0134

3.6.3.1.3 Secondary exposure of the general public

- **Scenario [2]**

Table 45

Description of Scenario [2]		
For secondary exposure it is assumed that a toddler (assuming 10 kg body weight) touches a sticker with the whole hand, which would result in contact to the total sticker (size of 1 hand approximately 100 cm²) and accordingly to 7.5 mg imidacloprid. The transfer coefficient is set as 20 %. In addition, 10 % oral exposure from hand-to-mouth transfer of the dermal load is assumed. An oral uptake of more than 10% of this amount is not expected since the biocidal product contains an aversive agent. The resulting loss for dermal exposure is not considered. Exposure of toddlers is expected to be an incidental event occurring only occasionally. According to the instructions of use the sticker is placed on the upper part of the window pane out of the reach of children. Thus, only acute exposure has to be considered. The secondary exposure assessment for toddlers is also applicable to children, adults and pets. Exposure to other domestic animals is not expected since the biocidal product is for household use only. In accordance with the explanations given in the description of the primary scenario “Unwrapping and fixing of the bait foil”, the impact of inhalation exposure is also low for secondary exposure and considered not relevant. Taking into account an inhalation rate of 0.1875 m^3/h and a body weight of 10 kg for infants estimated systemic inhalation exposure would only be 7.7 x 10^{-9} mg/kg bw (or 6.0 x 10^{-6} % of total systemic exposure).		
	Parameters	Value
Tier 1	Oral absorption (Default, CAR)	100 %
	Dermal absorption (Default, EFSA Guidance on Dermal Absorption, 2017)	70%
	Body weight toddler (HEADhoc Recommendation No 14, 2017)	10 kg
	Imidacloprid content on one foil (applicant)	7.5 mg/32.4 cm^2 or 0.23 mg/cm^2

	Transfer coefficient foil to skin (Biocides Human Health Exposure Methodology, 2015)	20 %
	Transfer coefficient hand-to-mouth (default and expert judgement)	10 %

Calculations for Scenario [2]

Systemic dermal exposure = Imidacloprid content (per foil) x transfer coefficient x dermal absorption / body weight

Systemic oral exposure = 10 % of potential dermal exposure x transfer coefficient hand-to-mouth x oral absorption / body weight

Systemic dermal exposure: 0.105 mg/kg bw

Systemic oral exposure: 0.015 mg/kg bw

Total systemic exposure: 0.120 mg/kg bw

Table 46

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 [2]	1	-	0.105	0.015	0.120

3.6.3.2 Dietary exposure

Table 47

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Imidacloprid
Type of formulation	self-adhesive bait stickers or stripes
Substance(s) of concern	None
Field(s) of use	indoors (residential houses)
Target organism(s)	flies (Muscidae), development stages: imago, adult
Application rate(s) and frequency	1 sticker (7.5 mg a.s./sticker) per 15 m^2 room, once per fly season
Category(ies) of users	Non-professional users
Waiting periods after treatment	/
Further information	/

Conclusion

The intended use descriptions of the imidacloprid-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The biocidal product is to be used for the control of fly pests by applying bait. Contact with food, feed stuff or livestock animals is not expected.

No further data are required concerning the residue behaviour.

The intended uses are not relevant in terms of consumer health protection.

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

- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.
- Do not store near food, drink and animal feeding stuff.

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 48

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1	Non-professional user	1	0.0134 mg/kg bw/d
2	General public, toddler (worst case)	1	0.120 mg/kg bw/d

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) as in Table 49.

Table 49

Reference values of the active substance Imidacloprid					
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
$AEL_{short-term}$	Acute neurotoxicity rat supported by 28-d dog (acute effects) Assessment report (RMS DE, revised 2015)	40 mg/kg bw	100	-	0.4 mg/kg bw
$AEL_{medium-term}$	2-gen.rat, supported by 90-d dog and developmental tox. Rabbit Assessment report (RMS DE, revised 2015)	20 mg/kg bw/d	100	-	0.2 mg/kg bw/d
$AEL_{long-term}$	2-yr rat Assessment report (RMS DE, revised 2015)	6 mg/kg bw/d	100	-	0.06 mg/kg bw/d
ARfD		-		-	Not derived
ADI		-		-	Not derived

3.6.4.2 Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value	Estimated food concentration (mg/kg)	MRL exceedance (Yes/No)
MRL (imidacloprid)	Reg. (EU) 2021/1881	food of plant and animal origin	0.01* - 15 mg/kg	Residues in food avoided by RMMs	No

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Risk for industrial users

Not relevant.

3.6.4.5 Risk for professional users

Not relevant.

3.6.4.6 Risk for non-professional users

Table 50: 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)
Unwrap-ping and fixing of the bait foil (1)	1	20	0.2	0.0134	6.7	yes

- **Local effects**

Not relevant.

Conclusion

Exposure of the non-professional user to the biocidal product containing 7.5 mg imidacloprid as active substance per 32.4 cm^2 of plastic foil is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.6.4.7 Risk for the general public

Table 51: 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)
Dermal and oral contact of infants to bait foil (2)	1	40	0.4	0.120	30	yes

- **Local effects**

Not relevant.

