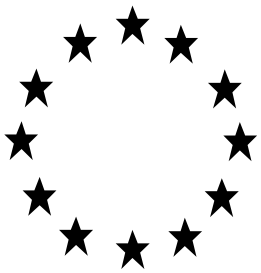
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



NEU 1222 l

PUBLIC

Product type 19

Vinegar as included in Annex I of the Biocidal Product Regulation

Case Number in R4BP: BC-XD066650-36

Evaluating Competent Authority: Austria

26/07/2022 (Final)

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1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product NEU 1222 l. The dossier submission date 28/05/2021 is to be taken into account for relevance of (new) guidance.

The ready-to-use product NEU 1222 l is a liquid formulation which contains 94.75%(w/w) of the active substance Vinegar. No substances of concern were identified.

The assessment considered:

- The restrictions for the active substance Vinegar as indicated in Annex I, Category 4 (Traditionally used substances of natural origin) of regulation (EU) no. 528/2012 [BPR]: "Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid (whether or not it is food)."
- The date of approval of vinegar for product-type 19 for the purposes of Article 89(3) is 1 June 2021.

The field of use is as follows:
Use # 1 – (adult) Fruit flies – non-professional (general public) – RTU liquid for traps - indoor

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex III of regulation (EU) no. 528/2012. The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product. The long-term storage stability study is ongoing, the final report has to be provided once the study is completed. Please cf. to the post-authorisation restriction at the end of the present section.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product have demonstrated sufficient efficacy against the target organisms. No resistance is expected.
- The biocidal product does not need to be classified in terms of human and environmental hazards. Furthermore, the bp does not contain any substances of concern and therefore a detailed human and environmental exposure assessment and risk characterisation is not considered necessary, in line with the frame of a Simplified Authorisation procedure according to Regulation (EU) 528/2012. No unacceptable risk for human health and the environment is expected.
- Based on the hazard profile, it is expected that the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups or animals, directly or through drinking water, food, feed, air, or through other indirect effects, as well as no unacceptable effects itself, or as a result of its residues, on the environment.

The product contains no active substances which are candidates for substitution.

The product has no indications for endocrine-disrupting properties.

It can be concluded that the conditions of Article 19 1)-4) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised.

The biocidal product will be authorised for a period of 10 years in accordance with Article 17(4) of Regulation (EU) No 528/2012.

The following **post-authorisation condition** is set and has to be fulfilled until **31/03/2026** by submitting a SA-MIC: The final report of the long-term storage stability study has to be submitted.

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)**
NEU 1222 l	EU

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	W. Neudorff GmbH KG
	Address	An der Mühle 3 EMMERTHAL 31860 Germany
Authorisation number	EU-0026702-0000	
Date of the authorisation	See authorisation letter	
Expiry date of the authorisation	See authorisation letter	

2.1.1.3 Manufacturer of the product

Name of manufacturer	W. Neudorff GmbH KG
Address of manufacturer	An der Mühle 3 EMMERTHAL 31860 Germany
Location of manufacturing site	An der Mühle 3 EMMERTHAL 31860 Germany

2.1.1.4 Manufacturers of the active substances

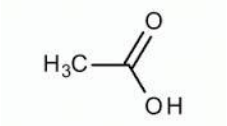
Active substance	Vinegar
Name of manufacturer	Carl Kühne KG (GmbH & Co.)
Address of manufacturer	Kühnehöfe 11 22761 Hamburg, Germany
Location of manufacturing sites	Kühnehöfe 11 22761 Hamburg, Germany

2.1.2 Product composition and formulation

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 ☒ (Not applicable for Annex I substances)

2.1.2.1 Identity of the active substances

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	100% (acetic acid ≤ 10 %)[1]
Structural formula	Acetic acid: 

[1]This is in line with the restrictions of BPR Annex I.

2.1.2.2 Candidate(s) for substitution

The active substance is no candidate for substitution.

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

Trade names		**NEU 1222 I** Lockstoff für Permanent Fruchtfliegen Falle Permanent Fruchtfliegen Falle Fruchtfliegenfalle Lockstoff für Fruchtfliegenfalle			
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Vinegar (acetic acid ≤ 10 %)	n.a.	Active substance	8028-52-2	n.a.	94.75

2.1.2.4 Information on technical equivalence

Not applicable.

