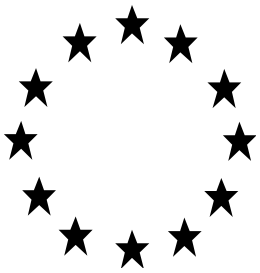
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION

(submitted by the competent authority)



Pritex Fruchtfliegenfalle

Product type(s)

19 (Repellents and Attractants)

Vinegar as included in the Annex I of Regulation (EU) No 528/2012

Case Number in R4BP: BC-VH066677-14

Competent Authority: DE (BAuA)

Date: 16.12.2021

Table of Contents

Changes history table

Not relevant (no changes yet).

Application type	eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	DE	BC-VH066677-14	16.12.2021	Initial assessment	

1 Conclusion

Pritex Fruchtfliegenfalle is a ready to use liquid biocidal product containing vinegar as active substance, used together with a sticky trap. The product is used as an attractant by non-professional users to attract and catch adult fruit flies (*Drosophila* spp.).

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised for indoor use by the general public, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance vinegar is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction that the vinegar is food and does not contain more than 10 % acetic acid (whether or not it is food);
2. The biocidal product does not contain any substance of concern;
3. The biocidal product does not contain any nanomaterials;
4. The biocidal product is sufficiently effective;
5. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification according to Regulation (EC) No 1272/2008[1] is not necessary.

The biocidal product does not contain any non-active substance (so called "co-formulant") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product does not contain any active substances having endocrine-disrupting properties.

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.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

[1] 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

Conclusions of the assessments for each area

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

This data is not required for a simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against adult fruit flies (*Drosophila* spp.) for all intended uses. More information is available in section 3.4 of the PAR.

Risk assessment for human health

A full risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

No substances of concern regarding human health were identified. The handling of the product and its intended use do not require personal protective equipment.

Risk assessment for the environment

A full risk assessment for the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.
No substances of concern regarding the environment were identified.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
The (interim) results of the long-term stability test (started in May 2021) have to be submitted in order to confirm the given shelf-life.	31.07.2023

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	19 (Repellents and Attractants)
Type(s) of formulation	AL – Any other liquid (Liquid attractant with sticky trap)

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA)	Comment (eCA)
1	Indoor use	PT19	Fruit fly (Drosophila spp.), Adults	Open system: diffusion Before opening, the bottle with the attracting liquid needs to be placed upright for 30 minutes. Remove the cap and place the bottle into the stand. The sticky trap needs folding along the pre-cut crease, so that a pyramid forms with one side open. Remove the protecting paper off the trap with a continuous and vigorous movement. Insert the sticky trap into the intended holes of the stand. The trap is now ready to use. Place the trap with the glue side directed to the infestation source.	1 bottle with attractant solution à 40 ml until all fruit flies were caught. Duration of efficacy of 40 ml is 6 weeks at 25°C. Exchange sticky trap in case it should be covered with fruit flies. Use only when fruit flies are present.	General public (non-professional)	Acceptable	The trap should be placed at a distance of 1 m to the infestation source

2.3 Identity and composition

The determination whether the identity and composition of the biocidal product are identical or not identical to the identity and composition of the product(s) evaluated in connection with the inclusion of the active substance in Annex I of Regulation (EU) No 528/2012, is not applicable.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

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

2.4 Identity of the active substance

Table 2.3 Identity of the active substance

Main constituent	
Common name	Vinegar
Chemical name	-
EC number	Not available
CAS number	8028-52-2
Index number in Annex VI of CLP	-
Maximum content	10 % acetic acid, food quality (Regulation (EU) 2019/1819)
Structural formula	n.a.

2.5 Information on the source of the active substance

The information on the source of the active substance Vinegar is not applicable.

2.6 Assessment of the endocrine-disrupting properties of the biocidal product

Active Substance

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Non-active substance

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.

2.7 Classification and labelling

The active substance is not classified under Reg. (EC) 1272/2008.

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is not required.
Since the biocidal product has no classification, no labelling according to Regulation (EC) No 1272/2008 is required.

2.8 Letter of access

No letter of access was submitted.

2.9 Data submitted in relation to product authorisation

Not relevant (no new data on the active substance was submitted).