Conclusion

Exposure of the general public to the biocidal product containing 7.5 mg imidacloprid as active substance per 32.4 cm^2 of plastic foil is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.6.4.8 Risk for consumers via residues in food

Residues in food or feed from the intended use are not expected (see section 3.7.3.2 Dietary exposure).

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.

3.6.4.9 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 imidacloprid and no SoC.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

Not relevant.

3.6.4.10.2 Summary of risk characterisation for professional user

Not relevant

3.6.4.10.3 Summary of risk characterisation for non-professional user

Table 52

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
1, Tier1	0.2	0.0134	6.7	yes

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 53

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
2, Tier 1	0.4	0.120	30	yes

3.7 Risk assessment for animal health

Exposure of pets is very unlikely as the biocidal product is placed in the upper parts of window panes. As a worst case the exposure and risk assessment for the general public can be adopted. Exposure to other domestic animals is not expected since the biocidal product is for household use only.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product ‘Fliegenköder’ contains no substance of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance Imidacloprid (see Assessment Report Imidacloprid PT 18, 18 February 2011 and CAR Imidacloprid (Bayer Environmental Science, RMS Germany; February 2011)).
New information on the effect of Imidacloprid to mayfly nymphs became available in 2013 in the form of a publication and is described in section 3.9.2.2.

3.8.2 Effects assessment

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

Exposure due to the use of the product is possible for the environmental compartments sewage treatment plant, surface water, sediment, soil and groundwater.

- **Screening Step 2:**

The product “Fliegenköder” contains imidacloprid as the only active substance and no substance of concern. Hence, no mixture toxicity assessment is required.

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

The product “Fliegenköder” contains imidacloprid as the only active substance and no substance of concern. Hence, there are no synergistic interactions.

Table 54

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

As the product contains only 1 active substance and no substance of concern, mixture toxicity assessment is not required.

3.8.2.2 Aquatic compartment (including sediment and STP)

Surface water

New information on the effect of Imidacloprid to mayfly nymphs became available in 2013 in the form of a publication.[6] The authors performed short and long-term toxicity tests with 10 (short-term) and 7 (long-term) aquatic invertebrate species from different taxonomic groups. In the acute tests 96h-EC_{50} values for the 10 test species range from 1.02 – 119 µg/L for the endpoint immobilization. Most sensitive species were *Cloeon dipterum* (1.02 µg/L), *Caenis horaria* (1.77 µg/L) and Limnephilidae (1.79 µg/L). Least sensitive were *Chaoborus obscuripes* (284 µg/L) and *Asellus aquaticus* (119 µg/L).
In the long-term tests 28d-EC_{10} values (immobilization) for the 7 tested species were in the range of 0.024 – 4.57 µg/L. Again the mayflies *Cloeon dipterum* (28d-EC_{10} = 0.033 µg/L) and *Caenis horaria* 28d-EC_{10} = 0.024 µg/L) were most sensitive (see DOC IIIA 7.4.1.2_05 and DOC IIIA 7.4.3.4_04).
The long-term effect values found for *Cloeon dipterum* and *Caenis horaria* are a factor of about 30 below the lowest available effect value in the CAR of 0.87 µg/L (*Chironomus riparius*) and even lower than the $PNEC_{water}$ derived in the CAR (0.174 µg/L). That means that the PNEC derived in the CAR may underestimate the risk caused by Imidacloprid. A discussion on the use of the new information for a revision of the environmental effects assessment for Imidacloprid was held at TM III/13 with the result that the data by Roessink et al. should be considered for the effect assessment. At the Biocides Working Group Meeting IV - 2014 in September 2014 it was agreed to derive a new $PNEC_{water}$ for Imidacloprid from the lowest long-term effect value for *Caenis horaria* by applying an assessment factor of 5. Therefore:

$PNEC_{water}$ =0.024 µg/L / 5 = 0.0048 µg/L = 4.8 ng/L.

Sediment

There are no tests with benthic organisms available in which the test substance was applied to sediment. Therefore, the $PNEC_{sediment}$ was derived from the $PNEC_{water}$ using the equilibrium partitioning method. Using a $K_{susp\text{-}water}$ of 6.3 and a RHO_{susp} of 1150 kg/m³ and the revised PNECaqua of 4.8 ng/L results in a **$PNEC_{sediment}$ of 26.3 ng/kg ww**.

Sewage Treatment plant

For sewage treatment plants a **$PNEC_{STP}$ of 100 mg/L** was derived in the CAR.

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[6] Roessink et al. (2013): "The neonicotinoid imidacloprid shows high chronic toxicity to mayfly nymphs;" (Environmental Toxicology and Chemistry, Vol 32, No. 5, pp 1096-1100)

3.8.3 3.9.2.3 Terrestrial compartment

From an earthworm reproduction study a $PNEC_{soil}$ of **15.75 µg/kg ww** was derived in the CAR.

