

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



COMPO BIO Fruchtfliegen-Falle

Product type 19

Vinegar and concentrated apple juice as included in the
Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-QW066509-94

Evaluating Competent Authority: Finland

Date: [24/January/2023]

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1 CONCLUSION

COMPO BIO Fruchtfliegen-Falle is a ready to use biocidal product containing vinegar and concentrated apple juice as active substances. The product is used as an attractant by consumers for the control of 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 the use as an attractant by the consumers, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

1.1 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 2.1.4 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 substances concentrated apple juice and vinegar are listed in Annex I of Regulation (EU) 528/2012 and vinegar satisfies the restriction that excludes vinegar that is not food and excludes vinegar that contains 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 is necessary. Detailed information on classification and labelling is provided in section 2.1.3 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product does not contain any non-active substances (so called "co-formulants") which are considered as substances 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.

The biocidal product contains vinegar and concentrated apple juice which do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered

as candidates for substitution. Therefore, a comparative assessment of the biocidal product is not required.

1.2 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 manufacturers of the biocidal product are listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in section 2.1.2 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

1.3 Conclusions of the assessment 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 2.2.2 of the PAR.

Physical hazards and respective characteristics

A physical hazard was identified. COMPO BIO Fruchtliegen-Falle will be classified as Met. Corr.1, H290: May be corrosive to metals. More information is available in section 2.2.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the acetic acid representing the concentration of the active substance vinegar is available. No analytical method for the concentrated apple juice is available and therefore the stability of concentrated apple juice is demonstrated by an efficacy test. More information on the analytical methods for the active substances is available in section 2.2.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against *Drosophila* spp. for all intended uses. More information is available in section 2.2.5 of the PAR.

Human health

No substances of concern regarding human health were identified.

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

Environment

No substances of concern regarding environment were identified.

1.4 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
An efficacy study with the 24 months aged product should be conducted and provided for evaluation to support the storage stability of the product.	31.12.2023

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
COMPO BIO Fruchtliegen-Falle	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	terrasan Haus- + Gartenbedarf GmbH
	Address	Rosenweg 2-4 86641 Rain am Lech Germany
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	terrasan Haus- + Gartenbedarf GmbH
Address of manufacturer	Rosenweg 2-4 86641 Rain am Lech Germany
Location of manufacturing sites	Compo GmbH Gildenstraße 38 48157 Münster Germany
	FormiChem GmbH Anna-von-Philipp-Str. B33 86633 Neuburg a.d. Donau Germany
	SFM Chemicals GmbH Floßhafenstraße 11 97199 Ochsenfurt Germany

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

Active substance	Concentrated apple juice
Name of manufacturer	Hans Zipperle AG/SpA
Address of manufacturer	via Max-Valier-Str. 3 39012 Meran/o (BZ) Italy
Location of manufacturing sites	via Max-Valier-Str. 3 39012 Meran/o (BZ) Italy

Active substance	Vinegar
Name of manufacturer	CARL KÜHNE KG (GmbH & Co.)
Address of manufacturer	Kühnehöfe 11 22761 Hamburg Germany
Location of manufacturing sites	Kühnehöfe 11 22761 Hamburg Germany

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential 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

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Vinegar
IUPAC or EC name	Not available
EC number	Not available
CAS number	8028-52-2
Index number in Annex VI of CLP	Not available
Minimum purity / content	Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food).
Structural formula	Acetic acid: $\begin{array}{c} \text{H} \\ \\ \text{H}-\text{C}-\text{C} \\ \quad // \quad \backslash \\ \text{H} \quad \text{O} \quad \text{O}-\text{H} \end{array}$

Main constituent(s)	
ISO name	Concentrated apple juice
IUPAC or EC name	Not available
EC number	Not available
CAS number	Not available
Index number in Annex VI of CLP	Not available
Minimum purity / content	Not available Excluding concentrated apple juice that does not fall within the definition in point (2) of Part I of Annex I to Council Directive 2001/112/EC.
Structural formula	Not available

2.1.2.2 Candidate(s) for substitution

The biocidal product does not contain candidates for substitution in accordance with Article 10 of the BPR.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Vinegar	-	Active substance	8028-52-2	-	39.00
Concentrated apple juice	-	Active substance	-	-	4.00

The whole composition can be found in the confidential annex. The biocidal product does not contain nanomaterials.