2.1.2.5 Information on the substance(s) of concern

NEU 1222 l does not contain any substances of concern, according to Article 3(f) of the BPR and the BPR Guidances Volume III Part B+C, version 4.0 December 2017 and Volume IV, part B+C, Version 2.0, October 2017).

Since 7 June 2018, the date when the Regulation (EU) 2017/2100 became applicable, the assessment of ED properties of co-formulants are mandatory according to Article 19. The procedure made available at EU level in the agreed CG-41 final version document CG-41-2020-03 AP 16.5 ED co-formulant_assessment by MS_vf_PUBLIC is used to perform the assessment of the potential endocrine disrupting properties of the co-formulants contained in the product NEU 1222 l.

Based on the screening of ED properties of co-formulants (and considering that the AS is not an ED), it is concluded that there is no indication of concern regarding ED properties of any of the co-formulants, hence the product is not an endocrine disruptor.

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	None
Hazard statement	None
Additional hazard statement	None
Labelling	
Hazard pictogram	None
Signal word	None
Hazard statement	None
Precautionary statement	P101 - If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children P103 – Read label before use.
Note	None

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 – (adult) Fruit flies – non-professional (general public) – RTU liquid for traps - indoor

Product Type	PT 19
Where relevant, an exact description of the authorised use	Attractant
Target organism (including development stage)	Common name: Fruit fly (Vinegar fly) Scientific name: *Drosophila melanogaster* Development stage: Adults
Field of use	Indoor **Field of Use description**: The product is used to attract fruit flies in indoor areas.
Application method(s)	Ready-to-use liquid to be used in combination with a suitable trap
Application rate(s) and frequency	30 mL
Category(ies) of users	Non-professional (general public)
Pack sizes and packaging material	Plastic bottle Material: HDPE Lid: Screw lid made of PP Volume: 30 mL, 50 mL, 100 mL, 200 mL, 250 mL, 500 mL, 1000 mL

2.1.4.2 Use-specific instructions for use

2.1.4.3 Use-specific risk mitigation measures

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

250. Close and open again the trap 2-3 times before adding the product.
To close the trap: Place the top part of the trap onto the bottom part according to the markings and turn it to the right.
To open the trap: turn the upper part of the trap to the left so that the markings meet each other. Now the upper and lower parts can be detached from each other.
2. Fill the product included in the package into the lower part of the trap. 30 mL are sufficient per filling.
3. Close the trap and position it in the area of intended use.
4. To avoid any spilling when emptying the trap or replacing the product, carefully open the trap on a non-slippery surface if possible.
5. Gently rotate the unit of the trap, this allows the product to develop its full aroma. Any flocculation in the solution is natural.
Caution, the product can stain marble and delicate materials.

2.1.5.2 Risk mitigation measures

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

If INHALED: if symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product residues and empty containers must be collected and disposed of in accordance with the national waste disposal legislation and any regional and/or local authority requirements.

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

Always store in original packaging at a temperature > 0°C.
Keep the container tightly closed.
Keep out of reach of children.
Keep away from food, drink and animal feedingstuffs.
Shelf-life : 24 months

2.1.6 Other information

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)
Bottle	30 mL	HDPE	screw cap with sealing disk	Non-professional	Yes
Bottle	50 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes
Bottle	100 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes
Bottle	200 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes
Bottle	250 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes
Bottle	500 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes
Bottle	1000 mL	HDPE	measuring screw cap with sealing disk.	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the list of studies in Annex 3.1 of this report.