3.9.2.4 Non-compartment specific effects

According to the AR of Imidacloprid (February, 2011) the bioconcentration factor of Imidacloprid for the aquatic compartment (BCF_{fish} = 0.61) and the terrestrial compartment ($BCF_{earthworm}$ = 0.88) were estimated on the basis of log Kow = 0.57. The value indicates that Imidacloprid has low potential to bioaccumulate in organisms. Thus, no assessment for secondary poisoning is required.

3.9.2.5 Summary of effects assessment

Table 55

Summary table on calculated PNEC values	
Compartment	**PNEC**
Surface water	4.8 ng/L
STP	100 mg/L
Sediment	26.3 ng/kg ww
Soil	15.75 µg/kg ww

3.9.3 Exposure assessment

3.9.3.1 General information

The product 'Fliegenköder' is intended to be used by non-professionals in private houses to control flies. The product is provided as either bait motif sticker or transparent strips consisting of inert ready-to-use paper/plastic strips where an insecticidal caloric bait formulation is printed in a thin layer onto the self-adhesive stripes. The insecticidal paste per one motif sticker or two transparent strips contains 7.5 mg Imidacloprid as active substance (a.s.). This ready to use products should be fixed to the inner side of windows glass or to window frame. One motif sticker or two strips per window are expected. So, a maximum amount of. After 6 month (maximum duration of the fly season) the product could be disposed with the municipal waste.

Table 56

Assessed PT	PT 18
Assessed scenarios	RTU Fly Bait strips/ stickers for non-professional use in domestic areas
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT 18 No. 18, 2008)
Approach	Average consumption
Distribution in the environment	Deposition from air calculated based on "ideal gass law". Calculation based on Guidance BPR IV ENV B + C (2017), SimpleTreat v. 4.0
Groundwater simulation	NO
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	

The predicted environmental concentrations (PECs) for each compartment are assessed applying the Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and evaluation (Part B+C) (Guidance BPR IV ENV B + C (2017)) and the emission scenario description is based on the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT 18 No. 18, 2008).

3.9.3.2. Fate and distribution in exposed environmental compartments

For the environmental exposure estimation, the following endpoints are considered:

Imidacloprid is stable to hydrolysis at pH 5 and 7 and shows slight hydrolysis degradation at pH 9. In conclusion, hydrolysis is not considered to be a significant degradation route for Imidacloprid at environmentally relevant temperature and pH. The solubility in demineralised water at 20°C and pH 7 is 613 mg/L.

The experimental investigation of photolysis in water shows, that Imidacloprid is rapidly photolytically degraded in pure water with half-lives < 1 day in spring and summer.

Imidacloprid is not considered to be volatile (vapour pressure $4 \cdot 10^{-10}$ Pa at 20°C). The Henry's constant is $1.677 \cdot 10^{-10}$ Pa·m^3 Mol^{-1} at 20°C, therefore Imidacloprid has a low potential of volatilizing from water.
A half-life of 2.54 hours is estimated due to phototransformation in air (OH radical concentration of 5×10^5 radicals·cm^{-3} over 24 hours). Consequently, Imidacloprid will be degraded by indirect photo-degradation processes in air immediately and no accumulation potential of the a.s. in the atmosphere is assumed.

According to the higher tier studies in water/sediment and soil systems, Imidacloprid is neither readily nor inherently biodegradable. In the soil simulation studies, the DT_{50} values were predominantly above 100 days and the mineralisation rates were below 10%.

The degradation rate constant in soil k_{bio_soil} is $5.13 \cdot 10^{-3}$ d^{-1}.

Based on the given organic carbon-water partitioning coefficient Ka_{oc} of 230 mL g^{-1}, the soil-water partitioning coefficient $K_{soil\text{-}water}$ of 7.073 m^3·m^{-3} is calculated and the partition coefficient suspended matter-water $K_{susp\text{-}water}$ equals to 6.627 m^3·m^{-3}. The medium Ka_{oc} value for Imidacloprid indicates that the mobility of the a.s. is expected to be moderately in soil.
Imidacloprid is not biodegradable and for that reason the degradation rate constant in sewage treatment plant is k_{STP}= 0 h^{-1} (Guidance BPR IV ENV B + C (2017) 2.3.6.4, table 4).

The bioconcentration factor of Imidacloprid for the aquatic compartment (BCFfish = 0.61) and the terrestrial compartment (BCFearthworm = 0.88) were estimated on the basis of log Kow = 0.57. The value indicates that Imidacloprid has low potential to bioaccumulate in organisms.