2.1.2.4 Information on technical equivalence

Vinegar and concentrated apple juice are listed in Annex I of the BPR and therefore technical equivalence is not applicable. No reference specifications are available.

2.1.2.5 Information on the substance(s) of concern

No substances of concern were identified.. For more information on the assessment of the co-formulants, please refer to the confidential annex.

2.1.2.6 Type of formulation

AL -Any other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard class and category	Met. Corr.1
Hazard pictograms	GHS05
Signal wor(s)	Warning
Hazard statements	H290: May be corrosive to metals
Precautionary statements	P234: Keep only in original container P390: Absorb spillage to prevent material damage
Labelling	
Hazard pictograms	None CLP Annex I: 1.3.6 Substances or mixtures classified as corrosive to metals but not classified as skin corrosion or as serious eye damage (cat.1) which are in the finished state as packaged for consumer use do not require on the label the hazard pictogram GHS05.
Signal words	Warning
Hazard statements	H290: May be corrosive to metals
Precautionary statements	P234: Keep only in original container P390: Absorb spillage to prevent material damage
Note	None

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 2. Use # 1 – Fruit flies - indoor

Product Type	19 Repellents and attractants
Where relevant, an exact description of the authorised use	Attractant in a trap, for reduction of fruit flies indoors
Target organism (including development stage)	Fruit flies (<i>Drosophila</i> spp.), adults
Field of use	Indoor, for use in any room
Application method(s)	Manual application
Application rate(s) and frequency	Place one trap where flies occur most. The trap is used upon infestation. The effect of the attractant lasts up to 6 weeks after opening the trap.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	200 ml PET bottle with PP closure, 130 ml PP bottle with PP closure 1 trap: vessel with 60 ml of attractant (Vinegar 390 g/ kg (39 % w/w)), concentrated apple juice 40 g/kg (4% w/w))

2.1.4.2 Use-specific instructions for use

See 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See 2.1.5.2

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

See 2.1.5.3

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

See 2.1.5.4

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

See 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Open the trap and place it where flies occur most (e.g. fruit bowls, bin for organic waste, kitchen).
Once opened the trap stays effective for 6 weeks.
Spilled product can be removed with a cloth. Rinse with water and dishwashing liquid.
For use in any room. Can be used everywhere in the household, even next to food.

2.1.5.2 Risk mitigation measures

Keep out of reach of children.
Only to be used according to the use instructions.
Not suitable for consumption.

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

If inhaled: Move to fresh air. If symptoms persist, call a physician.
In case of skin contact: Wash off with soap and plenty of water. If symptoms persist, call a physician.
In case of eye contact: Remove contact lenses. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists, consult a specialist.
If swallowed: Do NOT induce vomiting. Rinse mouth with water. If symptoms persist, call a physician.
If medical advice is needed, have product container or label at hand.

2.1.5.4 Instructions for safe disposal of the product and its packaging

The product can be discarded with general (household) waste.

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

1. Shelf-life: 2 years
2. Store below 40 °C.
3. Protect from frost.

2.1.6 Other information

No other information available

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Ready to use trap	Bottle of 200 mL	Vessel: PET Secondary packaging: carton	Lid: PP	Non-professional	Yes
Ready to use trap	Bottle of 130 mL	Vessel: PP Secondary packaging: carton	Lid: PP	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

All submitted data is new.

A study to assess storage stability at ambient temperature including physico-chemical properties and a test to demonstrate efficacy of the biocidal product have been conducted.

2.1.8.2 Access to documentation

Vinegar and concentrated apple juice are listed in Annex I of the BPR and no active substance dossiers are available, therefore no letters of access are required.