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	(40 ml) packed in: - Carton box (carton)	Poly(ethylene-terephthalate) (PET)	Wick for diffusion, made of non-woven wrapped fibre rod Cap	Non-professional	Yes

3.2 Physical, chemical, and technical properties

Since this document supports an application for a simplified authorisation, not all data are required.

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	Visual inspection	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	Yellow clear homogeneous liquid with weak odor of active substance	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle",* Study No. Mo6941 (Interim report)
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual inspection		liquid	
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual inspection		yellow	
3.1.3.	Odour at 20 °C and 101.3 kPa	Olfactory inspection		weak odor of active substance	
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3 (Determination of pH Values)	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	pH value: 2.9	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle",* Study No. Mo6941 (Interim report)
		CIPAC method MT 191 (acidity or alkalinity of formulations)		Alkalinity (NaOH): 8.42 [% m/m]	
3.3.	Relative density / bulk density	OECD Guideline 109 (Density of Liquids and Solids)	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	1.0262 (at 20°C)	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle",* Study No. Mo6941 (Interim report)
3.4.1.1.	Storage stability test – **accelerated storage**	CIPAC MT46.3; CIPAC MT 75.3, CIPAC MT 191, CIPAC MT 192/ OECD 114; Analytical method: GC with FID (SANCO/3030/99 rev. 22/03/19)	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	Accelerated storage test: Two weeks at 54°C in commercial packaging <u>Appearance:</u> ▫ t=0: yellow homogenous liquid ▫ t=after 2 weeks at 54°C: orange homogenous liquid	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle"*, Study No. Mo6941 (Interim report)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Odour: ▫ t=0: weak odor of active substance ▫ t=after 2 weeks at 54°C: weak odor of active substance Packaging: ▫ t=0: Test Item in sound condition, sealed and without leakages; No ballooning or change in the paneling was observed. No damage. ▫ t=after 2 weeks at 54°C: Test Item in sound condition, sealed and without leakages; No ballooning or change in the paneling was observed. No damage. Weight loss: The weight loss for the samples stored at 54°C for 2 weeks was between 0.72% and 0.78%. pH value (undiluted b.p.): ▫ t=0: 2.9 ▫ t=after 2 weeks at 54°C: 2.9 Alkalinity:	

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>▫ t=0: 8.42% m/m as NaOH
▫ t=after 2 weeks at 54°C: 8.42% m/m as NaOH

<u>Viscosity:</u>
Dynamic viscosity at 20°C:
<table>
<tr><td rowspan="2">Shear rate [1/s]</td><td colspan="2">Viscosity [mPa s]</td></tr>
<tr><td>t=0</td><td>t=14d (54°C)</td></tr>
<tr><td>20</td><td>2.04</td><td>2.34</td></tr>
<tr><td>40</td><td>1.57</td><td>1.99</td></tr>
<tr><td>60</td><td>1.52</td><td>1.62</td></tr>
<tr><td>80</td><td>1.46</td><td>1.57</td></tr>
<tr><td>100</td><td>1.44</td><td>1.47</td></tr>
</table>
Dynamic viscosity at 40°C:
<table>
<tr><td rowspan="2">Shear rate [1/s]</td><td colspan="2">Viscosity [mPa s]</td></tr>
<tr><td>t=0</td><td>t=14d (54°C)</td></tr>
<tr><td>20</td><td>0.77</td><td>1.51</td></tr>
<tr><td>40</td><td>0.68</td><td>1.16</td></tr>
<tr><td>60</td><td>0.63</td><td>0.93</td></tr>
<tr><td>80</td><td>0.67</td><td>0.85</td></tr>
<tr><td>100</td><td>0.69</td><td>0.77</td></tr>
</table>
<u>Active substance content:</u>
▫ t=0: 8.9% acetic acid
▫ t=after 2 weeks at 54°C: 9.0% acetic acid

After storage for 2 weeks at 54°C no significant change</td><td></td></tr>
</table>

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				in physical state, color, oder, the stability of packaging, pH-value, alkalinity and active substance content was observed. Based on the results of the accelerated storage test a provisional shelf-life of 24 months is assumed.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	CIPAC MT 75.3, CIPAC MT 191, CIPAC MT 192/ OECD 114; Analytical method: GC with FID (SANCO/3030/99 rev. 22/03/19)	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	Storage test (60 months at 20°C in commercial packaging) started in May 2021; interim results: samples will be tested after 12, 24, 36, 48 and 60 months.	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle",* Study No. Mo6941
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 (Low temperature stability test (liquids))	Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)	Storage for 1 week at 0°C: <u>Appearance:</u> ▫ t=0: yellow clear homogenous liquid ▫ t=after 1 week at 0°C: Corresponding to start value, 2.4 mL brown solid separation was observed.	Wirtz, S. (**2021**), *Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle",* Study No. Mo6941 (Interim report)