Table 57

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Other**
Fly Bait strips/ stickers	Yes*	Yes*	No	No	Yes	Yes*	Yes*	No	Not relevant

*Indirect exposure

Table 58

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	255.7	g/mol	CAR Imidacloprid PT18 (2011)
Melting point	144	°C	CAR Imidacloprid PT18 (2011)
Boiling point	-	°C	
Vapour pressure (at 20°C)	4×10^{-10}	Pa	CAR Imidacloprid PT18 (2011)
Water solubility (at 20°C)	613	mg/L	CAR Imidacloprid PT18 (2011)
Log Octanol/water partition coefficient	0.57	Log 10	CAR Imidacloprid PT18 (2011)
Organic carbon/water partition coefficient (Koc)	230	L/kg	CAR Imidacloprid PT18 (2011)
Henry's Law Constant (at 20°C)	1.677×10^{-10}	$Pa/m^3/mol$	CAR Imidacloprid PT18 (2011)
Biodegradability	Not biodegradable		CAR Imidacloprid PT18 (2011)
Rate constant for STP	0	h^{-1}	CAR Imidacloprid PT18 (2011)
DT_{50} for biodegradation in surface water	185.4	d (at 12ºC)	CAR Imidacloprid PT18 (2011)
DT_{50} for degradation in soil	295	d (at 12ºC)	CAR Imidacloprid PT18 (2011)
DT_{50} for degradation in air	2.54	hr	CAR Imidacloprid PT18 (2011)

3.9.3.3 Indoor air compartment

The potential environmental exposure routes resulting from the indoor use of the product 'Fliegenköder' is limited to direct emission to indoor air from volatilisation in the treated room. The vapour pressure of Imidacloprid is very low (4×10^{-10} Pa at 20 °C). For this reason, it is neither expected that relevant volatile losses of a.s. to air occur during application nor that Imidacloprid accumulates in air after sticking the baits. Wet cleaning of the treated room may lead to emissions to STP system via waste water.

However, to highlight the negligible concentrations in indoor air and subsequently the negligible amounts in waste water, the following calculations are done to demonstrate that the resulting indirect emissions via STP to soil and surface water can also be disregarded. Solid waste that results from the dry cleaning of rooms end up at a waste incineration and/or a municipal landfill, where emissions of a.s. to the environment are negligible.

Estimation of local emission to indoor air

The ready to use product is fixed to a window and a release to air of the a.s. is possible. This a.s. release can be evaluated with the ideal gas law assuming that the air in the treated room is saturated with gaseous Imidacloprid. Consequently, in the following estimations the highest possible concentration of a.s. in air is assumed and a worst-case scenario will be presented. The input parameters for calculating the saturated concentration of a.s. are summarised in Table 59. Due to the solely indoor use direct emission to the environment (soil, water, air) is negligible. Wet cleaning of the rooms where the product is applied leads to emissions to STP system via waste water.

Table 59: Maximum possible saturated concentration of Imidacloprid in the compartment air

Input	**Symbol**	**Value**	**S/D/O/P**
Vapour pressure	VP	$4 \cdot 10^{-10}$ Pa	S
Molecular weight of the a.s.	MOLW	255.7 g·Mol^{-1}	S
Ideal gas constant	R	8.314 Pa·m^3·Mol^{-1}·K	D
Room temperature	Temp	293 K	S
Equation			
$Csat = \frac{(VP \cdot MOLW)}{(R \cdot Temp)}$			
Output			
Saturated concentration in air of the a.s.	*Csat*	$4.2 \cdot 10^{-5}$ µg·m^{-3}	O

The saturated concentration of a.s. is referred to a standard room size and to the volume of the wet cleaning zone in a standard house. The used default values are presented in Table 60.

Table 60: Derivation of the volume of a standard wet cleaning zone

Input	**Symbol**	**Value**	**S/D/O/P**
Average room volume[1]	VOL_{room}	58 m^3	D
Average room surface[1]	$Surface_{room}$	22 m^2	D
Wet cleaning zone in a standard house[2]	$Surface_{wet}$	38.5 m^2	D
Equation			
$h_{room} = VOL_{room}/Surface_{room}$			

Input	Symbol	Value	S/D/O/P
$VOL_{wet} = Surface_{wet} \cdot h_{room}$			
Output			
Ceiling height of a standard room	h_{room}	2.6 m	O
Volume wet cleaning zone	VOL_{wet}	101.5 m^3	O

[1] according to ESD PT 18, p. 36

[2] TAB - ENV 140 (v.2.0, August, 2018)

Exchange processes between indoor and outdoor air by opening the windows will be disregarded. In Table 61 the calculation of local emission of a.s. to indoor air and the deposition of a.s. to floor and furniture from air is shown.

Table 61: Calculation of Elocalair indoor and Elocalwaste water

Input	Symbol	Value	S/D/O/P
Saturated concentration in air of the a.s	C_{sat}	$4.2 \cdot 10^{-5}$ µg·m^{-3}	S
Volume wet cleaning zone	VOL_{wet}	101.5 m^3	S
Maximum fraction exposed to cleaning (Cleaning efficiency)[1]	F_{CE}	0.5	P
Equation			
$Elocal_{air\_indoor} = C_{sat} \cdot VOL_{wet}$ $Elocal_{ww} = C_{sat} * Vol_{wet} * F_{CE}$			
Output			
Local emission to indoor air per day during the application = Local emission to the floor during the use of the b.p.	$Elocal_{\_air\_indoor}$ = $Elocal_{appl\_floor}$	$4.26 \cdot 10^{-3}$ µg·d^{-1}	O
Emission from floor to waste water during cleaning step	$Elocal_{ww}$	$2.13 \cdot 10^{-3}$ µg·d^{-1}	O

[1] according to ESD PT 18, p. 64

The local emission to indoor air is equal to the amount of a.s. deposit to the floor and furniture during the use of b.p.. Direct emission of a.s. from waste water to the STP has to be considered in the environmental exposure assessment due to wet cleaning of rooms where ‘Fliegenköder’ is applied. Even though the 2nd PT18 EG-Meeting concluded as a general approach in PT18 (indoor applications) in 2017 that only 29.6% of indoor floor is susceptible for wet cleaning processes, RefMS decided to stick to the first emission estimation for this product (2013). According to this conservative worst-case approach $2.13 \cdot 10^{-3}$ µg·d^{-1} Imidacloprid are released to the STP from one domestic premise.

