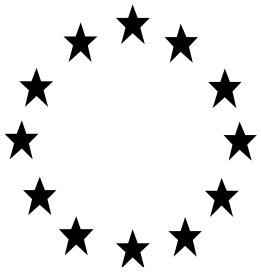
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION



Super Ninja against Fruit Flies

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-WU071226-05

Competent Authority: Finland

Date: 1 December 2022

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1 Conclusion

Super Ninja against Fruit Flies is a PT 19 biocidal product containing vinegar and concentrated apple juice as active substances. The product is used as a ready-to-use attractant trap by non-professionals for the control of fruit flies (*Drosophila melanogaster*).

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 control of fruit flies by non-professionals, 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 substances vinegar and concentrated apple juice are listed in Annex I of Regulation (EU) 528/2012 and satisfy the following restrictions: excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food) and 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 ;
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 necessary. Detailed information on classification and labelling is provided in section 2.8 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.

[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

More information is available in section 2.7 of the PAR and in the confidential annex.

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 substances 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 substances are listed in section 1.4 of the SPC.

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

A physical hazard was identified. Super Ninja against Fruit Flies will be classified as Met. Corr.1, H290: May be corrosive to metals. More information is available in section 3.3 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. Therefore the stability of the concentrated apple juice is demonstrated by an efficacy test. More information on the analytical methods for the active substances is available in section 3.4 and efficacy in section 3.5 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against fruit flies (*Drosophila melanogaster*) for all intended uses. More information is available in section 3.5 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.

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.	01.12.2023

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)	PT19
Type(s) of formulation	AL - other liquids to be applied undiluted

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[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (eCA/ refMS)[8]	Comment (eCA/refMS)[9]
1	Control of fruit flies (*Drosophila melanogaster*)	PT19	Fruit flies	Manual application	1 trap (18 ml)/30m³	Non-professional	A	

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

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(s) 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.
- All the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

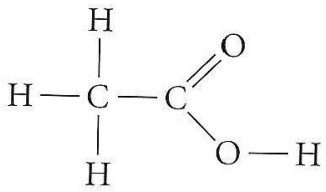
Main constituent(s)	
Common name	Vinegar
Chemical name	-
EC number	Not available
CAS number	8028-52-2
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	Natural substance vinegar Maximum 10 % acetic acid in solution Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food).
Structural formula	Acetic acid: 

Table 2.4 Identity of the active substance(s)

Main constituent(s)	
Common name	Concentrated apple juice
Chemical name	-
EC number	Not available
CAS number	Not available
Index number in Annex VI of CLP	Not applicable
Minimum purity / content	Not applicable 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 applicable

2.5 Information on the source(s) of the active substance(s)

The information on the source(s) of the active substance(s) is not applicable.

2.6 Candidate(s) for substitution

Not relevant.

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

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.

2.8 Classification and labelling

Table 2.8 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Met.Corr. 1	
Hazard Pictograms	GHS05	None**
Signal word(s)	Warning	Warning
Hazard statements	H290 – May be corrosive to metals	H290 : May be corrosive to metals
Precautionary statements*	P234: Keep only in original container P390: Absorb spillage to prevent material damage	P234: Keep only in original container P390: Absorb spillage to prevent material damage
Supplemental hazard statements	None	
Notes	-	

*P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

** 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 (Category 1) which are in the finished state as packaged for consumer use do not require on the label the hazard pictogram GHS05.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

Not applicable: the active substances are on Annex I of the BPR and the applicant is owner of all submitted product data.

2.10 Data submitted in relation to product authorisation

No new data on the active substances have been submitted.

2.11 Similar conditions of use across the Union

Not relevant.

