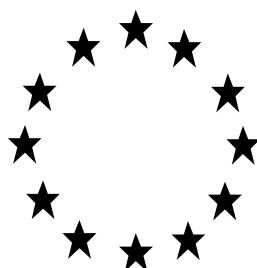


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

ADDENDUM: Minor Change



NEU 1222 I

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

04/08/2023 (Final)

PUBLIC

Table of Contents

CHANGES HISTORY TABLE	3
1 CONCLUSION	4
2 ASSESSMENT	5
2.1 BACKGROUND.....	5
2.2 DESCRIPTION OF CHANGES.....	5
2.3 EVALUATION OF CHANGES	5
2.3.1 <i>Identity and physico-chemical properties</i>	5
2.3.2 <i>Authorised use and General directions of use</i>	5
2.3.3 <i>Authorised use(s)</i>	5
2.3.3.1 Use # 1 – (adult) Fruit flies, Trap-type I – non-professional (general public) – RTU liquid for traps – indoor.	5
2.3.3.2 Use # 2 – (adult) Fruit flies, Trap-type II – non-professional (general public) – RTU liquid for traps - indoor	7
2.3.3.3 Use # 3 – (adult) Fruit flies, Trap-type III – non-professional (general public) – RTU liquid for traps – indoor	8
2.3.3.4 Use # 4 – (adult) Fruit flies, Trap-type IV – non-professional (general public) – RTU liquid for traps – indoor	9
2.3.3.5 Use # 5 – (adult) Fruit flies; use in combination with any suitable trap-type – non-professional (general public) – RTU liquid for traps – indoor.....	10
2.3.4 <i>General directions for use</i>	12
2.3.4.1 Instructions for use	12
2.3.4.2 Risk mitigation measures	12
2.3.4.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment.....	12
2.3.4.4 Instructions for safe disposal of the product and its packaging.....	12
2.3.4.5 Conditions of storage and shelf-life of the product under normal conditions of storage.....	12
2.3.5 <i>Other information</i>	12
2.3.6 <i>Packaging of the biocidal product</i>	13
2.3.7 <i>Documentation</i>	13
2.3.7.1 Data submitted in relation to product application	13
2.3.7.2 Access to documentation.....	13
2.4 ASSESSMENT OF THE BIOCIDAL PRODUCT	14
2.4.1 <i>Intended use(s) as applied for by the applicant</i>	14
2.4.2 <i>Efficacy</i>	14
2.4.3 <i>Human Health</i>	14
2.4.4 <i>Environment</i>	14
3 ANNEX	15
3.1 LIST OF STUDIES.....	15
3.2 LIST OF REFERENCES	15
3.3 CONFIDENTIAL INFORMATION	15
3.4 CONFIDENTIAL INFORMATION RESTRICTED TO AUTHORITIES.....	15

CHANGES HISTORY TABLE

Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	<i>Austria</i>	BC-XD066650-36	09.08.2022	<i>First authorisation</i>	
SA-MIC	<i>Austria</i>	BC-AS080483-26	On-going	<i>Change (Amendment of use instruction, addition of pack sizes)</i>	2.1.4

1 CONCLUSION

The authorisation holder W. Neudorff GmbH KG has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product *NEU 1222 I*. The change relates to addition of pack sizes and detailing the instructions for use.

The addition of further pack sizes is a minor change according to Reg.(EU) No. 354/2013, Annex, Title 2, point 7. The criteria for the minor change application are fulfilled because the new range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics, there is no change of user category, and the same risk-mitigation measures apply.

The change in the instructions for use is a minor change according to Reg.(EU)No. 354/2013, Annex, Title 2, point 3. The criteria for the minor change application are fulfilled because the change is not expected to adversely affect the exposure.

It is demonstrated that the proposed changes would not adversely affect the conclusions previously reached on the assessment of the biocidal product *NEU 1222 I*.

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 with the proposed changes.

2 ASSESSMENT

2.1 Background

The authorisation holder W. Neudorff GmbH KG has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorized product *NEU 1222 I*. The application contains a minor change (NA-MIC) related to the packaging sizes and the use instructions.

2.2 Description of changes

The following minor change is applied for:
In order to allow the use of the authorised lure in combination with varying trap types, the use of further traps was added as additional uses.
Furthermore a corresponding additional packaging size was included.

2.3 Evaluation of changes

2.3.1 Identity and physico-chemical properties

The described changes are not connected with any change of the identity. The intended additional packaging sizes are described in chapter 2.3.3. Regarding the physico-chemical properties of the product, the proposed additional packagings are deemed to be covered by the available storage studies. Read-across is deemed acceptable.

2.3.2 Authorised use and General directions of use

2.3.3 Authorised use(s)

The proposed additions are highlighted in yellow, proposed deletions are crossed out. Use 2 to 5 are added to better reflect the use instructions in combination with the packaging size.

2.3.3.1 Use # 1 – (adult) Fruit flies, Trap-type I – non-professional (general public)
– RTU liquid for traps – indoor

2.3.3.1.1 Use description

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: <i>Drosophila melanogaster</i> 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 With or without trap (the latter in case of refill-packs)

2.3.3.1.2 Use-specific instructions for use

<p>Instructions for use</p> <ol style="list-style-type: none"> 1. Close and open the trap 2-3 times before pouring in the attractant. <ul style="list-style-type: none"> • Closing the trap: Place the upper part of the trap on the lower part according to the markings and turn to the right • Open the trap: turn the upper part of the trap to the left so that the markings meet. Now the upper and lower parts can be detached from each other. 2. Place the trap on a non-skid surface and pour the contained attractant into the lower part of the trap. A 30 ml bottle (included in the package) is sufficient per filling. 3. Close trap and place in deployment area. 4. To ensure that the trap does not leak when emptying or replacing the attractant, open it carefully on a non-skid surface. 5. Gently rotate the unit of the trap, this allows the product to develop its full aroma. Replace the attractant after 4 weeks at the latest.