The applicant is the owner of all submitted data.

2.2 Assessment of the biocidal product

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

Table 3. Use # 1 – Fruit flies - indoor

Product Type	19 Repellents and attractants
Where relevant, an exact description of the authorised use	Decorative trap Effective up to 6 weeks For use in any room
Target organism (including development stage)	Fruit flies (<i>Drosophila</i> spp.), adults
Field of use	Indoor, for use in any room
Application method(s)	Ready to use trap, stored product protection / food protection, attractant in a trap
Application rate(s) and frequency	1 trap: vessel with 60 ml of attractant (Vinegar 390 g/ kg (39 % w/w)) , concentrated apple juice 40 g/kg (4% w/w)) The effect of the attractant lasts up to 6 weeks after opening the trap. The trap is used upon infestation.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see section 2.1.7.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	4.09 % total acidity (as acetic acid)	Liquid	Fieseler, A. (2021)= Fieseler A., 2022a
Colour at 20 °C and 101.3 kPa	Visual	4.09 % total acidity (as acetic acid)	Yellow 2.5Y/8.5/6 (according to Munsell colour system)	Fieseler, A. (2021)=Fieseler A., 2022a
Odour at 20 °C and 101.3 kPa		4.09 % total acidity (as acetic acid)	Vinegar	Fieseler, A. (2021)= Fieseler A., 2022a
Acidity / alkalinity	MT 75.3 MT 191	4.09 % total acidity (as acetic acid)	pH (1% suspension)= 3.5 Acidity 3.4%	Fieseler, A. (2021) =Fieseler A., 2022a

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Acidity / alkalinity	MT 75.3 MT 191	3.98 % total acidity (as acetic acid)	pH (1% suspension) = 3.4 pH (undiluted) = 3.0 Acidity 3.2%	Fieseler A., 2022b
Relative density / bulk density		4.09 % total acidity (as acetic acid)	1.015 g/cm ³	CoA
Storage stability test – accelerated storage	MT 46.4 MT 75.3 MT 191 SANCO/303 0/99 rev.5	3.98 % total acidity (as acetic acid)	8 weeks, 40 °C, 200 mL PET bottle (60 mL content) No change in packaging and appearance observed after storage Weight: 86.10 g (start), 83.87 g (8 wk), change -2.6% Acetic acid: 3.6% w/w (start), 3.7% w/w (8 wk); 103% of initial content Ethanol: 0.09% w/w (start), 0.08% w/w (8 wk); 95% of initial content pH (1% suspension): 3.4 (start), 3.4 (8 wk) pH (undiluted): 3.0(start), 3.0 (8 wk) Acidity: 3.2% (start), 3.2% (8 wk)	Fieseler A., 2022b