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 equipped with removable funnel	30 ml (filled with 18 ml product)	PET (bottle) PP (funnel) Carton (secondary packaging)	screw cap, PP	Non-professional	Yes

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

3.2 Physical, chemical, and technical properties

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	Observation	Super Ninja against Fruit Flies Batch T-U0710 37.5% (w/w) Vinegar and 5.0% (w/w) Concentrated apple juice	Liquid, clear, not viscous, strong acetic odour, brown colour	Gazzotti, L, 2021a study N° 21238-02C
3.1.1.	Physical state at 20 °C and 101.3 kPa	Observation (visual)		Liquid, clear, not viscous	
3.1.2.	Colour at 20 °C and 101.3 kPa	Observation (visual)		Brown colour	
3.1.3.	Odour at 20 °C and 101.3 kPa	Obervation (smelling)		Strong acetic odour	
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3 CIPAC MT 191		pH (neat): 2.84 pH (1%): 3.45 Acidity: 3.20% (w/w) as H_2SO_4	
3.3.	Relative density / bulk density	CIPAC MT 3.1/EEC A3		Density: 1.0136 g/ml	
3.4.1.1.	Storage stability test – accelerated storage	CIPAC method MT 46.3 - 2 weeks at 54 °C Appearance: observation (visual and smelling) Stability packaging: Visual assessment and weighing of bottles pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 Density: CIPAC MT 3.1/EEC A3 Analytical method acetic acid (representative for vinegar): Internal GC-FID method validated in study 21238-01C, see section 3.4 of this PAR		Commercial packages of Super Ninja (5 pcs) against Fruit Flies (plastic bottles) were stored for 2 weeks at 54±2 °C. Appearance: no change after storage Stability of the packaging: no change in packaging over storage, weight of the bottles decreased slightly (-0.68 g, -2.4%, from 28.82 to	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		As concentrated apple juice does not have a single defined active ingredient only the concentration of acetic acid (representing the concentration of the active substance vinegar) can be measured.		28.13 g) Density increased slightly over storage from 1.0136 g/ml to 1.0191 g/ml pH (neat) decreased slightly over storage from 2.84 to 2.79 pH (1%) increased slightly over storage from 3.45 to 3.46 acidity increased slightly over storage from 3.20 to 3.27 % w/w as H_2SO_4 acetic acid content (representative for vinegar content) did not change over storage (3.92 % w/w)	
3.4.1.2.	Storage stability test – long-term storage at ambient temperature	Appearance: observation (visual and smelling) Stability packaging: Visual assessment and weighing of bottles pH: CIPAC MT 75.3 Acidity: CIPAC MT 191 Density: CIPAC MT 3.1/EEC A3 Analytical method acetic acid (representative for vinegar): Internal GC-FID method validated in study 21238-01C,	Super Ninja against Fruit Flies Batch T-U0710 37.5% (w/w) Vinegar and 5.0% (w/w) Concentrated apple juice	Two year storage at ambient temperature of commercial packages of Super Ninja against Fruit Flies (plastic bottles) Study plan available Start date 26 August 2021. Expected end date: September	Gazzotti, L, 2021b study N° 21238-03C

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		see section 3.4 of this PAR		2023	
3.4.1.3.	Storage stability test – low temperature stability test for liquids			Not applicable (packaging will list 'protect from frost')	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – light			Effect of light is not relevant since the product is not exposed to light during storage as it is sold in a carton outer packaging.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity			Humidity is not relevant; the product is water based. Temperature: see 3.4.1.1.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material			The product is packed in PET/PP containers. There were no signs of interaction between the packaging material and the product during the accelerated storage stability test. The result has to be confirmed with the long-term storage	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				stability test results, when available.	
3.5.1.	Wettability *[indicate the concentration tested]*			Not required for this formulation type. For simplified authorisation, data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012	
3.5.2.	Suspensibility, spontaneity, and dispersion stability *[indicate the concentration tested]*				
3.5.3.	Wet sieve analysis and dry sieve test *[indicate the concentration tested]*				
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability *[indicate the concentration tested]*				
3.5.5.	Disintegration time				
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability *[the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]*				
3.5.7.	Persistent foaming *[indicate the concentration tested]*				
3.5.8.	Flowability/pourability/dustability				
3.5.9.	Burning rate — smoke generators				
3.5.10.	Burning completeness — smoke generators				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.11.	Composition of smoke — smoke generators				
3.5.12.	Spraying pattern — aerosols / spray				
3.6.1.	Physical compatibility			Not relevant: product is RTU and not intended to be used with other products.	
3.6.2.	Chemical compatibility				
3.7.	Degree of dissolution and dilution stability			Not required for this formulation type.	
3.8.	Surface tension			For simplified authorisation, data are not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012	
3.9.	Viscosity				