2.1.8.2 Access to documentation

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR (category 4). 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

Intended use # 1 –Attractant – PT19 –non-professional

Product Type(s)	PT 19 – Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Attractant The product is used to attract fruit flies, in indoors areas.
Target organism (including development stage)	Fruit and vinegar flies Adults
Field of use	Indoor
Application method(s)	Ready-to-use liquid to be used in combination with a suitable trap
Application rate(s) and frequency	Fill the suitable trap with 30 mL of NEU 1222 l.
Category(ies) of user(s)	Non-professional (general public)
Pack sizes and packaging material	Plastic bottle Material: HDPE Lid: Screw lid made of PP Volume: 30 to 250 mL

2.2.2 Physical, chemical and technical properties

Determination of physical, chemical and technical properties is not strictly required for simplified procedures according to Article 25 as detailed in Article 20(1)(b) of the BPR. However, because the Commission was of the opinion that the stability of the product directly affects the efficacy of the product, data on storage conditions, stability and shelf life should be provided (see doc. CA-May14-Doc.5.5 – Final).

For the purpose of identification of the product, physical, chemical and technical properties have been determined and are summarized in the table below.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference / Justification</th></tr>
<tr><td>Physical state at 20 °C and 101.3 kPa
Colour at 20 °C and 101.3 kPa
Odour at 20 °C and 101.3 kPa</td><td>Visual and organoleptic observation</td><td>Test item: NEU1222I
Nominal content of acetic acid: 9.47% w/w</td><td>The appearance of the test item NEU1222I was controlled by visual observations before and after the accelerated storage procedure for 14 days at 54 ± 2°C in its commercial packaging (HDPE bottle). The test item was found to be in the form of a slightly brownish clear solution with a characteristic smell of vinegar at initial time and after 14 days of storage at 54 ± 2°C.</td><td>Anonymous 2021a</td></tr>
<tr><td>Acidity / alkalinity</td><td>Waived</td><td>-</td><td>Not required acc. to Art.20(1)(b) of EU 528/2012.

pH = 2.2 at 22°C according to the SDS of the product</td><td>-</td></tr>
<tr><td>Relative density / bulk density</td><td>Waived</td><td>-</td><td>Not required acc. to Art.20(1)(b) of EU 528/2012.

Density = 1.01 g/mL at 22°C according to the SDS of the product</td><td>-</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.4 method
2 weeks at 54 ± 2°C

30 mL HDPE container

Liquid Chromatography with DAD detection
Validated analytical method (study No.</td><td>Test item: NEU1222I
Batch No. 212707
Nominal content of acetic acid: 9.47% w/w</td><td><table><tr><th rowspan="2">Test</th><th colspan="2">Results</th></tr><tr><th>At initial time</th><th>After 2 weeks at 54 ± 2°C</th></tr><tr><td>Appearance of the test item</td><td>Homogeneous, clear and non-viscous liquid Colour: yelow-brown (Munsell Book of colour code : 5 Y 7/10)</td><td>Homogeneous, clear and non-viscous liquid. Colour: brownish (Munsell Book of colour code : 2.5 Y 5/8))</td></tr><tr><td>Appe</td><td>Semi-</td><td>Semi-</td></tr></table></td><td>Anonymous 2022a

(Key study)</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference / Justification
	S21-05519)		**arance of the commercial packaging**: transparent, light brown 30 mL HDPE container with white screw cap / transparent, light brown 30 mL HDPE container with white screw cap. No damage to the container shape or size was observed. **Difference of weight of the commercial packaging (%)**: / / - 0.31 - 0.14 **Content of acetic acid (% w/w)**: 8.86 / 8.75 (- 1.2% *vs.* the value at initial time) The test item was considered to be stable after an accelerated storage procedure for 2 weeks at 54 ± 2°C in its commercial packaging (30 mL HDPE-bottle).	
	CIPAC MT 46.3 method	Test item: NEU1222I Nominal content of acetic acid: 9.47% w/w	The test item NEU1222I in its packagings (HDPE bottles) was considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2°C; no change in the appearance of the test item was observed. In addition, no significant weight change of the packagings was observed.	Anonymous 2021a (supplementary information)
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No.17, 2nd edition Croplife Internationa	Test item: NEU1222I Nominal content of acetic acid: 9.47% w/w	The long-term storage study (48 months at 20 ± 2°C) on the product NEU1222I is on-going. The results after 6, 18, 24, 30, 36, 42 and 48 months of storage related to the	Anonymous 2021b