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – long term storage at ambient temperature			<p>The shelf-life study is ongoing and will be finalised in July 2023. Results after 1 year storage:</p> <p>1 year, ambient temperature, 200 mL PET bottle (60 mL content)</p> <p>No change in packaging and appearance observed after storage</p> <p>Weight: 88.33 g (start), 84.79 g (1 Yr)</p> <p>Acetic acid: 4.2% w/w (start), 3.9% w/w (1 Yr); 94% of initial content</p> <p>Ethanol: <LOQ (start), <LOQ (1 Yr)</p> <p>pH (1% suspension): 3.5 (start), 3.4 (1 Yr)</p> <p>pH (undiluted): n.d(start), 3.0 (6 month), 3.0 (1 Yr)</p> <p>Acidity: 3.4% (start), 3.6% (1 Yr)</p>	Fieseler A., 2022a
Storage stability test – long term	-	-	A shelf life_and attractiveness	Garcia Carril, A. M.; Barra-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
storage at ambient temperature			of at least 24 months is demonstrated for the product "COMPO BIO Fruchtliegen-Falle" based on the positive results of the accelerated storage stability study together with the consideration of vinegar acting as a preservative and on the biological behaviour of fruit flies.	Jiménez, A.; Bruß, A. (2022)
Storage stability test – low temperature stability test for liquids			Not applicable. A statement "protect from frost" is included in the label.	
Effects on content of the active substance and technical characteristics of the biocidal product - light			Secondary packaging (carton) protects product from light.	
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity			Product is stable when stored in original container under dry and cool conditions.	
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material			No reactivity towards the container material was observed during the long term storage stability test (1 year) nor during the	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			accelerated storage stability test.	
Wettability			Not applicable. The biocidal product is not a solid preparation which is to be dispersed in water.	
Suspensibility, spontaneity and dispersion stability			Not applicable. The biocidal product is not a formulation forming a suspension on dilutions with water.	
Wet sieve analysis and dry sieve test			Not applicable. The biocidal product is a ready to use preparation.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable. The biocidal product is not an emulsion.	
Disintegration time			Not applicable. The biocidal product is not a water soluble or water dispersible tablet.	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable. The biocidal product is neither a powder nor consists of granules.	
Persistent foaming			Not applicable. The biocidal product is not intended to be applied in water for use.	
Flowability/Pourability/Dustability			Not applicable. The biocidal product is not a	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			granular formulation (Flowability), not a suspension concentrate, capsule suspension and suspoemulsion (Pourability) and no formulation that may be applied as a dust (Dustability).	
Burning rate — smoke generators			Not applicable. The biocidal product is no smoke generator.	
Burning completeness — smoke generators			Not applicable. The biocidal product is no smoke generator.	
Composition of smoke — smoke generators			Not applicable. The biocidal product is no smoke generator.	
Spraying pattern — aerosols			Not applicable. The biocidal product is no aerosol.	
Physical compatibility			Not applicable. The biocidal product is not intended to be used in combination with any other product.	
Chemical compatibility			Not applicable. The biocidal product is not intended to be used in combination with any other product.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Degree of dissolution and dilution stability			Not applicable. The biocidal product is not used in a water soluble bag and not provided as a water-soluble preparation, a water soluble tablet or water dispersible tablet.	
Surface tension			Not required, as physico-chemical properties are not a core requirement for simplified procedure authorisations.	
Viscosity			Not required, as physico-chemical properties are not a core requirement for simplified procedure authorisations.	

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

The biocidal product is a yellow liquid with a characteristic odour (vinegar). The diluted biocidal product (1% suspension) has a pH of 3.5 and the free acidity was determined as 3.4%. The undiluted biocidal product has a pH of 3.0. The product was found to be stable after the accelerated storage stability test (8 weeks at 40 °C) and after 1 year storage stability test at ambient temperature. A shelf life and attractiveness of 24 months is demonstrated for the biocidal product based on the positive results of the accelerated storage stability study together with the consideration of vinegar acting as a preservative and on the biological behaviour of fruit flies. A long term storage stability study at ambient temperature is ongoing. An efficacy study with aged product will be conducted as soon as the storage period of 24 months is reached and results will be provided as post-authorisation data.

No data on low temperature stability is available and thus 'protect from frost' has to be mentioned on the packaging. Store below 40 °C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives			Waived – the active substances are included in Annex I of the BPR and as such do not give rise to concern for explosiveness. In addition, the other components of the biocidal product do not contain relevant functional groups associated with explosive properties and therefore the product can be considered as not explosive.	MSDS
Flammable gases			Not applicable. The biocidal product is not a gas.	
Flammable aerosols			Not applicable. The biocidal product is no aerosol.	
Oxidising gases			Not applicable. The biocidal product is not a gas.	
Gases under pressure			Not applicable. The biocidal product is not a gas under pressure.	
Flammable liquids	EU A.9	3,98 % total acidity (as acetic acid)	No flash point up to 100 °C. At approximately	Grund, D., 2022a