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>3.4.2.3.</td><td>Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material</td><td>CIPAC guidline MT 46.3,MT 39.3</td><td>Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99/ vingar (8,9 % Acetic acid)</td><td>Test Item in sound conditions, sealed and without leakages.
No balloing or change in the paneling was observed.
Dimensionally stable.
No damage.</td><td>Wirtz. S. (2021) Mo6941 REC final Interim 2 weeks Report
„Determination of physico-chemical properties and accelerated storage stabilitytest for „Pritex Fruchtfliegenfalle”</td></tr>
<tr><td>3.8.</td><td>Surface tension [indicate the conditions of the test and the concentration tested]</td><td>EU Method A.5 (Surface Tension)</td><td>Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)</td><td>146.1 mN/m at 20 °C (corrected)</td><td>Wirtz, S. (2021), Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle", Study No. Mo6941 (Interim report)</td></tr>
<tr><td>3.9.</td><td>Viscosity [indicate the shear rate and the temperature tested]</td><td>CIPAC guideline MT 192 and OECD Guideline 114 (rotational viscometer (dynamic))</td><td>Pritex Fruchtfliegenfalle, Batch 1125, a.s.: 99% vinegar (8.9% Acetic acid)</td><td>Dynamic viscosity at 20°C:<table><tr><th>Shear rate [1/s]</th><th>Viscosity [mPa s]</th></tr><tr><td>20</td><td>2.04</td></tr><tr><td>40</td><td>1.57</td></tr><tr><td>60</td><td>1.52</td></tr><tr><td>80</td><td>1.46</td></tr><tr><td>100</td><td>1.44</td></tr></table>Dynamic viscosity at 40°C:<table><tr><th>Shear rate [1/s]</th><th>Viscosity [mPa s]</th></tr><tr><td>20</td><td>0.77</td></tr><tr><td>40</td><td>0.68</td></tr><tr><td>60</td><td>0.63</td></tr><tr><td>80</td><td>0.67</td></tr><tr><td>100</td><td>0.69</td></tr></table></td><td>Wirtz, S. (2021), Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle", Study No. Mo6941 (Interim report)</td></tr>
</table>

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Pritex Fruchtfliegenfalle is a ready to use liquid attractant with sticky trap (AL – any other liquid) . All given studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Based on the results of the accelerated storage test, a provisional shelf-life of 24 months is assumed. The (interim) results of the long-term stability test (started in May 2021) have to be submitted by July 2023 in order to confirm the given shelf-life. **Implications for labelling:** 'protect from frost'

3.3 Physical hazards and respective characteristics

This data is not required for a simplified authorisation according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.4 Assessment of efficacy against target organisms

3.4.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Main Group 03: Pest Control
Product Type 19: Repellents & Attractants

The attractant product "Pritex Fruchtfliegenfalle" is part of a ready to use fruit fly trap, containing 40 ml of liquid biocidal attractant solution in a plastic bottle and a sticky trap, for indoor use (e.g. kitchen, living room) by non-professionals. The product contains 99% of the active substance vinegar. The attractant product "Pritex Fruchtfliegenfalle" is intended to attract adult fruit flies (*Drosophila* spp.) of both sexes in infested rooms (i.e. from fruits and bins) by diffusion of vinegar from the solution. Attracted insects are caught and killed on the adhesive surface of the cardboard trap.
Fruit flies may cause inconvenience primarily indoors where they infest rotting organic material such as fermenting fruits and vegetables. Therefore, fruit flies can be considered as a relevant nuisance.

The submitted studies are suitable to prove the attractiveness of the product "Pritex Fruchtfliegenfalle" for the pyramid sticky trap form. Therefore, the claim "attracts and catches adult fruit flies (*Drosophila* spp.) within 48 hours at a distance of 1 m to the infestation source" is acceptable. Also a residual efficacy of 6 weeks was demonstrated.
An efficacy study with a product stored at ambient temperature at the end of the maximum storage period was not submitted.