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference / Justification
	l		appearance of the test item, the appearance and weight of the commercial packaging (30 mL HDPE bottle), the analytical quantifications of the active substance will be provided when available.	
Storage stability test – **low temperature stability test for liquids**	Waived	-	The product should be stored at a temperature > 0°C according to the label.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waived	-	Not determined as the product is packed in opaque packagings, so that effects of light can be excluded.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	- Effect of temperature: the product must be stored at a temperature > 0°C. The product was considered to be stable after 14 days at 54 ± 2°C. - Effect of humidity: negligeable as the commercial packagings are hermetically sealed, leak-tight and the product contains water.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	See the storage stability tests – long term storage at ambient temperature	-
Wettability	Waived	-	Not applicable. The product is a ready-to-use liquid.	-
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				
Persistent foaming				
Flowability/Pourability /Dustability				
Burning rate — smoke generators				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference / Justification
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility	Waived	-	Not applicable. The product is not intended to be used in conjunction with any other products or active substances	-
Chemical compatibility				
Degree of dissolution and dilution stability	Waived	-	Not applicable. The product is a ready-to-use liquid.	-
Surface tension	Waived	-	Not required acc. to Art.20(1)(b) of EU 528/2012.	-
Viscosity				

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

NEU 1222 l is a homogeneous, clear and non-viscous yellow-brown liquid with a characteristic smell of vinegar. Its pH is expected to be around 2.2 (pure).
The product must be stored at a temperature > 0°C.
The product in its commercial packaging (30 mL HDPE bottle) was considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2°C.

The long-term storage study (48 months at 20 ± 2°C) on the product NEU 1222 I is on-going. The results after 6, 12, 18, 24, 30, 36, 42 and 48 months of storage related to the appearance of the test item, the appearance and weight of the commercial packaging (30 mL HDPE bottle), the analytical quantifications of the active substance will be provided when available.

Based on the results of the GLP accelerated storage stability study, a shelf life of at least 24 months is claimed and a recommended storage temperature higher than 0°C is mentioned on the label.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference / Justification
Explosives	Waived	The active substance Vinegar, contained in the product, is included in Annex I of the BPR and thus is not expected to give rise to concern regarding explosiveness. It has no explosive properties according to its safety datasheet and has no chemical group associated with explosive properties. Moreover, none of the co-formulants is expected to have explosive properties according to their safety datasheets. And due to their low contents in the product, they are not considered as being able to lead to a classification of the product. As a result, the product NEU 1222 l is not expected to be explosive and test is considered as unnecessary.	-
Flammable aerosols	Waived	Not applicable. The product is not an aerosol.	-
Flammable gases Oxidising gases Gases under pressure	Waived	Not applicable. The product is a liquid.	-
Flammable liquids	Waived	The active substance Vinegar, contained in the product, is included in Annex I of the BPR and is not expected to give rise to any concern regarding flammability according to its safety datasheet. In addition, none of the co-formulants, is classified as flammable according to their safety datasheets. Therefore, the product NEU 1222 l is not expected to be flammable and flash point test is considered as unnecessary.	-
Flammable solids	Waived	Not applicable. The product is a liquid.	-
Self-reactive substances and mixtures	Waived	The active substance Vinegar, contained in the product, is included in Annex I of the BPR and thus is not expected to give rise to concern regarding self-reactive properties. It has no self-reactive properties according to its safety datasheet. In addition, none of the co-formulants is expected to have self-reactive properties according to their safety datasheets. Moreover, due to their low contents in the product, they are not considered as being able to lead to a classification of the product. Therefore, the product NEU 1222 l is not expected to present self-reactive properties and test is considered as unnecessary.	-
Pyrophoric liquids	Waived	Test is not required as the product does not contain any components classified as pyrophoric according to their safety data sheets. Moreover, experience in manufacture and handling shows that the product does not ignite spontaneously on	-