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			100 °C the test item begins to boil.	
Flammable solids			Not applicable. The biocidal product is not a solid.	
Self-reactive substances and mixtures			Not applicable. The active substances are included in Annex I of the BPR and as such do not give rise to concern for self-reactivity. The other components of the biocidal product do not contain chemical groups associated with explosive or self-reactive properties. Therefore the classification procedure does not need to be applied.	
Pyrophoric liquids			Not applicable because the product is known to be stable in contact with air at room temperature for prolonged periods of time (weeks) and hence, the classification procedure does not need to be applied.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Pyrophoric solids			Not applicable. The biocidal product is not a solid.	
Self-heating substances and mixtures			The study does not need to be conducted because the product is liquid and not adsorbed on a large surface. In addition product is known to be stable. Also vinegar is not a self-heating substance.	
Substances and mixtures which in contact with water emit flammable gases			The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	
Oxidising liquids			The study is not needed as none of the components of the mixture have oxidising properties. Components of the product have oxygen only bound to carbon or hydrogen.	
Oxidising solids			Not applicable. The biocidal	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			product is a liquid.	
Organic peroxides			Not relevant because the product does not contain organic peroxides.	
Corrosive to metals	UN C.1	3.98 % total acidity (as acetic acid)	Since the classification criterion of a hole depth of 360 µm/21 days was clearly exceeded, the test item was found to be corrosive to metals and has to be classified as metal corrosive substance of packing group III / category 1 according to the Manual of Test and Criteria.	Grund, D., 2022b
Auto-ignition temperatures of products (liquids and gases)			The biocidal product is a water-based non flammable product with no flash point up to boiling point and therefore auto-ignition temperature cannot be measured.	
Relative self-ignition temperature for solids			Not applicable. The biocidal product is not a solid.	
Dust explosion hazard			Not applicable. As the biocidal product is not a powder or	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			product containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air.	

Conclusion on the physical hazards and respective characteristics of the product

The biocidal product is classified as metal corrosive substance of packing group III / category 1 according to the Manual of Test and Criteria (Met.Corr.1, H290: May be corrosive to metals).

2.2.4 Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

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	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Precision (%)	Reference
					Range	Mean	RSD			
Acetic Acid	GC-FID	Fortification level 1: LOQ 160 mg/L (n=5) Fortification level 2: 1.5 x LOQ 240 mg/L (n=4)	range: 100-500 mg/l r: 0.9993 slope: 1771 intercept: -100535	Small interference in blank formulation (5% of LOQ)	Level 1: 104-107	Level 1: 106	Level 1: 0.9	160 mg/L 3.2 %, w/w	c = 4.2% (w/w) n = 5 RSD% = 1.0 RSD _r = 2.2 Horwitz ratio = 0.5	Fieseler A., 2022a
Ethanol	GC-FID	Fortification level 1:	range: 10-50 mg/l	Small interference in	Level 1:	Level 1:	Level 1:	20 mg/L	Not determined.	Fieseler A., 2022a

		LOQ 20 mg/L (n=5) Fortification level 2: 1.5 x LOQ 30 mg/L (n=4)	r: 0.999 1 slope: 3438 intercept: 2207	blank formulation (12% of LOQ)	95- 100 Level 2: 97- 99	97 Level 2: 98	2.0 Level 2: 1.1	0.4 %, w/w	The analyzed product did not contain ethanol.	
Apple juice concentrate	Technically not feasible as no marker is available									

Analytical methods for monitoring soil, air, water, animal and human body fluids and tissues, and for monitoring of active substances and residues in food and feeding stuff are not listed as requirements for biocidal products eligible for simplified authorisation according to Article 25 of the BPR.

Conclusion on the methods for detection and identification of the product

The biocidal product contains vinegar and concentrated apple juice as active substances. An analytical method for the determination of Acetic acid and Ethanol in the biocidal product was accurately validated according to SANCO/3030/99 rev.5 in study Fieseler 2022a. Specificity, linearity, accuracy and precision were checked and found acceptable. As concentrated apple juice does not have a single defined active ingredient and there is no analytical method available, the stability of the concentrated apple juice is demonstrated by an efficacy test with aged product. Analytical methods for monitoring soil, air, water, and animal and human body fluids and tissues are not required as vinegar and concentrated apple juice are included in Annex I of Regulation (EU) No. 528/2012.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Attractant in traps with PT19 active substance.
Indoor use.