3.9.3.4 Aquatic compartment (including sediment and STP)

The distribution and degradation of the a.s. in the STP was simulated using the model SimpleTreat (version 4.0):

Table 62

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 1	
Air	0.00	Model used SimpleTreat 4.0
Water	97.11	
Sludge	2.89	
Degraded in STP	0.00	

- **Emission estimation**

Table 63: Determination of local emission to water

Input	**Symbol**	**Value**	**S/D/O/P**
Equivalent habitat capacity of the STP[1]	CAP_{STP}	10000	D
Simultaneity factor indoor[1]	$F_{simultan}$	0.055	D
Number of inhabitants per house[1]	$N_{inhabitant}$	2.5	D
Emission from floor to waste water during cleaning step	*Elocal*$_{ww}$	$2.13 \cdot 10^{-3}$ µg·d^{-1}	S
Equation			
$Elocal_{water} = (F_{simultan} \cdot \frac{CAP_{STP}}{N_{inhabitant}}) \cdot Elocal_{ww}$			
Output			
Local emission to water per day	*Elocal*$_{water}$	0.469 µg·d^{-1}	O

[1] according to ESD PT 18, p. 39/40

According to the intended use of 'Fliegenköder' 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 are estimated as follows:

- **PEC$_{STP}$** (=Clocal$_{inf}$) and Clocal$_{eff}$ according to equation 35, 36 and 41, chapter 2.3.6.7, Guidance BPR Vol. IV B+C ENV (2017)
- **PEClocal$_{surfacewater}$** according to equation 51, chapter 2.3.7.3.1, Guidance BPR Vol. IV B+C ENV (2017)

- **PEClocal$_{sediment}$** according to equation 53, chapter 2.3.7.4, Guidance BPR Vol. IV B+C ENV (2017)

Table 64: Summary of STP influent (Clocal$_{inf}$) and effluent (Clocal$_{eff}$), PEC$_{STP}$, PEClocal$_{surface\ water}$ and PEClocal$_{sediment}$

	Clocal$_{inf}$ [µg/L]	**Clocal$_{eff}$** [µg/L]	**PEC$_{STP}$** [µg/L]	**PEClocal$_{surface\ water}$** [µg/L]	**PEClocal$_{sediment}$** [µg/kg]
Fly Bait strips/ stickers	$2.34 \cdot 10^{-7}$	$2.28 \cdot 10^{-7}$	$2.28 \cdot 10^{-7}$	$2.28 \cdot 10^{-8}$	$1.13 \cdot 10^{-7}$

3.9.3.5 Terrestrial compartment (including groundwater)

- **<u>Emission estimation</u>**

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PEC_{soil} is estimated according to equation 69, chapter 2.3.7.5.1, Guidance BPR Vol. IV B +C ENV (2017) and the $PEC_{groundwater}$ is calculated according to equation 71, chapter 2.3.7.6, Guidance BPR Vol. IV Part B + C ENV (2017) The Table 65 indicates the PEC in soil and groundwater for Imidacloprid according to the application scenario.

Table 65:Summary of PEClocalsoil and PEClocalgroundwater

Calculated PEC values		
	PEC$_{soil}$ (µg/kg ww)	**PEC$_{GW}$** (µg/L)
Fly Bait strips/ stickers	$2.61 \cdot 10^{-8}$	$4.32 \cdot 10^{-9}$

3.9.3.6 Atmosphere

In view of the limited volatility of Imidacloprid and excluded exchange between indoor and outdoor air, emission to air is expected to be not significant in relation to the intended use pattern. Furthermore, the indirect emission to air by volatilisation from STP is negligible.

3.9.3.7 Non-compartment specific effects

- **Primary poisoning**

Primary poisoning is excluded according to the design of the b.p..

- **Secondary poisoning**

Due to the low bioaccumulation potential of Imidacloprid (see also CAR Imidacloprid February 2011)) the assessment of secondary poisoning according to the Guidance BPR Vol. IV Part B + C ENV (2017) chapter 3.8. is not required. Furthermore, secondary poisoning due to the potential exposure of vertebrates (i.e. birds or mammals) consuming contaminated insects or taking their food (ref. to chapter 5 in ESD PT18 No. 18 (2008)) is excluded because of the indoor use of 'Fliegenköder' and negligible exposure to the environment.