Property	Guideline and Method	Results	Reference / Justification
		coming into contact with air at normal temperature. The product NEU 1222 l is not expected to be a pyrophoric liquid and test is not required.	
Pyrophoric solids	Waived	Not applicable. The product is a liquid.	-
Self-heating substances and mixtures	Waived	The active substance Vinegar, contained in the product, is included in Annex I of the BPR and thus is not expected to give rise to concern regarding self-heating properties. It has no self-heating properties according to its safety datasheet. In addition, none of the co-formulants are classified as self-heating according to their safety datasheets. Moreover, due to their low contents in the product, they are not considered as being able to lead to a classification of the product. Therefore, the product NEU 1222 l is not expected to present self-heating properties and test is considered as unnecessary.	-
Substances and mixtures which in contact with water emit flammable gases	Waived	Test is not required as the product NEU 1222 l contains water and forms a stable mixture.	-
Oxidising liquids	Waived	The active substance Vinegar, contained in the product is included in Annex I of the BPR and thus is not expected to give rise to concern regarding oxidizing properties. It has no oxidizing properties according to its safety datasheet, and contains acetic acid, which contains oxygen atoms but these elements are chemically bonded only to carbon and/or hydrogen atoms.Therefore, the classification procedure for the hazard class "oxidising liquids" shall not apply. In addition, none of the co-formulants is expected to have oxidizing properties according to their safety datasheets. Moreover, due to their low contents in the product, they are not considered as being able to lead to a classification of the product. As a result, the product NEU 1222 l is not expected to be oxidizing and test is considered as unnecessary.	-
Oxidising solids	Waived	Not applicable. The product is a liquid.	-
Organic peroxides	Waived	The active substance Vinegar is included in Annex I of the BPR and thus should not give rise to concern regarding organic peroxides. The product NEU 1222 l is not concerned by the physical hazard "organic peroxides" as its components are not expected to form or contain organic peroxides.	-
Corrosive to metals	Waived	Test is not required as the product does not contain any bases, halogens and complexing	-

Property	Guideline and Method	Results	Reference / Justification
		agents. The active substance Vinegar contains acetic acid but is not classified as Met. Corr. 1, H290 according to its safety datasheet. In addition, one of the co-formulants is an acid, but is present at such low content that it is not considered as being able to lead to a classification of the product. Therefore, the product NEU 1222 l is not expected to be corrosive to metals and test is not required.	
Auto-ignition temperatures of products (liquids and gases)	Waived	The active substance Vinegar, contained in the product is included in Annex I of the Biocidal Products Regulation (BPR) and thus is not expected to give rise to concern regarding auto-flammability. It is not self-flammable according to its safety datasheet. In addition, none of the co-formulants is expected to be self-flammable according to their safety datasheets. Moreover, due to their low contents in the product, they are not considered as being able to lead to a classification of the product. Therefore, the product NEU1222l is not expected to present a significant hazard for auto-flammability and test is not required.	-
Relative self-ignition temperature for solids	Waived	Not applicable. The product is a liquid.	-
Dust explosion hazard			

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product NEU 1222 l is not expected to present a significant hazard for explosive properties, flammability, self-reactivity, oxidising properties, corrosivity to metals and auto-inflammability. No tests are required according to the composition of the product. Therfore, no classification and labelling for chemical hazards is required for the biocidal product NEU 1222 l.

2.2.4 Methods for detection and identification

- ***Determination of Vinegar (Acetic acid) content in NEU 1222 l***

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method*:* Acetic acid is analysed after dissolution of the test item in water and quantified by liquid chromatography with a DAD detector (220 nm). Test item preparation: about 500 mg of the test item were weighed into a 100 mL measuring flask and filled to the mark with water. The obtained sample solution was homogenised by shaking.											
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 measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Acetic acid (active substance)	Calibra-tion range: 50.6 mg/L to 1011 mg/L (n = 6) y = 0.0150 *	A comparison of the UV-spectra of acetic acid of the sample and the standard	Low recovery: 4.8% w/w acetic acid High recovery: 12.3% w/w acetic acid	5 at each level	98.6 – 99.2 98.5 – 98.7	98.9 98.6	0.2 0.1			LOQ = 246.46 mg/L or 4.75% w/w	Anonymous 2022b

	x - 0.0019 (y = peak area (acetic acid), x = acetic acid amount (in mg/L) r = 1	showed a match of 100% between 190 and 400 nm. The specificity was assessed by checking for any interferenc e in HPLC-DAD at the retention time of the peak of acetic acid (about 6.1 min). In the reference item and in the test item, the peak at the retention time around 6.1 min represents acetic acid. No additional peak appears in each reference item	Formulated product	5	-	-	0.11 % Hr = 0.06	8.86% w/w	5		

		solution and in the test item near the retention time of the acetic acid peak.									