Table 3.2 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Super Ninja against Fruit Flies is a RTU liquid formulation of the AL – Any other liquid type. Super Ninja is a clear, non-viscous brown liquid with a characteristic strong acetic odour. It has a pH of 2.84 (neat) and acidity of 3.2% (w/w) as H_2SO_4. Super Ninja in commercial packages were found to be stable during the accelerated storage stability test (two weeks storage at 54 °C). Based on the CA document (CA-May14-Doc5.5 Final_Simplified_Procedure_stability_data.docx), the shelf life of the product must be demonstrated either by storage stability studies according to BPR Annex III, point 3.4 or by efficacy studies performed with aged product. Super Ninja against Fruit Flies contains two active substances: vinegar and concentrated apple juice - a UVCB substance. For the monitoring of the stability of vinegar, the concentration of acetic acid in the product can be measured. However, as concentrated apple juice is a UVCB substance, it is difficult to select one substance to monitor and to demonstrate the stability of the juice. As a result, the shelf life of Super Ninja against Fruit Flies has to be demonstrated by an efficacy study with aged product showing sufficient attractiveness of the product at the end of its maximum claimed shelf life (24 months). An efficacy study with aged product will be conducted as soon as the storage period of 24 months is reached and provided as Post-authorisation data (expected Q4/2023). Implications for labelling: As no data on low temperature stability are available, 'protect from frost' has to be mentioned on the packaging.

3.3 Physical hazards and respective characteristics

Super Ninja against Fruit flies is based on food grade vinegar and concentrated apple juice and as such does not give rise to concern for physical hazards. However, based on the presence of acetic acid (in vinegar) and the low pH of the product, information on the properties “flammable liquid” and “corrosive to metals” was requested. The information is included in the table below.

Table 3.3 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for explosiveness, this property is considered not applicable. Moreover, the other components of the biocidal product do not contain relevant functional groups associated with explosive properties and therefore product can be considered as not explosive.		
4.2.	Flammable gases	Waived - Not relevant because the product is a liquid.		
4.3.	Flammable aerosols	Waived - Not relevant because the product is a liquid.		
4.4.	Oxidising gases	Waived - Not relevant because the product is a liquid.		
4.5.	Gases under pressure	Waived - Not relevant because the product is a liquid.		
4.6.	Flammable liquids	ASTM D93 Pensky-Martens closed cup	Super Ninja against Fruit Flies (37.5 % vinegar, 5.0% concentrated apple juice)	Measurement was carried out until boiling temperature (100 °C); no flash point was found. Therefore, the product is not a flammable liquid.
4.7.	Flammable solids	Waived - Not relevant because the product is a liquid.		
4.8.	Self-reactive substances and mixtures	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for self-reactivity, this property is considered not applicable. The product contains low amount of a substance that contains chemical group associated with self-reactive properties but taking into account the phlegmatizing effect of high water content, the product is not considered to be self-reactive.		
4.9.	Pyrophoric liquids	Waived - Considering the composition of the product and the fact that		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for pyrophoric properties, this property is considered not applicable. Moreover, 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.		
4.10.	Pyrophoric solids	Waived - Not relevant because the product is a liquid.		
4.11.	Self-heating substances and mixtures	Waived – Not relevant because the product is a liquid and the product is not adsorbed on a large surface.		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waived - Not relevant because the formulation is manufacturd with water (water-based product) and experience shows that the product does not react with water.		
4.13.	Oxidising liquids	Waived - Considering the composition of the product and the fact that the active substances are included in Annex I of the BPR – category 4, and as such do not give rise to concern for oxidising properties, this property is considered not applicable. In addition, the other components of the mixture which might, based on functional groups, rise a concern regarding oxidising properties are present in low concentrations (<20% of solid compounds in aqueous solution) and are not considered to have an effect on oxidising properties.		
4.14.	Oxidising solids	Waived - Not relevant because the product is a liquid.		
4.15.	Organic peroxides	Waived - Not relevant because the product contains no organic peroxides.		
4.16.	Corrosive to metals	UN Manual of Tests and Criteria: Part III, sub-section 37.4 7 days exposure of aluminium and steel panels at 55°C	Super Ninja against Fruit Flies (37.5 % vinegar, 5.0% concentrated apple juice)	Loss of mass of steel and aluminium panels was max 5.2% and 0.5%, respectively, which did not exceed the limit of 13.5%. Localised corrosion was observed on the aluminium sample partially immersed in the liquid with a depth of intrusion of max 426 µm which exceeds the