3.9.3.8 Calculated PEC values

Table 6 summarizes all calculated PEC values for the a.s. imidacloprid resulting from the intended use:

Table 66

	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[µg/L]	**[µg/L]**	**[µg/kg_{wwt}]**	**[µg/kg]**	**[µg/L]**
Fly Bait strips/ stickers	$2.28 \cdot 10^{-7}$	$2.28 \cdot 10^{-8}$	$1.31 \cdot 10^{-7}$	$2.61 \cdot 10^{-8}$	$4.32 \cdot 10^{-9}$

3.9.3.9 Aggregated exposure (combined for relevant emission sources)

At the time of preparation of the environmental assessment for this PAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore, no detailed assessment has been made at this stage. This area may need to be re-assessed in the future once agreed guidance has been made available.

3.9.4 Risk characterisation

3.9.4.1 Aquatic compartment (sediment and STP)

Risk quotients for the aquatic compartment (water and sediment) including stp are indicated in Table 67.

Table 67

$PEC/PNEC_{STP}$	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
$2.28 \cdot 10^{-12}$	$4.75 \cdot 10^{-6}$	$5.04 \cdot 10^{-6}$

Conclusion

For the intended use of the b.p. “Fliegenköder” no unacceptable risks were identified for the aquatic compartment, including STP and sediment.

3.9.4.2 Terrestrial compartment (Soil/Groundwater)

- **Soil**

The risk quotient for the terrestrial compartment is given in Table 68.

Table 68

$PEC/PNEC_{soil}$
$1.66 \cdot 10^{-9}$

- **Groundwater**

According to directive 98/83/EC the limit value for pesticides in groundwater is 0.1 µg/L and must not be exceeded by the estimated PEC. For Imidacloprid the PECgroundwater of 4.32×10^{-9} µg/L is below the given limit value of 0.1 µg/L.

Conclusion

For the intended use of the b.p. “Fliegenköder” no unacceptable risks were identified for the terrestrial compartment, including groundwater.

3.9.4.3 PBT assessment

P-/vP-Criterion:

In an aquatic laboratory study under aerobic conditions a DT50 of 331 days (20 °C, in the dark) was measured for Imidacloprid. Converted to 12°C average EU outdoor temperature the half-life amounts to 628 days. For the water phase in two water/sediment systems DT50 values of 31.6 and 242 days at 12°C (corresponding to 14.2 and 108.7 days at 22 °C) were determined. The geometric mean DT50 for total system of all water/sediment-studies amounts to 185.4 d at 12°C (n=3). From four aerobic laboratory degradation studies in soil a geometric mean DT50-value of 295 days at 12 °C (corresponding to 156 days at 20 °C) was derived. Although field studies are in principle not appropriate for assessment of persistency criteria, the results of fourteen field studies in soil representative for northern as well as southern Europe resulted in an averaged DT50-value of 135 days at 12 °C average EU outdoor temperature and 100% field capacity (n=14) and reached maximum half-lives of 184.5 and 337.9 days thus confirming the high persistency of imidacloprid. From these data imidacloprid can definitely be considered to fulfil the P- as well as the vP-criterion.

B-/vB-Criterion:

The calculated bioconcentration factor in fish is 0.61 and the estimation on terrestrial bioconcentration leads to a value of 0.88 for earthworm. Therefore, neither the B- nor the vB-criterion is fulfilled.

T-Criterion:

EC_{10} (equivalent to NOEC) for chironomids (*Chironomus riparius*), is 0.87 µg/L after 28 days. For the most sensitive species, Caenis horaria, the 28d-EC10 is 0.024 µg/L. Therefore, the T-criterion is fulfilled.

Even though the P- and the T-criteria are fulfilled, the active substance imidacloprid is neither PBT - nor vP/vB - candidate as the B-criterion is not fulfilled.

3.9.4.4 Endocrine disrupting properties

According to the CAR for Imidacloprid (eCA: DE, 2013), there are no indications for endocrine disrupting properties of this active substance on environmental non-target organisms. However, a comprehensive ED-assessment for the active substance 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 results of the ED-assessment of the co-formulants are summarised in the confidential annex.

3.9.4.5 Summary of risk characterisation

The risk assessment presented in this PAR does not show any unacceptable risks from the intended use of the product 'Fliegenköder' for the relevant environmental compartments, as summarised in table 69:

Table 69

	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**$PEC/PNEC_{soil}$**
	$2.28 \cdot 10^{-12}$	$4.75 \cdot 10^{-6}$	$5.04 \cdot 10^{-6}$	$1.66 \cdot 10^{-9}$

Further emissions to the environment could be expected to occur during wet cleaning events of the window surfaces indoors during the service life of the biocidal product, when the wet cleaning cloth unintentionally may come into contact with the sticker during cleaning. When rinsing the cleaning cloth, imidacloprid residues may end up in the waste water stream and consequently in the sewer systems including sewage treatment plants (STP). Wet cleaning of the sticker is more likely to be an accidental event whereby the edge of the sticker is wiped while a person is cleaning around the outside of the device. This potential emission to the environment may cause exposure of the aquatic environment (incl. sediment). To avoid/minimise these emissions to surface water and sediment, the packaging of the window stickers should be clearly labelled with the following precautionary phrase: "*Avoid wet cleaning of the sticker. If this occurs, do not rinse out the cleaning cloth in sinks but immediately dispose it to domestic waste."*

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The biocidal product contains Imidacloprid which meets the conditions laid down in Article 10 (1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.