- ***Vinegar residues in soil, air, water, sediment, animal and human body fluids and tissues, in food/feed of plant and animal origins***

Analytical methods for monitoring, soil, air, water, animal and human body fluids and tisues, for monitoring of active substances and residues in food and feeding stuff are not required for simplified authorisations.

Conclusion on the methods for detection and identification of the product
The acetic acid content in the product NEU 1222 I was determined using Liquid Chromatography with DAD detection. Quantification was performed using external standard calibration. This analytical method for the determination of acetic acid content in the product NEU 1222 I was validated by definition of the specificity, the linearity of detector response, the recovery and the precision of the method and Guidelines requirements were fulfilled. The Limit of Quantification (LOQ) was also determined.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product is an attractant (PT 19) used in trap to catch fruit flies in indoor areas. It operates by diffusion of the vinegar into the ambient air, by what fruit flies were lured into the trap.

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

The product is used to attract adult specimens of fruit flies (*Drosophila melanogaster*) in a trap where they drown, in order to protect unpackaged food (i.e. fruit) and to prevent rapid increase of the fly population.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product reduces fruit flies population indoors by luring them into a trap, where they eventually drown.

2.2.5.4 Mode of action, including time delay

The product is an attractant (olfactive attraction) which lures fruit flies to a trap and hence reduces the fly population. Thus, it prevents an excessive development of fruit flies around unpackaged food in indoor areas. Once inside the trap, the target organisms drown eventually into the liquid. There is no time delay, as soon as the product is filled in the trap, vinegar diffuses into ambient air and attracts adult fruit flies.

2.2.5.5 Efficacy data

A single laboratory study (Simulated-Use test) was conducted with the product Permanent® Fruchtfliegen Falle, identical to NEU 1222 l.

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Flies attractant (PT19)</td><td>Indoor</td><td>Pemanent® Fruchtfliegen Falle Batch 32361</td><td>Drosophila melanogaster Fruit flies, adults</td><td>BPD BioG B 408-02 (modified)</td><td>Insects are introduced into 30 m^3 cages containing 1 trap with the test product attractant and alternative food in a beaker. Exposure during 48 hours.
The attractiveness of the test product is monitored.
Replicates: 5 replicates of 200 flies
5 replicates of untreated control (100 flies to check viability of the flies)
Assessment of the attractiveness done after 24 and 48 hours of exposure.
Attractivness measured as percentage of flies caught in the trap containing the test product.</td><td>Mean percentage of flies caught in the trap containing the test product (n=5, min-max)
<table><tr><td></td><td>D. melanogaster</td></tr><tr><td>24 hours</td><td>70% (55-79)</td></tr><tr><td>48 hours</td><td>86% (80-90)</td></tr></table>Mortality in control: 2 of 500 individuals (0.4 %) within 48 hours.

It can be conclude that Permanent® Fruchtfliegen Falle (identical to NEU 1222 l) is effective to attract common fruit flies in a trap.</td><td>Anonymous 2021c</td></tr>
</table>

Conclusion on the efficacy of the product

At the time of submission no specific efficacy protocols and guidances were available to evaluate PT19 products against fruit flies. Therefore the tests have been done using in-house protocols. The efficacy is determined as percentage of caught individuals. The efficacy data demonstrate that the product NEU 1222 l attracts fruit flies *Drosophila melanogaster,* when used indoor in a trap and show the required efficacy of >80% after 48h. The presented study only investigated the efficacy of freshly opened traps. Due to the internal experience of the applicant, that fruit flies are not attracted by the trap itself without vinegar, the control tests were performed to collect data about the natural mortality (and thus the vitality) of the target organisms during the whole test period. The vitality of the fruit flies was high, since only 2 individuals out of a total of 500 flies (5 beakers á 100 flies) died in the control study (without the biocidal product).