3.4.2 Mode of action and effects on target organisms, including unacceptable suffering

The active substance vinegar is an attractant for fruit flies. The mode of action does not depend on the fruit flies' sex. As soon as the bottle with the vinegard solution is opened, the vinegar diffuses, attracts the fruit flies and the flies will irreversibly stick on the trap. The sticky trap has a killing effect on the fruit flies. There is no time delay. The effect of the attractant lasts up to 6 weeks after opening the bottle.

3.4.3 Efficacy data

Table 3.4 Efficacy data

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr><td>PT19

indoor use</td><td>“Pritex Frucht-fliegenfalle” (99% vinegar) pyramid form; freshly opened and after aging (opened) for 4 and 6 weeks

Application: sticky trap with PT19 active substance</td><td>Attractant / adult fruit flies (Drosophila melano-gaster) mixed sex

100 fruit flies per replicate</td><td>simulated-use test:
- test room: 30 m³ containing 1 table (0.5 m high)
- dosage: 1 trap per room
- position of the product and the trap with water (placebo): close to the food source but in different rooms
- food source: 1 very ripe banana and ½ ripe apple; positioned in the center of the room
- temperature: 24 – 26°C
- rel. humidity: 33 – 57%
- light regime: artificial light during hours of work and a little day light</td><td>Efficacy of fruit fly traps tested in 30 m³ practical test rooms against Drosophila melanogaster, mixed sex, strain BioGenius 10:
Method: BioG B 408-02 (modified) 3 replicates temperature: 24 – 26 °C
Study: Mo6160 rel. humidity: 33 – 57 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Product age</th><th rowspan="2">Test after</th><th colspan="4">% caught flies (out of 100)</th></tr>
<tr><th>Rep. 1</th><th>Rep. 2</th><th>Rep. 3</th><th>Ø</th></tr>
<tr><td rowspan="6">Test solution containing vinegar (Yellow sticky surface with solution containing vinegar as attractant)</td><td rowspan="2">fresh</td><td>24 hours</td><td>61</td><td>80</td><td>94</td><td>78</td></tr>
<tr><td>48 hours</td><td>94</td><td>98</td><td>99</td><td>97</td></tr>
<tr><td rowspan="2">4 weeks after opening</td><td>24 hours</td><td>97</td><td>55</td><td>89</td><td>80</td></tr>
<tr><td>48 hours</td><td>100</td><td>64</td><td>98</td><td>87</td></tr>
<tr><td rowspan="2">6 weeks after opening</td><td>24 hours</td><td>80</td><td>97</td><td>46</td><td>74</td></tr>
<tr><td>48 hours</td><td>95</td><td>100</td><td>71</td><td>89</td></tr>
<tr><td rowspan="6">Placebo (Yellow sticky surface with water as attractant)</td><td rowspan="2">fresh</td><td>24 hours</td><td>24</td><td>34</td><td>32</td><td>30</td></tr>
<tr><td>48 hours</td><td>94</td><td>77</td><td>95</td><td>89</td></tr>
<tr><td rowspan="2">4 weeks after opening</td><td>24 hours</td><td>34</td><td>67</td><td>28</td><td>43</td></tr>
<tr><td>48 hours</td><td>77</td><td>67</td><td>36</td><td>60</td></tr>
<tr><td rowspan="2">6 weeks after opening</td><td>24 hours</td><td>48</td><td>73</td><td>5</td><td>42</td></tr>
<tr><td>48 hours</td><td>72</td><td>83</td><td>7</td><td>54</td></tr>
</table>
Note: All means rounded to integers.
Untreated controls showed not more than 11 % mortality after 48 hours and on average of 4 replicates.</td><td>Linn 2018a (Report no. BIO095a-18)</td><td>6.7/ BIO095a-18 Efficacy over 6 weeks with fresh and aged traps</td></tr>
</table>