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				limit of 120 µm. The product was found to be corrosive to metals.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waived - 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.		
4.17.2.	Relative self-ignition temperature for solids	Waived - Not relevant because the product is a liquid.		
4.17.3.	Dust explosion hazard	Waived - Not relevant because the product is a liquid.		

Conclusion on physical hazards and respective characteristics
The product is classified as corrosive to metals (Met. Corr. 1, H290: May be corrosive to metals).

3.4 Methods for detection and identification

Super Ninja against Fruit Flies contains vinegar and concentrated apple juice as active substances. As concentrated apple juice does not have a single defined active ingredient only the concentration of acetic acid (representing the concentration of the active substance vinegar) can be analysed and monitored in storage stability studies. The GC-FID method (Renolab Internal Method MA CCF 569-1) used to determine the acetic acid concentration in the product in the storage stability studies was validated in a separate study which is summarised in the table below. Storage stability of the concentrated apple juice will be demonstrated by efficacy study with aged product, see section 3.5 of the PAR.

Table 3.4 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues										
Principle of the method (Gazzotti, L, 2021c , study N° 21238-01C): 200 mg of Super Ninja against Fruit Flies was weighed in a 10 mL class A volumetric flask and diluted to volume with acetone containing 1 mg/mL of n-hexane as internal standard, well mixed thoroughly and analysed by GC-FID in comparison to the reference item (acetic acid).										
Analyte (type of analyte e.g. active substance)	Linearity	Specificity	Fortification range, level and number of measurements at each level		Recovery rate (%)			Precision (%)		Limit of Quantification LOQ – *only for impurit(y/ies)*	Reference
			Level	Number of	Range	Mean	RSD	Concentr	Number		

				measurements				ation tested	of replicates		
Acetic acid (representing the active substance vinegar)	range 2.55 - 6.36 % w/w, n = 5, r^2 = 0.9963 Slope = -0.0255 Intercept = 0.2577	The chromatogram and the retention times of acetic acid in the sample and in the recovery solutions matched the chromatogram and the retention times in the reference standards. Chromatograms provided (solvent blank, internal standard solution, reference item solution, fortified sample and formulation sample)	0.7635 mg/mL (equivalent to 3.82% w/w)	2	104.8-105.6	105.2	n.d.	3.92 % (w/w)	n =5 RSD = 1.27% RSDr = 2.18% Horwitz Ratio = 0.58	-	Gazzotti, L, 2021c study N° 21238-01C Gazzotti, L, 2021d CERTIFICATE OF ANALYSIS No. 087/21

Monitoring methods for soil, air, water, body fluids and tissues, food and feeding stuff are not required as vinegar and concentrated apple juice are included in Annex I of Regulation (EU) No. 528/2012.