2.2.5.6 Occurrence of resistance and resistance management

The target organisms get killed by drowning. Occurrence of resistance is therefore unlikely.

2.2.5.7 Known limitations

No limitations are known, when the product is used according to the label's recommandations.

2.2.5.8 Evaluation of the label claims

The label claim "Attracts fruit and vinegar flies" is sufficiently substantiated, since the attractiveness has been validated in a laboratory study (>80% efficacy within 48 hours). The test has been done with adults of *Drosophila melanogaster*, which is referred as fruit fly and also vinegar fly.

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

Not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The active substance Vinegar is an active substance included into Annex I of the BPR and also meets the specified restrictions.

According to Article 25 a simplified authorisation procedure may be applied where the product does not contain any substance of concern (SoC) (Article 25(b)), and the handling of the biocidal product and its intended use do not require personal protective equipment (PPE) (Article 25(e)).
The product does not contain any substance of concern according to the EU guidance on SoC (CA-Nov14-Doc.5.11- SoC guidance_final) and according to Article 3(f) of the BPR and Annex A of the BPR Guidance (Volume III Part B+C, version 4.0 December 2017) nor does it show any alert for endocrine disruptors or nano materials. Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008, and the product is not classified (see document 'A3.6_Confidential_Classification_20210527'). The use of PPE is therefore not required.

Based on the above, NEU 1222 l is eligible to get authorised via the simplified authorization procedure and hence detailed exposure assessments are not required according to Article 20(1)(b) of the BPR(see document 'A3.6_Confidential_Eligibility_NEU1222l_20210527').

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating or corrosive to skin.
Justification for the value/conclusion	The product NEU 1222 I only contains: - maximum 9.475% w/w of acetic acid (pure), which is below the specific concentration limits of 90%, 25 and 10% w/w to classify the product as Skin Corr. 1A, H314, Skin Corr. 1B or Skin Irrit.2, H315, respectively; - 0.15% w/w of ingredient 2, classified as Skin Corr. 1B, H314 is present below cut off value of 1% w/w. Moreover, the pH value of the acid is expected to be lower as 2 and the additivity therefore might not apply. Accordingly, the product is not classified as Skin Corr. 1A, H314, Skin Corr. 1B, H314 nor Skin Irrit.2, H315.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	No study has been performed on the product NEU 1222 l. Regarding the content of a.s. and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), no classification is required for skin corrosion and irritation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eye.
Justification for the value/conclusion	The product NEU 1222 I only contains: - maximum 9.475% w/w of acetic acid (pure), which is below the specific concentration limit of 10% w/w to classify the product as Eye Irrit. 2, H319; - 0.15% w/w of ingredient 2, classified as Eye Dam. 1, H318 is present below cut off value of 1% ww. Moreover, the pH value of the acid is expected to be lower as 2 and the additivity therefore might not apply. Accordingly, the product is not classified as Eye Irrit. 2, H319.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Eye irritation
Justification	No study has been performed on the product NEU 1222 l. Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Not irritating to the respiratory tract.
Classification of the product according to CLP and DSD	Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for repiratory tract irritation.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No study has been performed on the product NEU 1222 l. Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for repiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to the skin.
Justification for the value/conclusion	Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for skin sensitization.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin sensitization
Justification	No study has been performed on the product NEU 1222 l. Regarding the classification and/or content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for skin sensitization.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract.
Justification for the value/conclusion	Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for respiratory sensitization.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Respiratory sensitization
Justification	No study has been performed on the product NEU 1222 l. Regarding the classification and/or content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for respiratory sensitization.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	No acute oral toxicity.
Justification for the selected value	Regarding the classification content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute oral toxicity.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute oral toxicity
Justification	No study has been performed on the product NEU 1222 l. Regarding the classification and/or content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute toxicity by oral route.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No acute inhalation toxicity
Justification for the selected value	Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute inhalation toxicity.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	No study has been performed on the product NEU 1222 l. Regarding the classification and/or content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute toxicity by inhalation.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No acute dermal toxicity
Justification for the selected value	Regarding the content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute dermal toxicity.
Justification	No study has been performed on the product NEU 1222 l. Regarding the classification and/or content of the active substances and co-formulants, and according to the classification rules laid down in Regulation (EC) No 1272/2008 (CLP), the product NEU 1222 l is not classified for acute dermal toxicity.