<table>
<tr>
<td></td>
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<td></td>
<td>- acclimatisation: 1 hour before product application
- storage conditions of for aging (opened product): 24 ± 2°C; 40 ± 10% rel. humidiy; no ventilation
- replicates: 3 (untreated control: 3)
- control: 2 days before the test in clean rooms without product
- evaluation: 24 and 48 hours after product application
- test criteria: % caught individuals</td>
<td>
Untreated control for cleanliness of 30 m³ practical test rooms of Drosophila melanogaster, mixed sex, strain BioGenius 10.
Method: BioG B 408-02 (modified) 4 replicates temperature: 23 – 30 °C
Study: Mo6160 rel. humidity: 40 – 54 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Product age</th><th rowspan="2">Test after</th><th colspan="5">% KD and / or mortality of fruit flies (out of 100)</th></tr>
<tr><th>Room 1</th><th>Room 2</th><th>Room 3</th><th>Room 4</th><th>Ø</th></tr>
<tr><td rowspan="9">Untreated control</td><td rowspan="3">fresh</td><td>8 hours</td><td>4</td><td>4</td><td>2</td><td>8</td><td>5</td></tr>
<tr><td>24 hours</td><td>7</td><td>4</td><td>3</td><td>8</td><td>6</td></tr>
<tr><td>48 hours</td><td>9</td><td>5</td><td>5</td><td>10</td><td>7</td></tr>
<tr><td rowspan="3">4 weeks after opening</td><td>8 hours</td><td>10</td><td>8</td><td>10</td><td>7</td><td>9</td></tr>
<tr><td>24 hours</td><td>10</td><td>10</td><td>12</td><td>7</td><td>10</td></tr>
<tr><td>48 hours</td><td>12</td><td>12</td><td>12</td><td>8</td><td>11</td></tr>
<tr><td rowspan="3">6 weeks after opening</td><td>8 hours</td><td>10</td><td>8</td><td>10</td><td>7</td><td>9</td></tr>
<tr><td>24 hours</td><td>10</td><td>10</td><td>12</td><td>7</td><td>10</td></tr>
<tr><td>48 hours</td><td>12</td><td>12</td><td>12</td><td>8</td><td>11</td></tr>
</table>
Note: All means rounded to integers. KD = knock down
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</tr>
<tr>
<td>PT19
indoor use</td>
<td>“Pritex Frucht-fliegenfalle” (99% vinegar) pyramid form; freshly opened

Application: sticky trap with PT19 active substance</td>
<td>Attractant / adult fruit flies (Drosophila melano-gaster) mixed sex, approx. 7 days
100 fruit flies per replicate</td>
<td>simulated-use test:
- test room: 30 m³ containing 3 tables (0.5 m high)
- dosage: 1 trap per room
- position of the product and the trap with water (placebo): 0.5 m or 1 m distance to the food source in the same room
- food source: 1 very ripe banana and ½ ripe apple;</td>
<td>
Efficacy of fruit fly traps tested in 30 m³ practical test rooms against Drosophila melanogaster, mixed sex, strain BioGenius 10 at two distinct distances to alternative food.
Method: BioG B 408-02 (modified) 4 replicates temperature: 23 – 26 °C
Study: Mo6160 rel. humidity: 41 – 50 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Trap distance</th><th rowspan="2">Test after</th><th colspan="5">% caught flies (out of 100)</th></tr>
<tr><th>Rep. 1</th><th>Rep. 2</th><th>Rep. 3</th><th>Rep. 4</th><th>Ø</th></tr>
<tr><td rowspan="4"><u>Test solution containing vinegar</u>
(Yellow sticky surface with solution containing vinegar as attractant)</td><td rowspan="2">0.5 m</td><td>24 hours</td><td>67</td><td>57</td><td>52</td><td>44</td><td>55</td></tr>
<tr><td>48 hours</td><td>94</td><td>96</td><td>73</td><td>69</td><td>83</td></tr>
<tr><td rowspan="2">1 m</td><td>24 hours</td><td>66</td><td>63</td><td>44</td><td>83</td><td>64</td></tr>
<tr><td>48 hours</td><td>95</td><td>95</td><td>78</td><td>98</td><td>92</td></tr>
<tr><td rowspan="4"><u>Placebo</u>
(Yellow sticky surface with water as attractant)</td><td rowspan="2">0.5 m</td><td>24 hours</td><td>1</td><td>1</td><td>1</td><td>0</td><td>1</td></tr>
<tr><td>48 hours</td><td>1</td><td>2</td><td>2</td><td>0</td><td>1</td></tr>
<tr><td rowspan="2">1 m</td><td>24 hours</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>48 hours</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
</table>
Note: All means rounded to integers.
Untreated controls showed less than 10 % mortality after 48 hours on average of 4 replicates.
</td>
<td>Linn 2018b (Report no. BIO089a-18)</td>
<td>6.7/ BIO089a-18 Supportive study: Efficacy with two distances between trap and fruits</td>
</tr>
</table>