However, a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR (CA-June22-Doc.4.2[7]).

Therefore, a comparative assessment of the biocidal product is not required.

[7] The document is available in CIRCABC at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/aa098b99-9f78-4606-b9e0-9275764168d2/details.

4 Annexes

4.1 List of studies for the biocidal product

Table 72

No	IUCLID section (endpoint)	Title Reference type Report and/or Study No. Source or Testing facility, if different from Sponsor	Author(s)	Year	Study sponsor
1	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	Physico-chemical Properties of the Window Fly Sticker (Fly Bait) “Fly Bait Imidacloprid” before and after Accelerated Storage at 54°C for two weeks Study report Report No.: S12-0413 Eurofins Agroscience Services EcoChem GmbH	anonymous	2013	Aeroxon Insect Control GmbH
2	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	Statement on the colour and odour of the caloric bait paste of the biocidal product Fliegenköder (Fly Bait) Statement *Report and Study No. not provided* *Source and/or Testing facility not provided*	anonymous	2013	Aeroxon Insect Control GmbH
3	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	Determination of physico-chemical properties Fluidity (Penetrometer Test) Study report Report No.: CSL-21-0382.01 ; Study No.: CSL-21-0382.01 consilab Gesellschaft für Anlagensicherheit mbH Industriepark Höchst, G 830	anonymous	2021	Aeroxon Insect Control GmbH Bahnhofstraße 35 7 1332 Waiblingen, Germany

		/ G 840 65926 Frankfurt am Main Germany			
4	3.2 Acidity, alkalinity (pH)	pH of an aqueous dilution of Fly Bait (plain paste) Study report Report No.: S13-04117 Eurofins Agroscience Services EcoChem GmbH	anonymous	2013	Aeroxon Insect Control GmbH
5	3.3 Relative density (liquids) and bulk, tap density (solids) (density)	Fliegenköder Cypermethrin Determination of physico-chemical properties Relative Density (EC A.3. and OECD 109) Study report Report No.: CSL-22-0094.01 ; Study No.: CSL-22-0094.01 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2022	Aeroxon Insect Control GmbH
6	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Physico-chemical Properties of the Window Fly Sticker (Fly Bait) “Fly Bait Imidacloprid” before and after Accelerated Storage at 54°C for two weeks Study report Report No.: S12-04213 Eurofins Agroscience Services EcoChem GmbH	anonymous	2013	Aeroxon Insect Control GmbH
7	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Physico-chemical Properties of the Window Fly Sticker (Fly Bait) “Fly Bait Imidacloprid” over 4 Years Storage at 20ºC Study report Report No.: S12-04214 Eurofins Agroscience Services EcoChem GmbH/Eurofins Agroscience Services Ecotox GmbH	anonymous	2016	Aeroxon Insect Control GmbH
8	3.4.1 Storage stability tests (storage stability	Fliegenköder Cypermethrin Determination of physico-chemical properties Stability of liquid formulations at lower temperatures (CIPAC MT 39.3).	anonymous	2022	Aeroxon Insect Control GmbH

	and reactivity towards container material)	Study report Report No.: CSL-22-0094.04 ; Study No.: CSL-22-0094.04 consilab Gesellschaft für Anlagensicherheit mbH			
9	3.4.2.1 Light (stability: thermal, sunlight, metals, other)	Physico-chemical Properties of the Window Fly Sticker (Fly Bait) “Fly Bait Imidacloprid” before and after Accelerated Storage at 54°C for two weeks Study report Report No.: S12-04213 Eurofins Agroscience Services EcoChem GmbH	anonymous	2013	Aeroxon Insect Control GmbH
10	3.8 Surface tension (surface tension)	Fliegenköder Cypermethrin Determination of physico-chemical properties Surface Tension (EC A.5. and OECD 115) Study report Report No.: CSL-22-0094.02 ; Study No.: CSL-22-0094.02 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2022	Aeroxon Insect Control GmbH
11	3.9 Viscosity (viscosity)	Fliegenköder Cypermethrin Determination of physico-chemical properties Viscosity via rotational rheometer (OECD 114) Study report Report No.: CSL-22-0094.03 ; Study No.: CSL-22-0094.03 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2022	Aeroxon Insect Control GmbH
12	4.1 Explosiveness (explosiveness, other)	Fliegenköder Imidacloprid - Determination of physico-chemical properties Explosive Properties (EC A.14. and UN Class 1) Study report Report No.: CSL-21-0804.02	anonymous	2021	Aeroxon Insect Control GmbH