Table 3.4 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Super Ninja against Fruit Flies contains vinegar and concentrated apple juice as active substances. As concentrated apple juice does not have a single defined active ingredient only the concentration of acetic acid (representing the concentration of the active substance vinegar) can be analysed and monitored in storage stability studies. An analytical method (Gazzotti, L, 2021c, study N° 21238-01C) for the determination of acetic acid (representative for the active substance vinegar) in the biocidal product is available. Specificity, linearity, accuracy and precision were checked and found acceptable. No analytical method for the concentrated apple juice is available, therefore the stability of the concentrated apple juice is demonstrated by an efficacy test. Methods for the detection of vinegar and concentrated apple juice in 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.

3.5 Assessment of efficacy against target organisms

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

Super Ninja against Fruit Flies, containing active substances vinegar and concentrated apple juice, is used for the control of fruit flies (*Drosphila melanogaster*) by attracting the adult fruit flies to a trap. The biocidal product is intended for indoor use by non-professionals, to protect humans against nuisance pest.

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

Super Ninja against Fruit Flies contains the active ingredients vinegar and concentrated apple juice, which attract the fruit flies to the trap. The insects drown into the liquid in the trap.

3.5.3 Efficacy data

Table 3.5 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
Use 1: Control of fruit flies</td>
<td>Super Ninja against Fruit Flies
37.5% (w/w) Vinegar and 5.0% (w/w) Concentrated apple juice</td>
<td>Attractant
Drosophila melanogaster adults, mixed sexes
Number tested: 200
Number of replicates:5</td>
<td>Based on Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 – April 2018 - ECHA”.
Simulated use test.
Indoor.
Test chamber: 4.50 m depth x 2.50 m width x 2.70 m height = 30.38 m3 volume.
In the test chamber, 200 adult individuals (mixed sexes) of Drosophila melanogaster were released at the beginning of the test for each replicate.
Dose: 1 trap containing 18 mL attractant solution per test chamber.
After at least 1 hour of acclimatization of</td>
<td>No captures were observed in the negative control traps: the method is valid.
Test results:
<table>
<tr><th rowspan="2">Trap type</th><th rowspan="2">Replicate</th><th colspan="5">Number of captured flies (cumulative) after</th><th rowspan="2">Total number of captured flies after 24 h</th><th rowspan="2">Attraction efficacy/Pest control (%)</th></tr>
<tr><th>30 min</th><th>1 h</th><th>3 h</th><th>6 h</th><th>24 h</th></tr>
<tr><td rowspan="5">Control (water)</td><td>I</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0.0</td></tr>
<tr><td>II</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0.0</td></tr>
<tr><td>III</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0.0</td></tr>
<tr><td>IV</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0.0</td></tr>
<tr><td>V</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0.0</td></tr>
<tr><td rowspan="5">Super Ninja against Fruit Flies</td><td>I</td><td>0</td><td>0</td><td>0</td><td>3</td><td>169</td><td>169</td><td>84.5</td></tr>
<tr><td>II</td><td>0</td><td>0</td><td>0</td><td>4</td><td>162</td><td>162</td><td>81.0</td></tr>
<tr><td>III</td><td>0</td><td>0</td><td>0</td><td>2</td><td>175</td><td>175</td><td>87.5</td></tr>
<tr><td>IV</td><td>0</td><td>0</td><td>0</td><td>6</td><td>157</td><td>157</td><td>78.5</td></tr>
<tr><td>V</td><td>0</td><td>0</td><td>0</td><td>7</td><td>186</td><td>186</td><td>93.0</td></tr>
</table>
The mean percentage of attraction efficacy/pest control at 24 hours exposure was calculated to be 84.9%, while no captures were observed into the negative control traps.
Conclusion: Super Ninja against Fruit Flies used as ready-to-use attractant trap demonstrated ≥ 80% attraction efficacy within 24 hours. According to the results obtained in this study, “Super Ninja against Fruit</td>
<td>Rovetto, I, 2021
study N° 4540.I.SAG21</td>
<td>IUCLID section 6.7 /Efficacy data to support these claims.001
Test report title: Efficacy evaluation of “Super Ninja against Fruit Flies” attractant traps for the indoor control of Drosophila melanogaster – Italy 2021</td>
</tr>
</table>