			positioned in the center of the room - temperature: 23 – 29°C - rel. humidity: 37 – 50% - light regime: artificial light during hours of work and a little day light - acclimatisation: 1 hour before product application - replicates: 4 (untreated control: 4) - control: 1 day before the test in clean rooms without product - evaluation: 24 and 48 hours after product application - test criteria: % caught individuals	**Untreated control for cleanliness of 30 m³ practical test rooms of *Drosophila melanogaster*, mixed sex, strain BioGenius 10.** Method: BioG B 408-02 (modified) temperature: 27 – 29 °C Study: Mo6160 **4 replicates** rel. humidity: 37 – 41 % Note: All means rounded to integers. KD = knock down		

Product	Test after	% KD and / or mortality of fruit flies (out of 100)				
		Room 1	Room 2	Room 3	Room 4	Ø
Untreated control	8 hours	4	10	4	8	**7**
	24 hours	4	12	4	12	**8**
	48 hours	6	12	5	12	**9**

3.4.4 Efficacy assessment

For the efficacy assessment, the product "Pritex Fruchtfliegenfalle", containing 99% of the active stubstance vinegar in combination with a pyramid sticky trap, was tested against adult fruit flies (*Drosophila melanogaster*). The applicant submitted two simulated-use studies with the target species *Drosophila melanogaster* (detailed study summaries see table 3.4).

In one simulated-use study the freshly opened product "Pritex Fruchtfliegenfalle" as well as the 4 and 6 weeks opened product were tested (Linn 2018a). This test was conducted in 30 m³ test rooms. The product and the placebo (consisting of the same sticky yellow trap and water) were not tested simultaneously in the same room. The product was tested in close distance to the attractive food source (ripe banana and a halved ripe apple) in one test room and the placebo in another test room. The results demonstrated that the fresh product caught 97%, the 4 weeks old product 87% and the 6 weeks old product 89% of fruit flies 48 hours after product application. However, also on the fresh placebo stuck 89%, on the 4 weeks old placebo 60% and on the 6 weeks old placebo 54% of fruit flies. Mortality without trap (untreated control) was in all trials maximal 12%.
The applicant provided the following statement: "*Vinegar traps caught always more fruit flies than placebo traps. The percentage of caught flies in the placebos was higher than expected, though. The reason for these results might have been that traps were probably positioned too close to the ripened fruits. As the flight of fruit flies is only partly directed, many flies might have been trapped by chance to the sticky surfaces of either trap type. However, a positive attractive effect of the vinegar in terms of number of trapped flies was observed. To prove that the vinegar trap generally attracts and traps more fruit flies than the placebo trap a second test was performed taking two longer distances between the trap and the fruit plate into account (0.5 and 1 m). The results are reported under BIO089a-18 (Linn 2018b) and show a significant increased efficacy of vinegar traps compared to placebo traps without vinegar.*" The German CA accepts this statement and evaluates this test as supportive to prove the residual efficacy of this product.
In the second simulated-use study by Linn (2018b) the product "Pritex Fruchtfliegenfalle", was offered on a table in 0.5 m or 1 m distance from an attractive food source (ripe banana and a half ripe apple) in a 30 m³ test room simultaneously with a placebo consisting of the same sticky yellow trap and water. In direct comparison of the product and the placebo it was demonstrated that the fresh product caught 83% and 92% of the fruit flies in a distance of 0.5 m and 1 m, respectively after 48 hours. On the placebo trap, a maximum of 2% of flies got stuck. Mortality without trap (untreated control) was below 10% after 48 hours.

At the time of the authorisation of this product, requirements for testing and evaluating the efficacy of a fruit fly attractant were missing in the Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C; Version 3.0; April 2018). The German CA evaluates the methodology and the results (attraction >80%) of both simulated-use trials as acceptable, even if the number of flies per replicate and the number of replicates is lower than required in the draft of the Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C) (draft Version 3.1; March 2021; chapter 5.6.5.8.2.2.2 "Attractants without PT18 active substances"). At stage of renewal, when the new Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C) (draft Version 3.1; March 2021; chapter 5.6.5.8.2.2.2 "Attractants without PT18 active substances") is in force, additional data must be provided.