		consilab Gesellschaft für Anlagensicherheit mbH			
13	4.4 Oxidising properties (oxidising liquids)	Fliegenköder Imidacloprid - Determination of physico-chemical properties Oxidizing properties of liquids (UN Class 5, Division 5.1 Test O.2) Study report Report No.: CSL-21-0804.04 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2021	Aeroxon Insect Control GmbH
14	4.6 Flammable liquids (flash point of flammable liquids)	Fliegenköder Imidacloprid - Determination of physico-chemical properties Flash Point (EC A.9.) Study report Report No.: CSL-21-0804.01 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2021	Aeroxon Insect Control GmbH
15	4.8 Self-reactive substances and mixtures (self-reactive substances)	Fliegenköder Cypermethrin Determination of the SADT in the adiabatic heat-storage test according to UN Transport Regulation Study report Report No.: CSL-22-0094.05 ; Study No.: CSL-22-0094.05 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2022	Aeroxon Insect Control GmbH
16	4.8 Self-reactive substances and mixtures (self-reactive substances)	Fliegenkoder Imidacloprid Determination of the SADT in the adiabatic heat-storage test according to UN Transport Regulation Study report Report No.: CSL-22-1650 consilab Gesellschaft fUr Anlagensicherheit mbH Industriepark Hochst, G830/G840 65926 Frankfurt am Main Germany	anonymous	2022	Aeroxon Insect Control GmbH Bahnhofstrafle 35 71332 Waiblingen, Germany

17	4.16 Corrosive to metals (corrosive to metals)	Fliegenköder Imidacloprid - Determination of physico-chemical properties Corrosive Properties of Liquids (UN Test C.1) Study report Report No.: CSL-21-0804.06 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2021	Aeroxon Insect Control GmbH
18	4.17 Additional physical indicators for hazards (Pyrophoric Properties of Solids and Liquids)	Fliegenköder Imidacloprid - Determination of physico-chemical properties Pyrophoric properties of liquids (EC A.13., UN Test N.3) Study report Report No.: CSL-21-0804.05 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2021	Aeroxon Insect Control GmbH
19	4.17.1 Auto-ignition temperature (liquids and gases) (auto-ignition temperature (liquids))	Fliegenköder Imidacloprid - Determination of physico-chemical properties Auto-Ignition Temperature (Liquids and Gases) (EC A.15.) Study report Report No.: CSL-21-0804.03 consilab Gesellschaft für Anlagensicherheit mbH	anonymous	2021	Aeroxon Insect Control GmbH
20	5 Methods of detection and identification (analytical methods)	Development and Validation of an Analytical Method for the Determination of the Content of Active Ingredient Imidacloprid in Window Fly Sticker (Fly Bait) “Fly Bait Imidacloprid” Study report Report No.: S12-04212 Eurofins Agroscience Services EcoChem GmbH	anonymous	2013	Aeroxon Insect Control GmbH
21	6.7 Efficacy data to support these claims (efficacy data)	Biological test report; Efficacy of a window sticker against house flies. Product: Window sticker “Fly Bait Imidacloprid” Study report	anonymous	2012	Aeroxon Insect Control GmbH

		Report No.: BIO090b-12 BioGenius GmbH			
22	6.7 Efficacy data to support these claims (efficacy data)	Biological test report; Efficacy of a window sticker against house flies. Product: Window sticker “Fly Bait Imidacloprid” Study report Report No.: BIO090d-12 BioGenius GmbH	anonymous	2013	Aeroxon Insect Control GmbH
23	6.7 Efficacy data to support these claims (efficacy data)	Comparative assessment of the efficacy of variants of the product window fly bait under artificial conditions Study report Report No.: 14/382 i2LResearch Ltd	anonymous	2014	Aeroxon Insect Control GmbH
24	6.7 Efficacy data to support these claims (efficacy data)	Biological test report; Efficacy of a window sticker against house flies. Product: Window sticker “Fly Bait Imidacloprid” Study report Report No.: BIO070-15 BioGenius GmbH	anonymous	2015	Aeroxon Insect Control GmbH
25	6.7 Efficacy data to support these claims (efficacy data)	Efficacy of Window Sticker “Fly Bait Imidacloprid” after an aging process of 4 years in packaging and 6 months under usage conditions, against House flies Study report Report No.: BIO153-16 BioGenius GmbH	anonymous	2016	Aeroxon Insect Control GmbH

26	6.7 Efficacy data to support these claims (efficacy data)	Efficacy of window sticker “Fly Bait Imidacloprid” after an ageing process of 3 years and 7 months in packaging and 8 months under usage conditions, against house flies Study report Report No.: BIO089-16 BioGenius GmbH, Biology. Bergisch Gladbach, Germany	anonymous	2016	Aeroxon Insect Control GmbH

4.2 List of studies for the active substance(s)

4.2.1 Imidacloprid

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).
- The applicant submitted 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 (respectively the inclusion into Annex I of Directive 98/8/EC[8]) of the active substance Imidacloprid for use in Fliegenköder (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

8 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.2.1.2 New information on the active substance

Not relevant

4.2.1.3 List of studies 3rd party dossier

Not relevant

4.2.1.4 Values from list of endpoints and 3rd party dossier

Comparison of
values from agreed list of endpoints and from 3rd party dossier

not relevant