			the released flies into the test room, the attractant trap and the competition food source (Nekton Drosophila) were placed on shelves at about 0.5 m height and at minimum 2 m distance from each other. Number of flies captured into the traps was monitored at 0.5, 1, 3, 6 and 24 hours after introduction of the trap. Negative controls (same trap filled with water instead of attractant solution) were tested in an identical setting in a separate room. The test was performed with 5 replicates, and 5 negative controls were used. Climatic conditions: temperature 25±1°C; relative humidity 60-70%; photoperiod 16h:8h light/dark.	Flies" is efficacious against *Drosophila melanogaster*.		

3.5.4 Efficacy assessment

One simulated-use study has been provided to support the efficacy of Super Ninja against Fruit Flies. Adult *Drosophila melanogaster* were released into a chamber with the attractant trap or negative control and the competition food source. Fruit flies caught in the trap were monitored 0.5, 1, 3, 6 and 24h after placing the trap.
Super Ninja against Fruit Flies for the control of fruit flies (*Drosophila melanogaster*) has proven to be an efficacious attractant applying 1 attractant trap (containing 18 ml attractant solution) per 30 m^3 (>80% attraction efficacy within 24 hours).

Justification for provisional 2 year shelf life
The active substance vinegar has a double function in the formulation. Next to vinegar's main function as attractant (PT 19), it also has a preservative function, preserving the formulation during storage. Vinegar is well known and used extensively as a food and feed preservative. As such, the main acidic component of vinegar, acetic acid, is listed in the EU food additive list as preservative E 260. Vinegar will not only function as attractant during use, but will preserve the product during storage as well.

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 Super Ninja against Fruit Flies 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.

In further support of the claim of 24 months shelf life of Super Ninja against Fruit Flies it is noted that fruit flies, due to their biology, are mainly attracted to moist, fermenting fruits and vegetables. Over-ripe to decaying fruit is the perfect place for fruit flies to deposit their eggs on and for their larvae to grow in. 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. In combination with the shown stability of the vinegar content (as concentration acetic acid) of the product in the accelerated storage stability study (2 weeks at 54 °C), it is expected that the product Super Ninja against Fruit Flies is equally efficacious in attracting fruit flies after 24 months storage.

24 months shelf life is considered supported based on current efficacy data, however an

efficacy study is required as post-authorisation data to fulfill the physico-chemical requirements. An efficacy study with aged product will be conducted as soon as the storage period of 24 months is reached and provided as Post-authorisation data (expected Q4 2023).

3.5.5 Conclusion on efficacy

Based on the results from the simulated use test, authorisation can be granted for the use by non-professionals for the control of fruit flies at an application rate of 1 trap (18 ml) per 30 m^3.

3.5.6 Occurrence of resistance and resistance management

Resistance due to the use of Super Ninja against Fruit Flies is not applicable since the active substances are (components of) natural food sources of fruit flies and the attracted fruit flies are being trapped.

3.5.7 Known limitations

No limitations on efficacy have been observed during efficacy testing.

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

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

3.6 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.

3.6.1 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.

3.6.2 Information on dermal absorption

Not relevant.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Please refer to section 2 of this PAR's Confidential Annex for details.

3.6.4 Other

Not relevant.

3.6.5 Available toxicological data relating to endocrine disruption

The product contains no endocrine-disrupting formulants. For the assessment of endocrine-disrupting properties of the non-active substances, please refer to section 3 of this PAR's Confidential Annex.

3.6.6 Exposure assessment and risk characterisation for human health

Not relevant.

3.6.7 Monitoring data

Not relevant.

3.6.8 Dietary risk assessment

Not relevant.

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

Not relevant.

3.6.10 Overall conclusion on risk assessment for human health

Not relevant.

