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 NATIONAL AUTHORISATION APPLICATION

(submitted by eCA)

ADDENDUM: Minor Change

COMPO Mierenlokdoos
Insectex Mierenlokdoos

Product type PT 18

1R-trans-phenothrin as included in the Union list of approved active substances

Asset Number in R4BP: NL-0013401-0000

Evaluating Competent Authority: The Netherlands

Date: 12/05/2022

Table of Contents

1 CONCLUSION

The authorisation holder terrasan Haus- + Gartenbedarf GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised biocidal product COMPO Mierenlokdoos.

The changes refer to the shelf-life of the biocidal product and its palatability.

It is demonstrated that the new data on the long-term storage stability of the product and the palatability of aged product samples justify a shelf-life of 48 months, and would not adversely affect the conclusions previously reached on the assessment of the biocidal product. Therefore, A shelf-life of 4 years at ambient temperature is supported for the product COMPO Mierenlokdoos in the commercial packaging PS, HDPE and PP.

2 ASSESSMENT

2.1 Background

The authorisation holder terrasan Haus- + Gartenbedarf GmbH has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised biocidal product COMPO Mierenlokdoos.

2.2 Description of changes

The changes applied for refer to

- The shelf-life of the product changed from 2 years to 4 years.

2.3 Evaluation of changes

2.3.1 Identity and physical-chemical properties

To demonstrate the shelf-life of 4 years, stability tests have been performed. The long-term stability of the biocidal product was tested by storing commercial samples for 48 months at 20 °C.

Please find in the following table the summary of the results of the long-term stability studies.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	Storage stability for 4 years at 20 °C (comparable to GIFAP Monograph No. 17) The test was performed with commercial packages of the formulation (black thermoformed box)	Content 1R-trans-phenothrin: 0.1%	A storage stability study was performed at ambient temperature in HDPE (black thermoformed box). Initial active substance content: 0.115% Active substance after 48 months storage: 0.111% (3.5% decrease) The appearance before and after 48 months remains unchanged: Beige odourless paste. The packaging material (polystyrol high impact) was in sound condition, sealed and without leakage. Weight loss: between -1.32% and 1.20%. Initial pH (1% solution): 6.6 pH(1% solution) after 48 months: 6.1 The formulation is stable in its commercial packaging at ambient temperature for 48 months. No significant changes of physical-chemical properties and packaging stability occurred during the test.	
	Storage stability for 4 years at	Content 1R-trans-phenothrin: 0.1%	A storage stability study was performed at ambient temperature in HDPE (white screw-top box).	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	20 °C (comparable to GIFAP Monograph No. 17) The test was performed with commercial packages of the formulation (white screw-top box) Analytical method: HPLC-UV		Initial active substance content: 0.102% Active substance after 48 months storage: 0.099% (2.9% decrease) The appearance before and after 48 months remains unchanged: Beige paste with a weak caramel / sugar odour. The packaging material (HDPE) was in sound condition, sealed and without leakage. Weight loss during 48 months: less then 1.93% Initial pH (1% solution): 6.5 (average of two samples) pH(1% solution) after 48 months: 4.7 (average of two samples) The formulation is stable in its commercial packaging at ambient temperature for 48 months. No significant changes of physical-chemical properties and packaging stability occurred during the test.	

Conclusion on the physical, chemical and technical properties of the product
Although the study was performed in HDPE, extrapolation to all packaging materials is acceptable for solid preparations. A shelf-life of 4 years at ambient temperature is supported for the product COMPO Mierenlokdoos in the commercial packaging PS, HDPE and PP.

2.3.2 Efficacy

In order to demonstrate that the proposed changes in shelf-life will not adversely affect the efficacy of the product, palatability trials performed with four years aged product were submitted.

In the following table please find the summary of the results of the performed palatability studies.

<table>
<tr><th colspan="4">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>THG 128 01 IRB 0.1% d-phenothrin (=1R-trans-phenothrin)
4 y aged product Manufact-uring date: 06.08.2015
fresh product Manufact-uring date: 10.12.2019</td><td><u>Insects:</u>
Lasius niger,

Monomorium pharaonis</td><td>Laboratory choice-test (exposure time 14 days).
Aim of the test was to test the efficacy of aged bait compared to fresh bait.
The tests were carried out in 30 cm × 30 cm × 15 cm plastic arenas with 5 cm ground retrieved from the nest with competition food.
2 g bait gel per bait box (containing 1 g d-phenothrin (=1R-trans-phenothrin)/kg product)</td><td>
<table>
<tr><th colspan="3">Number of days of exposure to kill 100% of the ants</th></tr>
<tr><td>Lasius niger</td><td>fresh product</td><td>9 days</td></tr>
<tr><td>Lasius niger</td><td>aged product</td><td>13 days</td></tr>
<tr><td>Monomorium pharaonis</td><td>fresh product</td><td>9 days</td></tr>
<tr><td>Monomorium pharaonis</td><td>aged product</td><td>12 days</td></tr>
</table>
Untreated control showed 0 to 1% mortality during the whole test period.