3.4.5 Conclusion on efficacy

The submitted studies are suitable to prove the attractiveness of the product "Pritex Fruchtfliegenfalle" for the pyramid sticky trap form. Therefore, the claim "attracts and

catches adult fruit flies (*Drosophila* spp.) within 48 hours at a distance of 1 m to the infestation source" is acceptable. Also a residual efficacy of 6 weeks was demonstrated.
An efficacy study with a product stored at ambient temperature at the end of the maximum storage period was not submitted.

3.4.6 Occurrence of resistance and resistance management

No resistance was observed in the efficacy trials. No possible occurrence of resistance is known or reported. The relevant website for insecticide resistance (Arthropod resistance database) has no entries for *Drosophila* in combination with the a.s. vinegar (https://www.pesticideresistance.org/search.php). It is not expected that resistance will build up for vinegar as an attractant.

3.4.7 Known limitations

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

3.4.8 Relevant information if the product is intended to be authorised for use with other biocidal products

Not applicable

3.5 Risk assessment for human health

A full risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. However, it has to be assessed whethter the product fulfils all conditions for a simplified authorisation procedure as laid down in Article 25 *and Article 20(1)(b)* of Regulation (EC) No 528/2012.

3.5.1 Substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).
The biocidal product consists mainly of vinegar with an acetic acid content below 10 %. Other ingredients are not classified. Acetic acid is classified with Skin Corr. 1A. However, the SCL for Skin Irrit. 2 and Eye Irrit 2 is ≥ 10 %. Hence, classification of the biocidal product is not required.

3.5.2 Professional users (including industrial users and trained professional users)

Not relevant.

3.5.3 Non-professional users

The handling of the product and its intended use do not require personal protective equipment.

3.6 Risk assessment for the environment

A full risk assessment for the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. However, it has to be assessed whethter the product fulfils all conditions for a simplified authorisation procedure as laid down in Article 25 *and Article 20(1)(b)* of Regulation (EC) No 528/2012.

3.6.1 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)).

3.6.2 Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of non-active substance(s), refer to the respective section of the confidential annex.

4 Appendices

4.1 New information on the active substance(s) and substance(s) of concern

Not relevant (no new information on the active substance(s) is available).

Not relevant (no substance of concern was identified).

4.2 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title.** **Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Wirtz, S.	2021	3.1 3.2 3.3 3.4 3.8 3.9	Mo6941 REC final Interim 2 weeks Report.pdf	Determination of physico-chemical Properties and Accelerated Storage Stability Tests for "Pritex Fruchtfligenfalle". Study number Mo6941.	Study report	Applicant	Yes	Yes
Wirtz, S.	2021	5	Mo6940 MV266 Pritex Fruchfliegenfalle.pdf	Validation of Method MV266: "REC: HPLC-Determination of acetic acid in Pritex Fruchtfliegenfalle". Study number Mo6940.	Study report	Applicant	Yes	Yes
Catherine Linn	2018	6.7	BIO095a-18.pdf	Efficacy of yellow sticky trap with test solution containing vinegar, tested against Drosophila melanogaster in 30 m³ test rooms. Report number BIO095-18.	Study report	Applicant Study sponsor: Gejoca AG	Yes	Yes

				Study number Mo6160.				
Catherine Linn	2018	6.7	BIO089a-18.pdf	Efficacy comparison between yellow sticky trap with water vs. yellow sticky trap with test solution containing vinegar, tested against Drosophila melanogaster in 30 m³ test rooms. Report number BIO089a-18. Study number Mo6160.	Study report	Applicant Study sponsor: Gejoca AG	Yes	Yes
Catherine Linn	2020	6.7	Statement BioGenius REC Report BIO089a-18 and BIO095a-18.pdf	Statement to report BIO089a-18 and BIO095a-18 (Study MO6160) Product name if traps testes in study Mo6160	Statement	Applicant	-	Yes

4.3 References

4.3.1 References other than list of studies for the BP

Not relevant.

4.3.2 Guidance documents

Packaging
No guidance agreed yet.

Physical, chemical, and technical properties
- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2018

Efficacy
- Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C), 2018

4.3.3 Legal texts

- 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

4.4 Confidential information

Please refer to the separate document Confidential Annex of the PAR.