3.7 Risk assessment for animal health

For simplified authorisation, risk assessment for animal health is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8 Risk assessment for the environment

For simplified authorisation, risk assessment for the environment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

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

3.8.1.1 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)). Please refer to section 2 of this PAR's Confidential Annex for details.

3.8.1.2 Screening for endocrine disruption relating to non-target organisms

The product contains no endocrine-disrupting formulants. For the assessment of endocrine-disrupting properties of (the) non-active substance(s), please refer to section 3 of this PAR's

Confidential Annex.

3.8.2 Emission estimation

Not relevant.

3.8.3 Exposure calculation and risk characterisation

Not relevant.

3.8.4 Primary and secondary poisoning

Not relevant.

3.8.5 Mixture toxicity

Not relevant.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Not relevant.

3.8.7 Overall conclusion on the risk assessment for the environment

Not relevant.

3.9 Assessment of a combination of biocidal products

This biocidal product is not intended to be authorised for the use with other biocidal products.

3.10 Comparative assessment

For simplified authorisation, comparative assessment is not required according to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012.

4 Appendices

4.1 Calculations for exposure assessment

Not applicable.

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

No new information on the active substance(s) is available.

The product contains no substance(s) of concern.

4.3 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)
-	-	2 and 13	13/SDS formulants	SDS formulants	-	-	-	Yes
Gazzotti, L.	2021a 2021-10-15	3.1, 3.2, 3.3, 3.4.1.1	3.4.1/Storage stability tests.accelerated	Determination of the Physical-Chemical properties of the Product Super Ninja against Fruit Flies, Before and After Accelerated Storage for 2 weeks at 54±2 °C Report 21238-02C	Study report	Renolab S.r.l., Italy SUPER NINJA	Yes	No
Gazzotti, L.	2021b 2021-08-26	3.4.1.2	3.4.1/Storage stability tests.ambient	Determination of Two Year Storage Stability and Shelf-Life Data of the Product Super Ninja against Fruit Flies Report 21238-03C	Study plan	Renolab S.r.l., Italy SUPER NINJA	Yes	No
Struijk, W.	2022	4.6	4.6/Flammable liquids.001	Analytical report no 3010010059/2022 Report 3010010059/2022	Study report	Xpertlab, the Netherlands SUPER NINJA	No	No

Verstraeten, B.	2022	4.16	4.16/Corrosive to metals.001	Metal corrosion test on product Super Ninja against Fruit Flies Report 22/052	Study report	Belgian Welding Institute NPO, Belgium SUPER NINJA	No	No
Gazzotti, L.	2021c 2021-10-15	5.1	5.1/ Methods of detection and identification.001	Determination of the Active Ingredient Content of the Product Super Ninja against Fruit Flies, Including Validation of the Analytical Method and Emission of Certificate of Analysis Report 21238-01C	Study report	Renolab S.r.l., Italy SUPER NINJA	Yes	No
Gazzotti, L.	2021d 2021-10-15	5.1	5.1/ Methods of detection and identification.001	CERTIFICATE OF ANALYSIS No. 087/21	Certificate of Analysis	Renolab S.r.l., Italy SUPER NINJA	Yes	No
Rovetto, I	2021 2021-09-03	6.7	6.7/Efficacy data to support these claims.001	Efficacy evaluation of “Super Ninja against Fruit Flies” attractant traps for the indoor control of *Drosophila melanogaster* – Italy 2021 Report 4540.I.SAG 21	Study report	SAGEA Centro di Saggio s.r.l., Italy SUPER NINJA	Yes	No

4.4 References

4.4.1 References other than list of studies for the biocidal product

None.

4.4.2 Guidance documents

- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2018
- Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), 2018
- CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants_final, Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants, 2019
- Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C), 2017
- Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), 2017
- CA-May14-Doc.5.5 – Final, Consideration of storage stability, stability and shelf-life data in the context of applications for product authorisation under the simplified procedure, 2014
- Technical Agreements for Biocides Efficacy (EFF), Version 2.2, July 2020

4.4.3 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
- 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

4.5 Confidential information

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