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption
Justification	Assessment of dermal absorption is no data requirement for simplified procedures.

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

Data waiving	
Information requirement	Toxicological data on substances of concern.
Justification	According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment and to the criteria laid out in EU guidance on SoC (CA-Nov14-Doc.5.11), none of the ingredients of the product NEU 1222 l is considered as a substance of concern. See document 'A3.6_Confidential_Eligibility_NEU1222l_20210527'

Available toxicological data relating to a mixture

Not relevant.

2.2.6.2 Exposure assessment

NEU 1222 l is eligible for the simplified authorisation procedure in accordance with Article 25 of the BPR as the active substance is included into Annex I of the BPR and also meets the specified restrictions and as none of the coformulants are considered to be substances of concern. Detailed exposure assessments are therefore not required in accordance with Article 20(b)(1) of the BPR.

2.2.6.3 Risk characterisation for human health

NEU 1222 l is eligible for the simplified authorisation procedure in accordance with Article 25 of the BPR. Detailed exposure assessments are therefore not required in accordance with Article 20(b)(1) of the BPR.

2.2.7 Risk assessment for animal health

NEU 1222 l is eligible for the simplified authorisation procedure in accordance with Article 25 of the BPR as the active substance is included into Annex I of the BPR and also meets the specified restrictions and as none of the coformulants are considered to be substances of concern. A risk assessment for animal health is therefore not required in accordance with Article 20(b)(1) of the BPR.

2.2.8 Risk assessment for the environment

The active substance vinegar is included into Annex I of the BPR and meet the specified restrictions of the Article 25 of the BPR.

The product does not contain any substance of concern according to the EU guidances on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017) nor does it show any alert for endocrine disruptors or nano materials as required in the Regulation (EU) N° 528/2012, Article 25. The classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008, and the product is not classified with respect to environmental hazards.

Based on the above, NEU 1222 l is eligible to get authorised *via* the simplified authorisation procedure and hence detailed exposure assessments are not required according to Article 20(1)(b) of the BPR.

2.2.9 Measures to protect man, animals and the environment

The product does not contain any substances of concern, endocrine disruptors or nano materials. Therefore specific measures to protect man, animals and the environment are not required.

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not relevant. The active susbtances are no candidates for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

Section N° IUCLID	Author	Year	-Title -Source (laboratory) -Report N° -Report date -GLP; (un)pubished	Data protection (Y/N)	Owner
3.4.1	Anonymous	2022a	Physicochemical Properties of NEU 1222 I before and after Accelerated Storage for 14 days at 54°C Report number: S21-07615 GLP	Y	W. Neudorff GmbH KG
3.1 3.4.1	Anonymous	2021a	Storage stability test Appearance / Weight / Acetic acid content NEU1222I STO_Neu 1222 I:2021 Non GLP; unpublished	Y	W. Neudorff GmbH KG
3.4.1	Anonymous	2021b	Shelf-life storage stability of NEU 1222 l over 4 years at 20 °C Report number: S21-05520 GLP	Y	W. Neudorff GmbH KG
5	Anonymous	2022b	Development and Validation of an Analytical Method for the Content Determination of Acetic Acid in NEU 1222 l Certificate of Analysis Report number: S21-05519 GLP	Y	W. Neudorff GmbH KG
6.7	Anonymous	2021c	- Efficacy of a Fruit fly trap against *Drosophila melanogaster* in 30 m^3 test rooms - BioGenius - BIO054-21 - April 2021 - GLP; unpublished	Y	W. Neudorff GmbH KG

3.2 Output tables from exposure assessment tools

Not applicable for simplified procedures. No exposure assessments are required.

3.3 New information on the active substance

None.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies

Please refer to Section 6.7 of the IUCLID file and study summaries in Section 2.2.5.5 of this report.

3.6 Confidential annex

Please cf. to separate document.

3.7 Other

3.7.1 Reference list (excluding list of studies, cf. to chapter 3.1)

No additional references.