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

Adult fruit and vinegar flies (*Drosophila* spp.) are to be controlled. Fruit flies may cause inconvenience primarily indoors where they infest rotting organic material such as fermenting fruits and vegetables. In Europe, species of the family Drosophilidae (fruit flies or vinegar flies) can be considered as a relevant nuisance.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The adult flies are attracted into the trap, where they will die.

2.2.5.4 Mode of action, including time delay

The fruit flies, attracted by the attractant, enter the trap and fall into the attractant liquid in the trap and drown. The mode of action does not depend on the fruit flies' sex. The effect starts immediately after opening the trap. A good result is visible within 24 hours. The effect of the attractant lasts 6 weeks after opening the bottle.

2.2.5.5 Efficacy data

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
Attractant in traps with PT19 active substance	Indoor	Ready to use terrasan Home Fruchtfliegen-Falle (identical with COMPO BIO Fruchtfliegen-Falle) filled with 1) Vinegar test solution, batch 18/017 2) Water (untreated control trap)	<i>Drosophila melanogaster</i> , 7 days old mixed sex adults	Simulated use trial, In House method in accordance with BPR guidance Vol. II, Version 3.0	Test chamber 30m ³ ; 5 replicates à 200 flies; Untreated control in separate test chambers with traps filled with water; 23-25°C; 40-55% RH; Water and competitive food (fruit fly food "Alcaine-Colet"); 60min acclimatization of flies in test chamber; Trap is placed in centre of the room. Number of trapped flies is counted 24, 48, 72h after placing the trap. Test is repeated at t(0) (right after opening), t(2), t(4) and t(6), i.e. 2, 4 and 6 weeks after opening the trap.	<u>T(0)</u> 1) Vinegar test solution: 90% trapped after 24 h, 2) Untreated: 0% <u>T(2)</u> 1) Vinegar test solution: 92% trapped after 48 h, 2) Untreated: 0% <u>T(4)</u> 1) Vinegar test solution: 91% trapped after 72 h, 2) Untreated: 1% <u>T(6)</u> 1) Vinegar test solution: 91% trapped after 72 h, 2) Untreated: 0%	Linn, C. (2021) Report No. BIO059a-21
Attractant in traps with PT19 active substance	Indoor	-	<i>Drosophila melanogaster</i>	Scientific statement	COMPO BIO Fruchtfliegenfalle Demonstration of shelf life Statement on the function of vinegar and on the preferences of fruit flies	A shelf life of 24 months is demonstrated for the product "COMPO BIO Fruchtfliegen-Falle" based on the consideration of vinegar acting as a preservative and on the biological behaviour of fruit flies.	Garcia Carril, A. M.; Barra-Jiménez, A.; Bruß, A. (2022); Report no. 220411-3.4-01;

							<i>Submitted under 3.4.1</i>
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Conclusion on the efficacy of the product

One simulated-use-study was provided in support of the product's efficacy. The claimed target organisms are adult fruit flies or vinegar flies, which belong to *Drosophila spp.*. The product has been tested with *Drosophila menalogaster*, as recommended according to BPR guidance Vol II.

The formulation and trap as intended were tested according to instructions of use. One trap was used in a 30 m³ test chamber. The trap was placed at 1m distance to alternative food. The test chamber was larger than recommended in the BPR guidance Vol II, which represents a worst case for testing.

In the provided simulated-use-test, the trap was shown to attract and trap $\geq 90\%$ of the fruit flies. The product was tested immediately after opening and the same test was repeated 2, 4 and 6 weeks after opening. The fresh product reached 90% efficacy in 24h, 2 weeks aged product in 48h, 4 and 6 weeks aged product in 72h. The FI CA therefore considers that the product has been proven efficient in reducing fruit fly population by attracting and trapping fruit flies. The product remains efficacious 6 weeks after opening.