2.3.3.1.3 Use-specific risk mitigation measures

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

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

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

2.3.3.2 **Use # 2** – (adult) Fruit flies, **Trap-type II** – non-professional (general public)
– RTU liquid for traps - indoor

2.3.3.2.1 Use description

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: <i>Drosophila melanogaster</i> 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	20 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: 20 mL With or without trap (the latter in case of refill-packs)

2.3.3.2.2 Use-specific instructions for use

<p>Instructions for use:</p> <ol style="list-style-type: none"> 1. To open the trap: unscrew the cover. Fill in the attractant. One 20 ml bottle is sufficient for each filling. 2. To close the trap: screw down the cover. Position the jar close to the fruit, now open the flip top. 3. Mix the attractant in the trap 1-2 times a week with a circular motion so that the attractant develops its full aroma. Renew the attractant after 4 weeks at the latest or as soon as the trap is filled with fruit flies. 4. To avoid leakage when emptying or replacing the attractant, the trap should be opened carefully on a non-slip surface.

2.3.3.2.3 Use-specific risk mitigation measures

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

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

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

2.3.3.3 Use # 3 – (adult) Fruit flies, Trap-type III – non-professional (general public) – RTU liquid for traps – indoor

2.3.3.3.1 Use description

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: <i>Drosophila melanogaster</i> 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	20 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: 20 mL With or without trap (the latter in case of refill-packs)

2.3.3.3.2 Use-specific instructions for use

Open the trap and fill in the attractant. One 20ml bottle is sufficient for each filling. Twist the trap tight and open the flip-top lid. Place the trap close to the fruit. Mix the

trap 1-2 times a week with circular movements so that the attractant unfolds its full aroma again. Renew the attractant after 4 weeks at the latest.

2.3.3.3.3 Use-specific risk mitigation measures

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

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

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

2.3.3.4 Use # 4 – (adult) Fruit flies, Trap-type IV – non-professional (general public) – RTU liquid for traps – indoor

2.3.3.4.1 Use description

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: <i>Drosophila melanogaster</i> 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	20 to 30 mL
Category(ies) of users	Non-professional (general public)
Pack sizes and packaging material	Plastic bottle Material: HDPE or PET Lid: Screw lid made of PP

	Volume: 250 mL With or without trap (the latter in case of refill-packs)
--	---

2.3.3.4.2 Use-specific instructions for use

<p>Do not fill the trap through the funnel!</p> <ol style="list-style-type: none"> 1. Remove the yellow funnel, e.g. with a crochet hook or gently press the container and then lift the funnel from the container. 2. Carefully pour the lure liquid up to the... 3. ... recommended height in the container. There is a measurement level on the label 4. Push the funnel back flush onto the container. <p>The trap is now ready for use. Place the trap where there is a high concentration of fruit flies.</p>
--

2.3.3.4.3 Use-specific risk mitigation measures

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

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

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

2.3.3.5 Use # 5 – (adult) Fruit flies; use in combination with any suitable trap-type – non-professional (general public) – RTU liquid for traps – indoor

2.3.3.5.1 Use description

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: <i>Drosophila melanogaster</i> 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	Depending on the used trap type
Category(ies) of users	Non-professional (general public)
Pack sizes and packaging material	Plastic bottle Material: HDPE Lid: Screw lid made of PP Volume: 20 mL, 30 mL, 50 mL, 100 mL, 200 mL, 250 mL, 500 mL, 1000 mL

2.3.3.5.2 Use-specific instructions for use

Fill a suitable trap body with the attractant.
Place the trap where the fruit flies prefer to be, e.g. near fruit or the organic waste container

Mix the trap 1-2 times a week with circular movements so that the attractant unfolds its full aroma again.
Renew the attractant after 4 weeks at the latest.

2.3.3.5.3 Use-specific risk mitigation measures

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

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

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

2.3.4 General directions for use

2.3.4.1 Instructions for use

Fill a suitable trap body with the attractant.
Place the trap where the fruit flies prefer to be, e.g. near fruit or the organic waste container

Mix the trap 1-2 times a week with circular movements so that the attractant unfolds its full aroma again.
Renew the attractant after 4 weeks at the latest.

Any flocculation in the solution is natural.

Caution, the product can stain marble and delicate materials.

2.3.4.2 Risk mitigation measures

2.3.4.3 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.

2.3.4.4 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.

2.3.4.5 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

2.3.5 Other information

2.3.6 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	20 mL	HDPE	screw cap with sealing disk	Non-professional	Yes
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	250 mL	PET	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

2.3.7 Documentation

2.3.7.1 Data submitted in relation to product application

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

2.3.7.2 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.

2.4 Assessment of the biocidal product

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

Intended use # 1 to # 5 –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 an appropriate amount of NEU 1222 I.
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: 20 to 1000 mL

2.4.2 Efficacy

The described changes do not influence the efficacy of the product.

2.4.3 Human Health

The described changes have no impact on human health risk assessment.

2.4.4 Environment

The described changes have no impact on the environment risk assessment.

3 ANNEX

3.1 List of studies

None.

3.2 List of references

None.

3.3 Confidential information

None.

3.4 Confidential information restricted to authorities

None.