Conclusion: Results show that both fresh and over 4 year aged product have sufficient efficacy against ants and tropical ants (Lasius niger and Monomorium pharaonis).
</td><td></td></tr>
</table>

<table>
<tr><th colspan="4">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>COM 128 01 IRB – (1R-trans-phenothrin 0.1% w/w)

4 y aged product Manufact-uring date: 09.02.2017
fresh product Manufact-uring date: 11.12.2020</td>
<td><u>Insects:</u>
Lasius emarginatus,

Tetramorium caespitum,

Tapinoma erraticum,

Linepithema humile</td>
<td>Laboratory choice-test (exposure time 14 days).
Aim of the test was to test the efficacy of aged bait compared to fresh bait.
The tests were carried out in 30 cm × 30 cm × 15 cm plastic arenas with competition food (sugar water+pet bisquit).
1 bait box per arena
5 replicates,
50 adults per replicate</td>
<td>
<table>
<tr><td colspan="3">Number of days of exposure to kill 100% of the ants</td></tr>
<tr><td>Lasius emarginatus</td><td>fresh product</td><td>9 days</td></tr>
<tr><td>Lasius emarginatus</td><td>aged product</td><td>12 days</td></tr>
<tr><td>Tetramorium caespitum</td><td>fresh product</td><td>8 days</td></tr>
<tr><td>Tetramorium caespitum</td><td>aged product</td><td>11 days</td></tr>
<tr><td>Tapinoma erraticum</td><td>fresh product</td><td>10 days</td></tr>
<tr><td>Tapinoma erraticum</td><td>aged product</td><td>10 days</td></tr>
<tr><td>Linepithema humile</td><td>fresh product</td><td>9 days</td></tr>
<tr><td>Linepithema humile</td><td>aged product</td><td>13 days</td></tr>
</table>
Untreated control showed less than 5% mortality in all cases.

Conclusion: Results show that both fresh and 4 year aged product have sufficient efficacy against the tested ants.
</td>
<td></td>
</tr>
</table>

Conclusion on the efficacy of the product

The test results show that the aged bait is still attractive for the ants and both fresh and four year aged product have sufficient efficacy (100% mortality within 2 weeks) against ants and tropical ants (*Lasius niger, Monomorium pharaonis, Lasius emarginatus, Tetramorium caespitum, Tapinoma erraticum* and *Linepithema humile*). Therefore, authorisation of this product with a shelf life of 4 years is considered possible.

2.3.3 Human Health

Based on the shelf-life studies performed with the biocidal product the active substance is stable in the biocidal product for a storage period of 48 months at 20 °C. Since the active substance concentrations and the physical-chemical properties of the biocidal product were not affected during storage, the conclusion of the previous evaluation, i.e. that the active substance will not present an unacceptable risk to humans and animals during and after the intended use of the product, remains the same. Thus, the human and animal health risk assessment is not adversely affected.

2.3.4 Environment

Based on the shelf-life studies performed with the biocidal product the active substance is stable in the biocidal product for a storage period of 48 months at 20 °C. Since the active substance concentration and the physical-chemical properties of the biocidal product were not affected during storage, the conclusion of the initial evaluation remains the same: The use of the biocidal product will not present an unacceptable risk to the environment.

3 DECISION

Long term storage stability studies (4 years) for the product COMPO Mierenlokdoos were submitted in June 2020.
A shelf-life of 4 years at ambient temperature is supported for the product COMPO Mierenlokdoos in the commercial packaging PS, HDPE and PP.

4 ANNEX

4.1 List of studies

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2019a	Determination of Physico-Chemical Properties and Storage Stability Test for THG 128 01| RB Date: 2019-09-03	[redacted]	Mo5265	No	No	Yes	COMPO GmbH	3.4.1_03
[redacted]	2019b	Determination of Physico-Chemical Properties and Storage Stability Test for THG 128 01| RB Date: 2019-09-03	[redacted]	Mo5264	No	No	Yes	COMPO GmbH	3.4.1_04
[redacted]	2020	Laboratory Assessment Of The Efficacy Of An Insecticidal Ant Granule Against *Lasius niger* Palatability trial Date: 2020-01-30	[redacted]	2455e/0419	No	No	Yes	COMPO GmbH	6.7_05

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2021	Palatability trial of the efficacy of an insecticidal ant bait against four species of ants *Lasius emarginatus, Tetramorium caespitum, Tapinoma erraticum, Linepithema humile* Date: 2021-04-09	[redacted]	2656/0321	No	No	Yes	COMPO GmbH	6.7_06

4.2 List of references

Not applicable.

4.3 Confidential information

Not applicable.

4.4 Confidential information restricted to authorities

Not applicable.