Justification for provisional 2 year shelf life

The applicant has provided a scientific statement in support of a provisional 2 year shelf life. The statement is based on two main points: vinegar serving as a preservative and the biology of fruit flies being attracted to fermenting fruits and vegetables. Some natural changes in the composition of the concentrated apple juice component of the product due to aging over the 24 months shelf life are therefore considered not likely to decrease attractiveness of the product to fruit flies.

The active substance vinegar has a double function in the formulation. In addition to the vinegar's main function as attractant (PT 19), it also has a preservative function. Vinegar is used extensively as a food and feed preservative. The main acidic component of vinegar, acetic acid, is also listed in the EU food additive list as preservative E 260.

In the Technical Agreements on Biocides for Efficacy guidance is given on requirements for palatability (attractiveness) studies in relation to shelf life claims. The following requirements for shelf life of PT 18 bait products stated in TAB EFF 4 can also be applied to PT19 traps:

Q: Could 'a long period storage' agreed for PT14 products be accepted with reference to the requirements on palatability studies corresponding to more than 24 months also for PT18 biocidal products?

A: The palatability testing defined for PT14 products can also be applied to PT18 biocidal products. Therefore, efficacy testing should only be provided for the following cases:

- bait products with preservatives that claim a shelf life longer than 24 months;*
- bait products without preservatives that claim a shelf life longer than 12 months;*
- bait products for which the degradation of the active content is >10% and assessment of the degradation on the efficacy is needed to substantiate the shelf life claim.*

For bait products with a shorter shelf life claim than stated above, no efficacy tests of aged bait (i.e. product at the end of maximum storage) have to be

provided. For these products it is sufficient to provide tests on fresh bait (i.e. newly produced product)

As COMPO BIO Fruchtliegenfalle contains the preservative vinegar, a provisional shelf life of 24 months can be established based on the efficacy test with fresh product as included in the dossier.

2.2.5.6 Occurrence of resistance and resistance management

No resistance was found in the presented efficacy trial. 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>). Resistance due to the use of COMPO BIO Fruchtliegen-Falle is highly unlikely since the active substances are (components of) natural food sources of fruit flies and the attracted fruit flies are being trapped. Furthermore since the product is an olfactory attractant, and mechanisms of resistance do not occur to this type of attractant, it is not to be expected that resistance will build up for vinegar and hence no resistance management strategy is required for this product.

2.2.5.7 Known limitations

There are no known limitations of the product.

2.2.5.8 Evaluation of the label claims

The label claims for the product which are supported by the data package are:

- Attracts and traps adult fruit and vinegar flies (*Drosophila* spp.)
- Trap will remain effective for 6 weeks after opening.

Label claims have been addressed by the available efficacy study. The results of the study show that the product is fully effective.

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

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

2.3 Risk assessment for human health

For simplified authorisation, risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Safety data sheets for the active substance, the biocidal product and any co-formulant are provided with this submission.

2.3.1 Assessment of effects on human health

The product has not been tested for any human health endpoints. It contains only one substance classified for human health endpoints, which is present in the formulation at less than 0.1%. Hence the product will not be classified for human health endpoints.

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

The biocidal product is mainly composed of ingredients that are food stuffs of food grade quality (>99% w/w). None of the co-formulants are leading to a classification of the product in the sense of Regulation (EC) No 1272/2008 or meeting the criteria for being persistent, bioaccumulative or toxic (POP, PBT or vPvB).

COMPO BIO Fruchtliegen-Falle does not contain any substance of concern according to Art 3 (f) of Regulation (EC) 528/2012) or meeting other criteria laid down in Annex A of the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C). Please refer to Confidential Annex for details.

2.3.3 Available toxicological data relating to endocrine disruption

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed using the tiered approach according to "CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants.pdf".

After this screening it was concluded that none of the co-formulants shows an alert for endocrine disruptors. See the Confidential Annex for more information on the screening results.

2.3.4 Available toxicological data relating to a mixture

Not relevant.

2.3.5 Other

Not relevant.

2.3.6 Exposure assessment

The biocidal product does not contain any substance of concern, is not classified for human health hazards and consists mainly of food grade co-formulants. Hence, the handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

For simplified authorisation, risk assessment for human health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012. Therefore, no further exposure assessment for human health is required for the current registration.

2.3.7 Risk for consumers via residues in food

Not relevant. Risk assessment for consumers via residues in food is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

2.3.8 Risk assessment for animal health

Not relevant. Risk assessment for animal health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

2.4 Risk assessment for the environment

Risk assessment for the environment is not defined as a requirement in Article 25 and Article 20 point 1. (b), relating to biocidal products eligible for simplified authorisation.

The product COMPO BIO Fruchtliegen-Falle contains no substances of concern and is not classified for environmental endpoints.

2.4.1 Effects assessment on the environment

Not relevant. Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

2.4.2 Exposure assessment

Not relevant. Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

2.4.3 Risk characterisation

Not relevant. Not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

2.4.4 Measures to protect man, animals and the environment

Please refer to Point 2.1.4 and the relevant section in IUCLID.

2.4.5 Assessment of a combination of biocidal products

The product COMPO BIO Fruchtliegen-Falle is not intended to be authorised for the use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Section No / Reference No	Title. Source (where different from company), Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Fieseler, A.	2021 = 2022a	2.2.2, 2.2.4	terrasan Home Fruchtfliegen-Falle: Storage Stability at Ambient Temperature. Ibacon GmbH Arheilger Wg 17 64389 Rossdorf Germany, Study No.: 156211228, GLP, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany
Fieseler, A.	2022b	2.2.2	terrasan Home Fruchtfliegen-Falle: Accelerated Storage Stability (8 weeks at 40 °C). Ibacon GmbH Arheilger Wg 17 64389 Rossdorf Germany, Study No.: 156211227, GLP, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany
Garcia Carril, A. M.; Barra-Jiménez, A.; Bruß, A. (2022)	2022	2.2.2	Scientific statement COMPO BIO Fruchtfliegenfalle Demonstration of shelf life Statement on the function of vinegar and on the preferences of fruit flies. Vali Consulting GmbH Im Technologiepark 5 69469 Weinheim, Germany, Report No.: 220411-3.4-01, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany
Grund, D.	2022a	2.2.3	Determination of the Flash Point (EU A.9) of the test item COM 145 02I AL. Henkel AG & Co. KGaA Corporate Scientific Solutions 40191 Düsseldorf, Report No.: 22-02161-3, GLP, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany
Grund, D.	2022b	2.2.3	Determination of the Corrosion to metals (UN C.1) of the test item COM 145 02 I AL. Henkel AG & Co. KGaA Corporate Scientific Solutions 40191 Düsseldorf, Report No.: 22-02161-2, GLP, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany

Linn, C.	2021	2.2.5	Efficacy of a Fruit fly trap against Fruit flies, <i>Drosophila melanogaster</i> in 30 m ³ test rooms. BioGenius GmbH, Biology Campus 1 Friedrich-Ebert-Straße 75 51429 Bergisch Gladbach, Germany, Study No.: BIO2021-005, Unpublished	Yes	COMPO GmbH Gildenstraße 38 48157 Münster Germany
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3.2 Output tables from exposure assessment tools

Not relevant.

Not part of the requirements for biocidal products eligible for simplified authorisation as per Article 19, point 1, nor are they defined as requirements in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorisation.

3.3 New information on the active substance

Not relevant.

No new information on the active substance Vinegar is provided nor considered to be required.

3.4 Residue behaviour

Not relevant.

Not part of the requirements for biocidal products eligible for simplified authorisation as per Article 19, point 1, nor are they defined as requirements in Article 25 and Article 20 point 1. (b), pertaining to biocidal products eligible for simplified authorisation.

3.5 Summaries of the efficacy studies

Not relevant. A IUCLID file was submitted with this application. For details, please see summary table in 2.2.5.5 and IUCLID file.

3.6 Other

Not relevant. No other information required.